Health and Community Services

ABACAVIR/DOLUTEGRAVIR/LAMIVUDINE (TRIUMEQ 600 MG-50 MG-300MG TAB)

For the treatment of HIV in both treatment-naïve and treatment-experienced adults.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2015

Health and Community Services

ABATACEPT (ORENCIA 250 MG VIAL, ORENCIA 125 MG/ML SYRINGE)

Rheumatoid Arthritis (RA):
250mg/15mL vial DIN 02282097
125mg/mL pre-filled syringe DIN 02402475

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.

Clinical Notes:
- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- **Intravenous infusion**: 500mg for patients <60 kg, 750mg for patients 60-100 kg and 1000mg for patients >100 kg, given at 0, 2, and 4 weeks then every 4 weeks thereafter.
- **Subcutaneous injection**: a single IV loading dose of up to 1,000mg may be given, followed by 125mg subcutaneous injection within a day, then once-weekly 125mg subcutaneous injections.
- Initial Approval: 6 months.

- Renewal Approval: 1 year. Confirmation of continued response is required

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Juvenile Idiopathic Arthritis (pJIA)
250mg/15mL vial DIN 02282097

- For children (6-17 years of age) with a diagnosis of juvenile idiopathic arthritis / who are intolerant to, or have not had an adequate response from etanercept.

Claim Notes:
- Initial treatment should be limited to a maximum of 16 weeks. Re-treatment should only be permitted for children who had an adequate initial treatment response and subsequently experience disease flares.
- Combined use of more than one biologic DMARD will not be reimbursed.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Updated October 2023

Health and Community Services

ABEMACICLIB (VERZENIO) 50 MG, 100 MG, AND 150 MG TABLET

1. In combination with a nonsteroidal aromatase inhibitor (NSAI) (i.e. letrozole, anastrozole or exemestane) for the treatment of post-menopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor (HER2)-negative advanced or metastatic breast cancer, who have not received any prior endocrine-based treatment for metastatic disease.

   Renewal Criteria:
   - Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

   Clinical Notes:
   1. Patients may have received up to one prior line of chemotherapy for advanced disease.
   2. Patients must have a good performance status and not be resistant to prior (neo)adjuvant AI therapy (i.e. have the potential to benefit from first-line endocrine based therapy), without active or uncontrolled metastases to the central nervous system.
   3. Treatment with abemaciclib should be discontinued upon disease progression or unacceptable toxicity.

   Claim Notes:
   - Patients will be eligible for either abemaciclib plus an AI in the first line setting or everolimus plus exemestane as a subsequent line of therapy, but not both therapies.
   - Requests will not be considered for patients previously treated with a CDK4/6 inhibitor.
   - Patients with prior adjuvant treatment with a CDK 4/6 inhibitor plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant CDK 4/6 inhibitor therapy.
   - Approval period: 1 year

2. In combination with fulvestrant for the treatment of patients with hormone receptor (HR)-positive, HER2-negative, advanced or metastatic breast cancer, with disease progression following endocrine therapy.

   Renewal Criteria:
   - Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

   Clinical Notes:

1. Patients must have a good performance status and without active or uncontrolled metastases to the central nervous system.
2. Patients may have received up to one prior line of chemotherapy for advanced/metastatic disease.
3. Treatment with abemaciclib should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients who experience disease progression on a prior CDK 4/6 inhibitor therapy, fulvestrant, or everolimus are not eligible for treatment with abemaciclib with fulvestrant.
- Patients with prior adjuvant treatment with a CDK 4/6 inhibitor plus endocrine therapy are eligible if disease progression occurred 6 months or greater after completion of adjuvant CDK 4/6 inhibitor therapy.
- Approval period: 1 year

3. In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, HER2-negative resected invasive early-stage breast cancer at high risk of disease recurrence who meet one of the following criteria:
   - Pathological tumour involvement in 4 or more ipsilateral axillary lymph nodes (ALNs); or
   - Pathological tumour involvement in 1 to 3 ipsilateral ALNs and at least one of:
     - histologic grade 3 disease
     - primary tumour size of 5 cm or greater
     - Ki-67 index score of 20% or greater

   Renewal Criteria:
   - Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

   Clinical Notes:
   1. Patients must have a good performance status and no evidence of metastatic disease or inflammatory breast cancer.
   2. Patients must have undergone definitive surgery of primary breast tumour within 16 months of initiating treatment.
   3. Treatment with abemaciclib should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 2 years of adjuvant therapy, whichever occurs first.

   Claim Notes:
   - Requests will not be considered for patients previously treated with a CDK4/6 inhibitor or olaparib.
   - Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

ABIRATERONE (ZYTIGA and generic brands) 250MG and 500MG TABLETS

Metastatic Castration-sensitive Prostate Cancer
In combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) who have had no prior ADT in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Funding will be provided for either concurrent use of abiraterone and prednisone with docetaxel, OR sequential use of docetaxel followed by abiraterone and prednisone, for patients with newly diagnosed mCSPC.
2. Patients must have a good performance status.
3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:
- Requests for abiraterone will not be considered for patients who experience disease progression on apalutamide or enzalutamide.
- Approval period: 1 year.

Metastatic Castration-resistant Prostate Cancer
1. In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC).

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 1 year.

2. In combination with olaparib and prednisone for the first-line treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who meet all of the following criteria:

- Presence of deleterious or suspected deleterious germline and/or somatic mutation in BRCA1 or BRCA2 genes; and
- Have not received prior treatment with an androgen receptor pathway inhibitor for metastatic castration-resistant prostate cancer.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients receiving abiraterone and prednisone as first-line therapy for mCRPC for less than 4 months may have olaparib added once BRCA mutation is confirmed provided there has been no disease progression on treatment.
- Approval period: 1 year

Non-metastatic Prostate Cancer

In combination with prednisone and androgen deprivation therapy (ADT) for the treatment of patients with very high-risk prostate cancer who have had no prior systemic therapy for prostate cancer, and who are:

- Node positive, OR
- Node negative with 2 of the following:
    - Clinical tumor stage T3 or T4
    - Gleason sum score 8 to 10
    - PSA ≥ 40mcg/L

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment may be continued for up to 2 years, or until development of unacceptable toxicity, or disease progression whichever comes first.
3. Abiraterone will not be funded for patients with non-metastatic prostate cancer who have a biochemical recurrence.

Claim Notes:

- Abiraterone will not be funded in combination with enzalutamide.
- Initial approval period: 1 year.
- Renewal approval period: 1 year

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http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Health and Community Services

ABOBOTULINUMTOXIN-A (DYSPORT Therapeutic 300U and 500U Vial)

- For the treatment of cervical dystonia (spasmodic torticollis) in adults.
- For the treatment of upper and lower limb focal spasticity in adults (due to stroke or spinal cord injury)
- For the treatment of lower limb spasticity (secondary to cerebral palsy) in patients two years of age or old.

Renewal Criteria:

- Documentation of continued benefit including the patient's functional and/or symptomatic improvement, as well as the dosage and injection schedule.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 3 years.

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http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2025

Newfoundland Labrador

Health and Community Services

ABROCITINIB (CIBINQO 50mg, 100mg, 200mg TABLETS)

For the treatment of patients aged 12 years and older with refractory moderate to severe atopic dermatitis (AD), including the relief of pruritus, who meet all of the following:

- Refractory or intolerant to an adequate trial with maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy (where available), and
- Refractory, intolerant, or contraindicated to an adequate trial of maximally tolerated prescription topical therapies for atopic dermatitis combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine), and
- The physician must provide the Eczema Area and Severity Index (EASI) score and validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) at the time of initial request for reimbursement.

Renewal Criteria

- The maximum duration of initial authorization is 6 months. For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 20 weeks after treatment initiation.
- For subsequent renewal, the physician must provide proof of maintenance of EASI 75 response from baseline every 6 months for subsequent authorizations.

Prescribing Criteria

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD.
- Coverage will not be used in combination with phototherapy, any immunomodulatory agents (including biologics) or other JAK inhibitor treatment for moderate to severe AD.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated December 2024

Health and Community Services

ACALABRUTINIB (CALQUENCE) 100MG TABLETS

Chronic Lymphocytic Leukemia/Small Cell Lymphoma

1. In combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL).

   Clinical Notes:
   1. Patients must have a good performance status.
   2. Patients with central nervous system (CNS) involvement, Richter's syndrome, uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenic purpura are not eligible.
   3. Treatment should be given for a total of 14 cycles (two cycles of acalabrutinib monotherapy followed by 12 cycles of acalabrutinib in combination with venetoclax), or until disease progression or unacceptable toxicity, whichever occurs first.

   Claim Notes:
   - Requests for re-treatment with acalabrutinib in combination with venetoclax will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
   - Approval period: 14 cycles.

2. As monotherapy for adult patients with previously untreated CLL / SLL for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).

3. As monotherapy for adult patients with relapsed or refractory CLL / SLL who have received at least one prior therapy.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status and no CNS involvement or Richter's transformation.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase inhibitor (BTKi) or idelalisib.

- Patients who experience disease progression during or within one year of completing a BTKi in combination with venetoclax are not eligible for acalabrutinib in the relapsed setting.
- Approval period: 1 year.

Mantle Cell Lymphoma
In combination with bendamustine and rituximab for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are ineligible for autologous stem cell transplant (ASCT).

Renewal criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression

Clinical Notes:
1. Patients must have a good performance status and no history of central nervous system lymphoma or leptomeningeal disease.
2. Treatment with acalabrutinib should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for acalabrutinib will not be considered for tumour debulking prior to ASCT.
- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2026

Health and Community Services

ACLIDINIUM /FORMOTEROL (DUAKLIR GENUAIR 400-12 MCG INHALER)

- For the treatment of moderate to severe COPD (CAT score ≥ 10 or mMRC ≥ 2) **OR**
- For patients who have experienced an exacerbation of COPD in the previous 12 months while on a LAMA or LABA inhaler.

Clinical Notes

- Coverage of a LABA and LAMA as two separate inhalers will not be considered.
- mMRC Grade 2 is described as: walking on level ground slower than people of same age because of breathlessness or having to stop for breath when walking at your own pace on the level.
- The COPD assessment test (CAT) is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at https://www.catestonline.org/patient-site-test-page-english.html

Limitations to coverage:

- ICS inhalers will not be reimbursed concurrently with a LAMA/LABA inhaler. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control.

LAMA/LABA inhaler as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

ADALIMUMAB (ABRILADA 20mg/0.4ml prefilled syringe, 40mg/0.8ml prefilled syringe, 40mg/0.8ml prefilled pen**, YUFLYMA** 40mg/0.4ml prefilled pen, 40mg/0.4ml prefilled syringe with and without needle guard, 80mg.0.8ml prefilled pen, 80mg/0.8ml prefilled syringe with and without needle guard **, SIMLANDI** 40mg/0.4mL PREFILLED SYRINGE, 40mg/0.4ml AUTOINJECTOR, 80mg/0.8ml PREFILLED SYRINGE**, AMGEVITA** 40mg/0.8ml PREFILLED SYRINGE**, AMGEVITA** 40mg/0.8ml PREFILLED AUTOINJECTOR**, HULIO** 20mg/0.4mL prefilled syringe, 40mg/0.8ml PREFILLED SYRINGE, 40mg/0.8ml PREFILLED PEN**, IDACIO** PREFILLED AUTOINJECTOR 40mg/0.8ml, HYRIMOZ, 20mg/0.4ml PREFILLED SYRINGE**, HYRIMOZ** 20mg/0.4ml PREFILLED SYRINGE**,** HYRIMOZ 20mg/0.2ml PREFILLED SYRINGE, HYRIMOZ 40mg/0.8ml PREFILLED SYRINGE, HYRIMOZ 40mg/0.8ml AUTOINJECTOR, HYRIMOZ 40mg/0.4ml PREFILLED SYRINGE, HYRIMOZ 40mg/0.4ml AUTOINJECTOR, HYRIMOZ 80mg/0.8ml PREFILLED SYRINGE, HYRIMOZ 80mg/0.8ml AUTOINJECTOR, **HADLIMA** 40mg/0.4ml SYRINGE, HADLIMA 40mg/0.4ml PUSHTOUCH, Halima 40mg/0.8ml SYRINGE, HADLIMA 40mg/0.8ml PUSHTOUCH**)**

Rheumatoid Arthritis (RA)

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.

- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approval period: Long term
- Maximum Dosage Approved: Adalimumab: 40mg every two weeks with no dose escalation permitted

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https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ankylosing Spondylitis:

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms and who have failed to respond to the sequential use of at least two NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least two NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Clinical Notes:
- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- combined use of more than one biologic DMARD will not be reimbursed)

Claim notes:
- Must be prescribed by a rheumatologist or internist.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 40mg every two weeks.
- Approval period: Long term.

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https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis*:*

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 40mg every two weeks.
- Approval period: Long term

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https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Polyarticular juvenile idiopathic arthritis (pJIA)

For patients aged 2-17 years with moderately or severe pJIA who have had an inadequate response to one or more disease-modifying anti-rheumatic drugs (DMARDs).

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist who is familiar with the use of biologic DMARDs in children.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 40mg every two weeks.
- Approval period: Long term

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https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Crohn's Disease*:*

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approvals will be for a maximum of 160mg followed by 80 mg two weeks later, then 40mg every two weeks.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Chronic Plaque Psoriasis*:*

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Clinical notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 80mg followed by 40mg in one week, then 40mg every two weeks thereafter.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Ulcerative colitis

For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or

- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Consideration will be given for patients who have not received a four-week trial of aminosalicylates if disease is severe (partial Mayo score > 6).

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Initial dose: 160 mg at Week 0 (administered as four subcutaneous injections in one day or as two subcutaneous injections per day for two consecutive days), followed by 80 mg at Week 2. Beginning at Week 4, continue with a dose of 40 mg every other week.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Hidradenitis suppurative (HS)

For the treatment of patients with moderate to severe hidradenitis suppurative who have not responded to conventional therapy (including systemic antibiotics) and who meet all of the following:

- A total abscess and nodule count of 3 or greater
- Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III
- An inadequate response to a 90 day trial or oral antibiotics
- Prescribed by a practitioner with expertise in the management of patients with HS.

Claim Notes:

- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 160 mg followed by 80 mg two weeks later, then 40 mg every week beginning four weeks after the initial dose.
- Approval period: Long term

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https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated April 2025

Health and Community Services

Afatinib (Giotrif 20mg, 30mg and 40mg)

For first line treatment of patients with EGFR mutation positive advanced or metastatic adenocarcinoma of the lung and with an ECOG performance status 0 or 1

Approval period: 12 months

Dosing: 40mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of afatinib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Health and Community Services

AFLIBERCEPT (EYLEA HD 8 MG/0.07 MLVIAL, EYLEA HD 8mg/0.07ml pre-filled syringe)

For patients with Neovascular (wet) age-related macular degeneration (AMD) and Diabetic Macular edema (DME) who meet the following criteria:

- have failed to respond to three consecutive injections of Avastin, OR
- have contraindications to the use of Avastin, OR
- are unable to tolerate Avastin; AND
- provide written confirmation from an ophthalmologist detailing the contraindication (s) as noted below.

Neovascular (wet) age-related macular degeneration (AMD):

A diagnosis of neovascular (wet) age-related macular degeneration (AMD);

- o Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual acuity between 6/12 and 6/96;
  - o Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea;

Criteria for Exclusion:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%

Contraindications to use of (Avastin) bevacizumab:

- Allergy or hypersensitivity to bevacizumab
- Documented acute intra-ocular inflammation or endophthalmitis following intravitreal bevacizumab
- History of recent (within 6 months) thromboembolic event (stroke, myocardial infarction, etc)
- Thromboembolic event during treatment with bevacizumab
- Patient deemed very high risk for thromboembolic event
  - o Multiple previous events with or without permanent deficits

- Documented treatment failure with intravitreal bevacizumab
  - o No response (no reduction in central foveal thickness or no improvement in visual acuity) following 3 monthly bevacizumab treatments

- Disease progression (increase in central foveal thickness, decrease in visual acuity or new hemorrhage) despite monthly bevacizumab treatments

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Ophthalmic-VEG-F-inhibitor-Form-1.pdf

Updated February 2025

Health and Community Services

AFLIBERCEPT (AFLIVU Pre-Filled Syringe 2mg/0.05mL, Vial 2mg/0.05mL, YESAFILI Pre-Filled Syringe 2mg/0.05mL, Vial 2mg/0.05mL, ENZEEVU 2mg/0.05ml Pre-Filled Syringe, EYDENZELT 2 mg/0.05ml Pre-filled syringe, 2mg.0.5ml VIAL)

For patients with Neovascular (wet) age-related macular degeneration (AMD), Diabetic Macular edema (DME), and Macular edema secondary to retinal vein occlusion who meet the following criteria:

- have failed to respond to three consecutive injections of Avastin, OR
- have contraindications to the use of Avastin, OR
- are unable to tolerate Avastin; AND
- provide written confirmation from an ophthalmologist detailing the contraindication (s) as noted below.

Neovascular (wet) age-related macular degeneration (AMD):

A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
    - o Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual acuity between 6/12 and 6/96;
    - o Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea;

Criteria for Exclusion:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%

Macular edema secondary to retinal vein occlusion:

For the treatment of visual impairment due to macular edema secondary to retinal vein occlusion in patients meeting one of the following criteria:

- clinically significant macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)

Contraindications to use of (Avastin) bevacizumab:

- Allergy or hypersensitivity to bevacizumab
- Documented acute intra-ocular inflammation or endophthalmitis following intravitreal bevacizumab

- History of recent (within 6 months) thromboembolic event (stroke, myocardial infarction, etc)
- Thromboembolic event during treatment with bevacizumab
- Patient deemed very high risk for thromboembolic event
    - Multiple previous events with or without permanent deficits

- Documented treatment failure with intravitreal bevacizumab
    - No response (no reduction in central foveal thickness or no improvement in visual acuity) following 3 monthly bevacizumab treatments
    - Disease progression (increase in central foveal thickness, decrease in visual acuity or new hemorrhage) despite monthly bevacizumab treatments

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Ophthalmic-VEG-F-inhibitor-Form-1.pdf

Updated May 2026

Health and Community Services

ALECTINIB (ALECENSARO 150MG CAPSULES)

Early-Stage Non-Small Cell Lung Cancer

For the adjuvant treatment of adult patients with stage IB to stage IIIA (tumors are ≥ 4cm and/or are locoregional lymph node positive with no distant spread of disease) anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) who have undergone tumor resection.

Renewal Criteria

- Written confirmation that the patient is responding to treatment.

Clinical Note:

1. Patients must have a good performance status
2. Treatment should be discontinued upon disease progression, unacceptable toxicity, or upon completion of 2 years of therapy.
3. Alectinib is funded regardless of whether adjuvant chemotherapy is administered but should be administered sequentially after chemotherapy is completed if administered.

Claim Notes:

- Patients will be eligible for ALK inhibitors in the advanced setting if disease recurrence occurs at least 6 months after the last dose of adjuvant alectinib.
- Approval period: 1 year.

Locally Advanced or Metastatic Non-Small Cell Lung Cancer

For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer when used:

- as first-line therapy, OR
- following disease progression on, or intolerance to, crizotinib.

Renewal Criteria

- Written confirmation that the patient is responding to treatment.

Clinical Note:

1. Patients must have a good performance status
2. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests for alectinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib.
- No further ALK inhibitor will be reimbursed following disease progression on alectinib.

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2025

Health and Community Services

ALEMTUZMAB (LEMTRADA 12mg/1.2mg IV SOLUTION)

For the treatment of adult patients with highly active relapsing remitting multiple sclerosis (RRMS), defined by clinical and imaging features, despite an adequate course of treatment with at least two other disease modifying treatments (DMTs), if the following criteria is met:

- At least two attacks (first episode or relapse) in the previous two years, with at least one attack in the previous year;
- At least one relapse while on at least six months of a disease modifying therapy within the last 10 years;
- An Expanded Disability Status Scale (EDSS) score of five (5) or less;

Clinical Notes:

- Disease modifying treatments (DMTs) is defined as any of the following: cladribine, dimethyl fumarate, fingolimod, glatiramer acetate, interferon beta, natalizumab, ocrelizumab, ofatumumab, peginterferon beta, teriflunomide.
- Must be prescribed by specialist with expertise in the treatment of multiple sclerosis
- A maximum of two years of therapy (i.e. two treatment courses; 8 vials) will be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2026

Health and Community Services

AGALSIDASA ALFA (REPLAGAL 1 mg/mL Concentrate for solution for intravenous infusion)

For the treatment of Fabry Disease provided the following criteria are met:

Clinical Note:

- Must be eligible for the disease specific Fabry Disease criteria as determined by the Canadian Fabry Disease Treatment Guidelines, supported by the Canadian Fabry Disease Initiative (CFDI), and which may be amended by the CFDI from time to time.

Claim Notes:

- Combined use of more than one disease specific therapy (i.e. enzyme replacement therapy or chaperone therapy) will not be reimbursed
- Initial approval period: 1 year.
- Renewal approval period: 1 year. Renewal criteria will be based on the criteria set out in the Canadian Fabry Disease Treatment Guidelines, which may be amended by the CFDI from time to time.

Please visit the link below if you require our standard special authori**zation form:**
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2021

Health and Community Services

AGALSIDASE BETA (FABRAZYME) 5MG AND 35MG VIALS

For the treatment of Fabry Disease provided the following criteria are met:

Clinical Note:

- Must be eligible for the disease specific Fabry Disease criteria as determined by the Canadian Fabry Disease Treatment Guidelines, supported by the Canadian Fabry Disease Initiative (CFDI), and which may be amended by the CFDI from time to time.

Claim Notes:

- Combined use of more than one disease specific therapy (i.e. enzyme replacement therapy or chaperone therapy) will not be reimbursed
- Initial approval period: 1 year.
- Renewal approval period: 1 year. Renewal criteria will be based on the criteria set out in the Canadian Fabry Disease Treatment Guidelines, which may be amended by the CFDI from time to time.

Please visit the link below if you require our standard special authori**zation form:**
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2021

Newfoundland Labrador
Health and Community Services

ALIROCUMAB (PRALUENT 75mg/mL pre-filled pen, 150mg/mL pre-filled pen)

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (LDL-C less than 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite confirmed adherence to at least 3 months of continuous treatment with:
    - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
    - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial renewal criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent renewal criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance have been ruled out.

- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).

- Must be prescribed by a cardiologist or physician with expertise in the diagnosis and treatment of heterozygous familial hypercholesterolemia (HeFH).

Claim Notes:

- Approvals will be for a maximum of 300mg every 4 weeks.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2024

Health and Community Services

AMANTADINE HCL 50 MG/5ML SYRUP

For use in patients who are unable to swallow the oral capsule formulation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2023

Newfoundland Labrador

Health and Community Services

AMBRISENTAN (VOLIBRIS 5mg, 10mg TABLET and generics)

For the treatment of idiopathic pulmonary arterial hypertension (PAH) or pulmonary hypertension associated with connective tissue disease in patients with:

- with at least WHO functional class III pulmonary arterial hypertension (either idiopathic or associated with connective tissue disease)
- confirmed by right heart catheterization
- for doses up to 10mg daily

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2021

Health and Community Services

AMIFAMPRIDINE PHOSPHATE (FIRDAPSE 10mg TABLET)

For the treatment of adult patients (18 years of age and older) with Lambert-Eaton myasthenic syndrome (LEMS).

For initial coverage, the Baseline pre-treatment Triple Timed Up and Go (3TUG) test must be provided.

Renewal Criteria

- Patients should be assessed for a response to treatment within 3 months of initiating then yearly thereafter.
- A response to treatment is defined as an improvement of at least 30% on the Triple Timed Up and Go (3TUG) test.

Clinical Notes:

- The patient must be under the care of a neurologist or other specialist with expertise in managing LEMS.
- The 3TUG test score must be provided with initial and renewal requests.
- Doses to be individualized to optimal effect, up to a maximum recommended total daily dose of 80 mg. The maximum single dose is 20mg.
- Initial Coverage: 3 months.
- Renewal Coverage: 1 year.
- Ongoing coverage may be considered only if patients have maintained a minimum improvement of at least 30% on the 3TUG test from baseline at the end of each 12-month period.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated February 2024

Health and Community Services

AMIFAMPRIDINE (RUZURGI 10mg Tablet)

For the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years and older.

For initial coverage, the Baseline pre-treatment Triple Timed Up and Go (3TUG) test must be provided.

Renewal Criteria

- Patients should be assessed for a response to treatment within 3 months of initiating then yearly thereafter.
- A response to treatment is defined as an improvement of at least 30% on the Triple Timed Up and Go (3TUG) test.

Clinical Notes:

- The patient must be under the care of a neurologist or other specialist with expertise in managing LEMS.
- The 3TUG test score must be provided with initial and renewal requests.
- Approvals will be up to a maximum daily dose of 40 mg for patients weighing less than 45 kg and 100 mg for patients weighing 45 kg or more.
- Initial Coverage: 3 months.
- Renewal Coverage: 1 year.
- Ongoing coverage may be considered only if patients have maintained a minimum improvement of at least 30% on the 3TUG test from baseline at the end of each 12-month period.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated August 2023

Health and Community Services

AMLODIPINE 1 MG/ML SOLUTION (PDP-AMLODIPINE 1 MG/ML SOLUTION)

For use in patients who are unable to swallow the tablet formulation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2023

Health and Community Services

ANIFROLUMAB (SAPHNELO 300mg vial (150mg/ml vial)

For the treatment of adult patients with active, autoantibody positive, systemic lupus erythematosus (SLE) who meet the following criteria:

- Patients with moderate-severe SLE (defined as systemic Lupus Erythematosus Disease Activity Index 2000 (SLEDAI-2K) score of at least 6 prior to treatment initiation with Saphnelo and;
- Is inadequately controlled with oral corticosteroids (OCS) dose of at least 10 mg/day of prednisone or its equivalent in addition to standard of care.

* Standard therapy includes an antimalarial drug (e.g., hydroxychloroquine) or immunosuppressive agents (e.g., azathioprine, methotrexate, mycophenolate mofetil) with or without nonsteroidal anti-inflammatory drugs (NSAIDs)

A SLEDAI-2K pre-treatment baseline score must be provided.
If a British Isles Lupus Activity Group (BILAG)-2004 will be used for renewal assessment, a BILAG-2004 pre-treatment baseline assessment of organ systems must also be provided. The same scale should be used on all subsequent renewals.

Coverage will not be provided patients with any of the following:

- severe or unstable neuropsychiatric SLE
- active severe SLE nephritis

The maximum duration of initial reimbursement is for 12 months at a dose of 300mg administered every four weeks.

Renewal:
Treatment can be renewed as long as all of the following are met:

- OCS dose decreased to reduction in disease activity measured by:
  - Reducing the SLEDAI-2K score to 5 or less, OR
  - BILAG improvement in organ systems and no new worsening

For subsequent renewal, the physician must provide proof that the initial response achieved after the first 12 months of therapy with Saphnelo has been maintained. Subsequent renewals should be assessed annually.

Clinical Notes:

- Saphnelo should not be reimbursed when used in combination with other biologic treatments.
- Patient should be under the care of a physician with expertise in the diagnosis and management of SLE.

- Saphnelo should not be reimbursed when used in combination with other biologic treatments.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated January 2024

Health and Community Services

APALUTAMIDE (ERLEADA) 60MG, 240MG TABLET

Non-metastatic Castration-resistant Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who meet all of the following criteria:

- No detectable distant metastases by either CT, MRI or technetium-99m bone scan
- Prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with apalutamide.
3. Patients must have a good performance status and no risk factors for seizures.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide or darolutamide.
- Approval period: 1 year.

Metastatic Castration-sensitive Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC) who have had no prior ADT, or are within 6 months of beginning ADT, in the metastatic setting.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no risk factors for seizures.
2. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Requests for apalutamide will not be considered for patients who experience disease progression on enzalutamide or darolutamide.
- Requests will not be considered for patients who are within 1 year of completing adjuvant ADT in the non-metastatic setting.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2024

Health and Community Services

Aprepitant (Emend 80mg and 125mg tablets)

In combination with a 5-HT_3 antagonist class of anti-emetics and dexamethasone for the prevention of acute and delayed nausea and vomiting due to highly emetogenic cancer chemotherapy (eg cisplatin ≥70mg/$m^{2)}$ in patients who have experienced emesis despite treatment with a combination of a 5-HT_3 antagonist and dexamethasone in a previous cycle of highly emetogenic chemotherapy.

Please Note: The $5HT_3$ antagonist should only be used on the first day of chemotherapy (eg cisplatin ≥70mg/$m^{2)}$ with Aprepitant continuing on
Day 2 & 3).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ARIPIPRAZOLE (ABILIFY MAINTENA 300mg, 400mg prolonged release injectable suspension)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

ARIPIPRAZOLE (ABILIFY ASIMTUFII 720 mg/2.4 mL, 960 mg/3.2 mL for extended release injectable suspension)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2026

Health and Community Services

ASCIMINIB (SCEMBLIX) 20MG, 40MG TABLET

1. For the first-line treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML).

2. For the treatment of adult patients with chronic phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) who have treatment failure on or intolerance to two or more prior tyrosine kinase inhibitor (TKI) therapies.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and has not developed unacceptable toxicities that require discontinuation of therapy.

Clinical Note:

1. Patients must have a good performance status.
2. Patients must not have evidence of T315i or V299L mutations.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients with CML in accelerated phase or blast phase.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

ASENAPINE MALEATE (SAPHRIS 5 MG TAB, 10MG TAB SUBLINGUAL)

For the acute treatment of bipolar disorder as either:

- Monotherapy, after inadequate response to a trial of lithium or divalproex sodium, and there is a history of inadequate response, or intolerance to at least one less expensive antipsychotic agent.
- Co-therapy with lithium or divalproex sodium, and there is a history of inadequate response or intolerance to at least one less expensive antipsychotic agent.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Newfoundland Labrador
Health and Community Services

ASFOTASE ALPHA (STRENSIQ 18mg/0.45ml, 28mg/0.7ml, 40mg/1ml, 80mg/0.8ml single use vials)

For enzyme replacement therapy (ERT) in patients with a confirmed diagnosis of perinatal/infantile or juvenile -onset hypophosphatasia (HPP) who meet the following criteria:

These patients must have been diagnosed prior to 12 years of age and have documented onset of signs/symptoms of HPP prior to 12 years of age.

Initiation Criteria:

- Diagnosis confirmed by genetic testing (documented tissue-nonspecific alkaline phosphatase (TNSALP) gene mutations(s) **AND**
- Serum alkaline phosphatase (ALP) level below the age-adjusted normal range (these are age and gender adjusted norms developed through the Canadian Laboratory Initiative on Pediatric Reference Intervals (CALIPER) can used as reference. **AND**
  NOTE: Below upper limit of normal refers to 2 or lower standard deviations above the mean.
- Plasma pyridoxal-5-phosphate (PLP) above the upper limit of normal **AND**
- Radiologic confirmation HPP-related skeletal abnormalities:

  For Infantile HPP: Full skeletal survey done at baseline – examine chest, wrist, knees, and skull.
  Changes to monitor include: abnormalities of skeletal mineralization including severely undermineralized and even "absence" of some or all bones; undermineralized skull; functional craniosynostosis; gracile bones; thin ribs; chest deformities; evidence of recent/ healed fractures; non-traumatic fractures, recurrent or poorly healing fractures; at the ends of long bones evaluate widening of the growth plate (physis) with irregularity of the provisional zone of calcification; metaphyseal radiolucencies, flaring and fraying at ends of metaphyses and metadiaphyseal patchy focal sclerosis

  For Juvenile HPP: Similar to above however generally milder

  AND

- Assessed by a metabolic specialist who determines that the criteria noted above has been met as well as documented signs/symptoms that includes:

a. **For Infantile HPP:** Failure to thrive AND poor growth AND gross motor delay with substantial skeletal disease. May also have hypercalcemia, B6-responsive seizures and/or respiratory failure, respiratory compromise, including decreased thoracic volume and/or pulmonary hypoplasia; need for respiratory support; .
b. **For Juvenile HPP:** Poor weight gain; unusual gait or running; delayed walking (>15 months); impaired mobility, need for ambulatory assistance; knock- knees; or rickets/bowed legs; muscle weakness/hypotonia; joint pain; muscle pain; bone pain sufficient to limit activity and require medication
c. **Childhood HPP** (after 6 months of age): gait disturbance, fractures, rickets and RGIC score(NOTE: RGIC score is a 7-point score of Radiographic Global Impressive of Change ie RGIC score assesses changes from baseline and is obtained on paired sequential radiographs with a score of +2 indicating substantial healing/improvement in HPP-related skeletal abnormalities), Thacher score (NOTE: Thacher score is a 10- point Rickets Severity Scale validated for Vitamin D deficiency rickets (and also valid for HPP); score of 10= severe rickets and 0 = no rickets based on quantified growth plate abnormalities at wrists and knees) , bowing of legs, short stature unexplained by other reasons and/or pain score. RGIC and Thacher scores are ideal as they are validated in HPP but a comparable radiologic assessment by an expert bone pediatric radiologist could also be considered

- Patient is not an adult (ie > 18 years of age) at the time treatment is initiated **AND**

- Patient does not have odontoHPP,IE premature loss of deciduous teeth alone or pseudo-HPP and vitamin D deficiency to be ruled out. Patients with craniosynostosis alone who do not have other criteria noted above for the diagnosis of HPP need to be followed closely as initiation of treatment with ERT may be indicated if other systemic signs and symptoms develop including muscle weakness, fractures, rickets, pain or nephrocalcinosis and/or if bony disease develops clinically and radiologically **AND**

- Patients should be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of HPP. Goals of therapy should be developed on a case-by-case basis prior to the initiation of therapy depending on age and signs and symptoms at presentation.

  Signs and symptoms to be monitored depend on age at diagnosis and may include:

  a) For perinatal / infantile would expect in addition to above parameters to be followed goals of therapy should include discontinuation or reduction of ventilatory support, increased mobility (improvement in gait vs. baseline), attainment of age- appropriate gross motor milestones . Clinical, radiological and biochemical criteria should be surveilled and these pre-specified goals met at Coverage should be reassessed following a trial of 24 weeks of therapy or more frequently depending on clinical status of patient at initiation of therapy.

b) For juvenile Healing of rickets, improvement of bone mineralization and/ bony deformities, fewer fractures. less pain, need for less pain medication, improved growth, increased mobility.

Of Note: Treatment with ERT may not be recommended for newborns who are unable to be successfully ventilated and who have respiratory failure, irreversible pulmonary hypoplasia (underdeveloped lungs with reduced number of alveoli for air exchange) as assessed postnatally by established clinical and radiologic criteria (narrow chest circumference and apparent low lung volumes, evidence for increased pulmonary resistance, MRI changes consistent with lung hypoplasia), very small chest walls, very thin or absent ribs radiologically as assessed by pediatric respirologist, radiologist and treating metabolic specialist. A 6 month trial of ERT may however be recommended for such infants by the treating metabolic specialist and consultants with the consent of the parents. Discontinuation of ERT should be considered at this point and baby moved to palliative care.

Initial Approval:

- 6 months. Renewal will require reassessment by the metabolic specialist.

Continuation Criteria:

- Assessed by a metabolic specialist who determines that the pre-specified goals have been met and includes documented signs/symptoms noted above
- Documented compliance by patient and family with respect to follow up visits and reevaluation of laboratory and radiological parameters.
- First renewal: 6 months. Renewal will require reassessment by metabolic specialist.
- Subsequent renewals: 12 months. Renewal will require reassessment by metabolic specialist.

If Continuation Criteria are not met, the treatment should not be continued. In addition, ERT should be discontinued for lack of compliance or if patient does not come for follow-up appointments, despite all efforts to assist patient and family in this regard, development of craniosynostosis or premature loss of deciduous teeth alone would not signify failure of treatment and ERT should be continued provided other continuation criteria are met.

Stopping Criteria:

- Consider discontinuation after growth is completed based on objective measurement of height and closure of growth plates (closure to be confirmed by Xray criteria and report from a Radiologist)
- Criteria for tapering and discontinuing treatment should be developed by expert committee and evaluated on a case – by- case basis at all age groups.
- Babies with perinatal/ infantile HPP who fail treatment trials of 6 months as described above may be discontinued from ERT and moved to palliative care.

Clinical Notes:

- Must be prescribed by a Metabolic Specialist.
- Initial approval: 6 months. Renewal will require reassessment by metabolic specialist.

- First renewal: 6 months. Renewal will require reassessment by metabolic specialist.
- Subsequent renewals: 12 months. Renewal will require reassessment by metabolic specialist.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2025

Health and Community Services

ATOGEPANT (QULIPTA 10mg, 30mg, 60mg tablet)

For the prevention of migraine headaches in patients with a confirmed diagnosis of episodic or chronic migraine who at baseline are refractory or intolerant to at least two oral prophylactic migraine medications of different classes.

Renewal:

- a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- At subsequent renewals the physician must provide proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

Clinical Notes:

- The average number of headache and migraine days per month must be provided on initial and renewal requests.
- According to the International Headache Society criteria, episodic or chronic migraine are defined as:
    - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
    - Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

Claim Notes:

- The patient should be under the care of a physician expertise in the management of patients with migraine headaches.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.
- The maximum recommended daily dose is 60 mg.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Migraine-1.pdf

Updated February 2025

Health and Community Services

AVAPRITINIB (AYVAKYT) 25MG, 50MG, 100MG, 200MG TABLET

As monotherapy for the treatment of adult patients with advanced systemic mastocytosis (AdvSM), which includes aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SMAHN), and mast cell leukemia (MCL) based on the WHO diagnostic criteria.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression

Clinical Notes:

1. Patients must have a good performance status.
2. Patients must not have any of the following:
   - Platelet count < 50,000/µL or be receiving platelet transfusions; or
   - High risk of intracranial bleeding (clinician judgement); or
   - Primary brain malignancy or metastasis
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Avapritinib is not funded for non-advanced systemic mastocytosis, including bone marrow mastocytosis (BMM), indolent systemic mastocytosis (ISM), and smoldering systemic mastocytosis (SSM)
- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Health and Community Services

AXITINIB (INLYTA) 1 MG and 5 MG TABLET

1. In combination with pembrolizumab for the treatment of patients with advanced or metastatic renal cell carcinoma (RCC) who have not received prior systemic therapy for advanced RCC, and do not have active CNS metastases.

2. As monotherapy for the second-line treatment of patients with advanced or metastatic RCC following disease progression on:
   - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or
   - immunotherapy in combination with a TKI (i.e., pembrolizumab in combination with lenvatinib or nivolumab in combination with cabozantinib).

3. As monotherapy for the third-line treatment of patients with advanced or metastatic RCC following disease progression on first-line immunotherapy (i.e., nivolumab in combination with ipilimumab) and second-line VEGFR TKI (i.e., sunitinib or pazopanib).

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for axitinib will not be considered for patients who experience disease progression on everolimus or cabozantinib or single agent nivolumab.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2025

Health and Community Services

AZACITIDINE (ONUREG) 200mg and 300mg tablets

As maintenance therapy for the treatment of adult patients with newly diagnosed acute myeloid leukemia (de novo or secondary to prior MDS or CMML) who meet all of the following criteria:

- Intermediate or poor risk cytogenetics.
- Have achieved complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following induction therapy, with or without consolidation treatment.
- Are not eligible for hematopoietic stem cell transplantation (HSCT).

Renewal Criteria:

- Written confirmation that the patient continues to be in complete remission or complete remission with incomplete blood count recovery.

Clinical Notes:

1. Patients must have an ECOG performance status of 0 to 3 and adequate organ function.
2. Last dose of chemotherapy should be within 4 months of starting azacitidine maintenance.
3. Treatment should be discontinued upon disease relapse (i.e., appearance of >5% blasts in the bone marrow or peripheral blood), unacceptable toxicity, or the patient becomes eligible for allogeneic bone marrow or stem cell transplantation during the treatment period.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on hypomethylating agents.
- Approvals will be for a maximum of 300 mg daily for 14 days every 28-day cycle.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2023

Health and Community Services

AZITHROMYCIN (ZITHROMAX 600 MG TABLET & generics)

For the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in persons with advanced HIV infections.

Please note: Special Authorization is not required when the prescription is filled through the Regional Health Authority.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2012

Health and Community Services

CAYSTON 75MG INHALTION SOLUTION (AZTREONAM)

For the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections when used as cyclic treatment (28-day cycles) in patients with moderate to severe cystic fibrosis (CF) **and** deteriorating clinical condition despite treatment with inhaled tobramycin[1].

Please note:
[1] failure of inhaled tobramycin therapy should include at least one of the following:
(i) growth of resistant pseudomonas strains (to tobramycin), OR
(ii) increased symptoms, OR
(iii) increased frequency of exacerbations

Clinical Note:

- The drug is prescribed by a clinician with experience in the diagnosis and treatment of CF.
- The drug is not used in combination with another inhaled antibiotic(s) to treat pulmonary P. aeruginosa infections, either concurrently or for antibiotic cycling during off-treatment periods.
- CAYSTON is used in alternating cycles of 28 days on treatment followed by 28 days off treatment.
- Restricted to patients under the Select Needs Program.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2019

Health and Community Services

BARICITINIB (OLUMIANT 2mg TABLET, 4mg TABLET)

Alopecia areata (AA):

For the treatment of adult patients with severe alopecia areata (AA) the following conditions are met:

- The patient has a Severity of Alopecia Tool (SALT) score of 50 or above AND
- The patient has experienced a current episode of AA of more than 6 months but less than 8 years.

Renewal

- The patient must demonstrate beneficial clinical effect, defined as achieving a SALT score of 20 or less at 36 weeks after treatment initiation.
- Maintenance of a SALT score of 20 or less is required at renewal for continuation of therapy.

Clinical Notes:

- Must be prescribed by a dermatologist with expertise managing patients with severe AA.
- Baricitinib treatment should not be used in combination with other JAK inhibitors, biologic immunomodulators, or systemic immunosuppressants.
- The maximum duration of initial authorization is 36 weeks.
- Approval will be considered for the recommended dose of 2mg once daily. The maximum dose approved will be 4mg once daily.
- Initial Approval: Maximum 36 weeks
- Renewal after initial approval: 12 months

Rheumatoid Arthritis (RA):

For the treatment of moderate to severely active rheumatoid arthritis, alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs), in patients who are refractory, intolerant or have contraindication to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; OR
  - Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- For patients who have intolerances preventing the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended dose and for duration of treatment specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist or other specialized physician with experience treating rheumatoid arthritis.
- Combined use of more than one biologic DMARD or Janus kinase inhibitors will not be reimbursed.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Approvals will be for a maximum of 2 mg daily.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

UPDATED March 2026

Health and Community Services

BELIMUMAB (BENLYSTA 120 mg / 5 mL vial, 400 mg / 20 mL vial, 200 mg / mL autoinjector)

For the treatment of adult patients with active lupus nephritis (LN) who are diagnosed with any of the following:

- class III with or without class V or
- class IV with or without class V or
- class V (i.e., pure class V).

AND

- The patient must have started standard induction therapy within the previous 60 days.

Coverage will not be considered in patients who have any of the following:

- Previously failed both cyclophosphamide and mycophenolate mofetil (or other forms of mycophenolate) induction therapies; or
- Patients with an eGFR < 30 mL/min/1.73 m^2.

Renewal:

For renewal, the physician must provide information to support clinical benefit and improvement in proteinuria outlined below:

- reduction in glucocorticoids to ≤ 7.5 mg/day after 12 months of therapy, AND
- an estimated eGFR that is no more than 20% below the value before the renal flare (preflare value) or ≥ 60 mL/min/1.73 m^2 after 12 months of therapy, AND
- proteinuria no greater than 0.7 g/24 hours after 12 months of therapy if baseline proteinuria is < 3.5 g/24 hours, OR
- proteinuria no greater than 0.7 g/24 hours after 18 to 24 months of therapy if baseline proteinuria is in the nephrotic range (i.e., > 3.5 g/24 hours).

Discontinuation:

Treatment must be discontinued if the patient does not meet all of the renewal criteria or if the patient has any of the following:

- an eGFR decrease to less than 30 mL/min/1.73 m^2
- the addition of other immunosuppressant agents (other than as part of the induction and maintenance regimens), corticosteroid use outside of the limits, anti–tumor necrosis factor therapy, or other biologics.

Clinical Notes:

- The patient should be under the care of either a rheumatologist or a nephrologist experienced in the management of lupus nephritis.
- Standard induction therapy includes products such as corticosteroids and mycophenolate or cyclophosphamide. Standard maintenance treatment may include products such as mycophenolate or azathioprine.
- A baseline proteinuria level must be provided.

- Belimumab intravenous (IV) infusion: 10 mg/kg at 2-week intervals for the first three doses and at 4- week intervals thereafter.
- Belimumab subcutaneous (SC) injection: 400 mg dose (two 200 mg injections) once weekly for 4 doses, then 200 mg once weekly thereafter.
- Initial Approval: The maximum duration of initial authorization is 12 months.
- Subsequent Renewals: annually. The physician must provide proof that the initial response achieved after the first 12 months of therapy has been maintained.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated April 2024

Health and Community Services

BELUMOSUDIL (REZUROCK 200mg tablet)

For the treatment of patients 12 years and older with chronic graft-versus-host disease (cGVHD) who meet all of the following criteria:

- Patient has moderate to severe cGvHD according to National Institutes of Health (NIH) consensus criteria, AND
- Patients has experienced inadequate response to corticosteroids[1] or corticosteroids with other systemic therapies[2].

[1]Corticosteroid refractory cGvHD is defined, based on 2014 NIH consensus criteria, by one or more of the following criteria:

- A lack of response or disease progression after administration of minimum prednisone 1 mg/kg/day for at least 1 week (or equivalent)
- Disease persistence without improvement despite continued treatment with prednisone at > 0.5 mg/ kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent)
- Increased prednisone dose to > 0.25 mg/ kg/day after 2 unsuccessful attempts to taper the dose (or equivalent).

[2] Treatment with belumosudil may be added to patients' concurrent treatment of steroids with or without calcineurin inhibitor (CNI) and/or stable systemic therapies for cGVHD, but once belumosudil is started no new therapies for cGVHD can be initiated.

Renewal:

- Treatment with belumosudil should be renewed for patients who have achieved an overall response (i.e., complete response (CR) or partial response (PR), or stable disease with significant reduction in steroid doses), according to NIH criteria after 24 weeks of therapy (approximately 6 months) and maintains an on-going clinical benefit

Discontinuation criteria:

Belumosudil should be discontinued upon the occurrence of any of the following:

- progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms
- the dose of corticosteroids remains at or above baseline dose for more than 6 weeks
- a patient experiences more than 2 cGVHD flares that require increased corticosteroid therapy within a 6-month period of belumosudil treatment

Clinical Notes:

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with cGvHD.
- Moderate chronic GVHD defined according to the NIH cGVHD severity definition: at least 1 organ or site with a maximum score of 2 in any affected organ or site, or 3 or more organs or sites with a maximum score of 1 in all affected organs or sites, or a lung score of 1.
- Severe chronic GVHD defined according to the NIH cGVHD severity definition: at least 1 organ or site with a score of 3, or a lung score of 2 or greater.
- Initial Approval: 24 weeks
- Renewal period: 24 weeks

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated May 2026

Health and Community Services

BELZUTIFAN (WELIREG) 40 MG TABLET

For the treatment of adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated non-metastatic renal cell carcinoma, central nervous system hemangioblastomas, or non-metastatic pancreatic neuroendocrine tumors, not requiring immediate surgery.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2025

Health and Community Services

BENRALIZUMAB (FASENRA 30mg/ml SYRINGE, 30 MG/ML AUTO-INJECTOR)

As an add-on maintenance treatment for adult patients with severe eosinophilic asthma, if the following criteria and conditions are met:

Initiation Criteria:

- Patient must have a documented diagnosis of asthma.
- Patient is inadequately controlled with high-dose inhaled corticosteroids, defined as greater or equal to 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., long-acting beta agonists).
- Patient has one of the following:
    - blood eosinophil count of ≥ 300 cells/μL AND has experienced two or more clinically significant asthma exacerbations in the past 12 months
    - blood eosinophil count of ≥ 150 cells/μL AND is receiving maintenance treatment with oral corticosteroids (OCS).

Clinical Notes:

- Benralizumab should not be used in combination with other biologics used to treat asthma.
- A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of Benralizumab treatment.
- Patients should be managed by a physician with expertise in treating asthma

Renewal Criteria:

- The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue.
- Treatment should be discontinued if:
    - the 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment, OR
    - the asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, OR
    - the number of clinically significant exacerbations has increased within the previous 12 months, OR
    - in patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment, OR
    - in patients on maintenance treatment with OCS, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained subsequently.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Asthma-1.pdf

Updated November 2024

Health and Community Services

BEROTRALSTAT (ORLADEYO 150mg capsule)

For prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age or older who have experienced at least three HAE attacks within any four-week period and required injectable treatment.

Renewal criteria:

- An assessment of a response to treatment should be conducted three months after initiating treatment.
- A response to treatment is defined as a reduction in the number of HAE attacks for which acute injectable treatment was received within the initial three months of treatment compared to the rate of attacks observed before initiating treatment with berotralstat.
- Following the initial three-month assessment, patients should be assessed for continued response every six months.
- Continued response is defined as no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to initiating treatment.

Discontinuation criteria:

Treatment should be discontinued in patients who either respond inadequately or exhibit a loss of response, defined as follows:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with berotralstat compared to number of attacks observed before initiation treatment with berotralstat.
- An increase in the observed number of HAE attacks for which acute injectable treatment was received before initiating treatment with berotralstat.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients already receiving long-term prophylactic treatment for HAE and intend to transition to berotralstat.
- A record of the baseline total of HAE attacks requiring use of an acute injectable treatment in the three months prior to initiating berotralstat is required.
- The patient must be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.
- Berotralstat should not be used in combination with other medications used for long-term prophylaxis (LTP) treatment of angioedema (e.g., C1-esterase inhibitors or plasma kallikrein inhibitor).
- Approvals will be for a maximum of 150mg once daily.
- Initial approval period: 3 months
- Renewal approval period: 6 months.

- **Billing Instructions: For claims that exceed the maximum allowable claim amount of $9,999.99 per claim, please contact (709) 729-1780 for billing guidance.**

Please visit the link below if you require the special authorization request form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated August 2025

Newfoundland Labrador

Health and Community Services

CALCIPOTRIOL/BETAMETHASONE (DOVOBET GEL 50 mcg-0.5 mg/gram gel and generics)

For the topical treatment of scalp psoriasis in patients unresponsive to high-potency corticosteroid scalp solutions.

Coverage will be provided for up to 4 weeks. If recurrence takes place after discontinuation, treatment may be reinstituted.

The maximum daily dose including other calcipotriol-containing products on the body should not exceed 15 g and the maximum weekly dose should not exceed 100 g.

Dovobet Ointment is NOT considered for coverage.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2023

Health and Community Services

BICTEGRAVIR/EMTRICITABINE/TENOFOVIR ALAFENAMIDE (BIKTARVY 50mg/200mg/25mg)

For the treatment of human immunodeficiency virus-1 (HIV-1) infection in adults with no known substitution associated with resistance to the individual components of BIKTARVY (BICTEGRAVIR, EMTRICITABINE, and TENOFOVIR ALAFENAMIDE)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2019

Newfoundland Labrador

Health and Community Services

BIMEKIZUMAB (BIMZELX 160mg/ml pre-filled syringe, 160mg/ml autoinjector, 320mg/2mL Pre-filled Syringe, 320mg/2mL Autoinjector)

Ankylosing spondylitis:

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:

- Decrease of at least 2 points on the BASDAI scale compared with the pre-treatment score,

OR

- An adequate clinical response as indicated by significant functional improvement (e.g., measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- combined use of more than one biologic DMARD will not be reimbursed)

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approved for 160mg (given as one subcutaneous injection) every 4 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.

- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approved for 160 mg (given as 1 subcutaneous injection of 160 mg) every 4 weeks.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response criteria).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Chronic Plaque Psoriasis

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:

For continued coverage, patients must meet the following criteria:

- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for 320 mg given every 4 weeks for 16 weeks then 320 mg every 8 weeks thereafter.
- Initial approval: 6 months
- Renewal approval period: 1 year.
    - Ongoing coverage for maintenance therapy should only be provided for responder, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Updated November 2025

Health and Community Services

BINIMETINIB (MEKTOVI) 15MG TABLET

In combination with encorafenib for the treatment of patients with locally advanced unresectable or metastatic melanoma with a BRAF V600 mutation.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Binimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2023

Health and Community Services

Bismuth Subsalicylate (Pepto-Bismol 262mg Caplets, 262mg Chewables, 35.2mg/ml Extra)

For the treatment of H. Pylori infection as part of a Bismuth quadruple therapy (PBMT) regimen.

Clinic Notes:

- Please provide the specific medications and doses in the intended regimen. NLPDP will also approve the indicated PPI at BID dosing provided the PPI is a benefit of the program. A second request will not be required for the PPI.
- Requests will be approved for 524mg four times daily for 14 days.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated June 2026

Newfoundland Labrador

Health and Community Services

BOSENTAN (TRACLEER 62.5mg, 125mg TABLETS and generics)

Idiopathic Pulmonary Arterial Hypertension (IPAH) functional class III and IV

- For the treatment of World Health Organization (WHO) functional class III and IV idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB) or are intolerant to CCB.

Pulmonary Arterial Hypertension (PAH) secondary to scleroderma, congenital heart disease or HIV (functional class III and IV)

- For the treatment of World Health Organization (WHO) functional class III and IV pulmonary arterial hypertension (PAH) associated with scleroderma, congenital heart disease or HIV who do not respond to conventional therapy.

- Written initial request by a pulmonary arterial hypertension (PAH) specialist only.
- Diagnosis of PAH should be confirmed by right heart catheterization.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2021

Newfoundland Labrador

Health and Community Services

BOSUTINIB (BOSULIF) 100 MG, 500MG TABLET

For the treatment of patients with chronic, accelerated or blast phase Philadelphia chromosome positive (Ph+) chronic myelogenous leukemia (CML) who have resistance/disease progression or intolerance to prior tyrosine kinase inhibitor (TKI) therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and has not developed unacceptable toxicities that require discontinuation of bosutinib

Clinical Note:

- Patients must have a good performance status

Claim Notes:

- Initial approval period: 12 months
- Renewal approval period: 12 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2021

Health and Community Services

BRIGATINIB (ALUNBRIG) 30MG, 90MG, 180MG TABLET, and Starter Kit

For the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who have not been previously treated with an ALK inhibitor.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

Clinical Note:

- Patients must have a good performance status
- Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- No further ALK inhibitor will be reimbursed following disease progression on brigatinib.
- Patients may be switched to brigatinib from an alternate ALK inhibitor in case of intolerance without disease progression
- Initial approval period: 1 year
- Renewal approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2022

Health and Community Services

BRIVARACETAM (BRIVLERA 10mg, 25mg, 50mg, 75mg, 100mg and generics)

For adjunctive therapy in patients with refractory partial-onset seizures who meet all of the following criteria:

- Are under the care of a neurologist or a physician experienced in the treatment of epilepsy, AND
- Are currently receiving two or more antiepileptic drugs,
- Are not receiving concurrent therapy with Levetiracetam AND
- In whom all other less costly antiepileptic drugs are ineffective or not appropriate

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Health and Community Services

BRODALUMAB (SILIQ 210MG/1.5ML SC SOLUTION)

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:
For continued coverage, patients must meet the following criteria:

- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Clinical notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be considered for brodalumab 210 mg administered by subcutaneous injection at Weeks 0, 1, and 2 followed by 210 mg every 2 weeks.
- Initial Approval: 6 months
- Renewal Approval: 1 year.

- Ongoing coverage for brodalumab maintenance therapy should only be provided for responders, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Updated April 2025

Newfoundland Labrador

Health and Community Services

BROLUCIZUMAB (BEOVU 6mg/0.05ml pre-filled syringe)

For patients with Neovascular (wet) age-related macular degeneration (AMD) or Diabetic Macular edema (DME) who meet the following criteria:

- have failed to respond to three consecutive injections of Avastin, OR
- have contraindications to the use of Avastin, OR
- are unable to tolerate Avastin; AND
- provide written confirmation from an ophthalmologist detailing the contraindication(s) as noted below

Neovascular (wet) age-related macular degeneration (AMD):

- A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
  - Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual Acuity (VA) between 6/12 and 6/96;
  - Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension.
- When there is no permanent structural damage to the central fovea.
- The interval between doses should be no less than eight weeks.

Criteria for Exclusion:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular Edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%,

Contraindications to use of (Avastin) bevacizumab:

- Allergy or hypersensitivity to bevacizumab
- Documented acute intra-ocular inflammation or endophthalmitis following intravitreal bevacizumab
- History of recent (within 6 months) thromboembolic event (stroke, myocardial infarction, etc)
- Thromboembolic event during treatment with bevacizumab

- Patient deemed very high risk for thromboembolic event
    - Multiple previous events with or without permanent deficits

- Documented treatment failure with intravitreal bevacizumab
    - No response (no reduction in central foveal thickness or no improvement in visual acuity) following 3 monthly bevacizumab treatments
    - Disease progression (increase in central foveal thickness, decrease in visual acuity or new hemorrhage) despite monthly bevacizumab treatments

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2024

Newfoundland Labrador

Health and Community Services

BUDESONIDE/FORMOTEROL (SYMBICORT 100MCG, 200MCG TURBUHALER)

Asthma

For the treatment of asthma in patients who are using optimal doses of inhaled corticosteroids but remain poorly controlled.

- Poorly controlled is defined as require additional symptom control because of asthma symptoms (e.g., cough, awakening at night, missing activities such as school, work or social activities) and resulting in increased amounts of short-acting beta2-agonists.

Clinical Note:

- Patients who have a diagnosis of both asthma and COPD do not need to have a trial of inhaled corticosteroids before requesting special authorization of a Symbicort.

Limitations to coverage:

- LAMA inhalers will not be reimbursed concurrently with LABA/ICS inhalers. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control (see Triple Therapy criteria below).

LABA/ICS as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

BUDESONIDE/GLYCOPYRRONIUM/FORMOTEROL FUMARATE DIHYDRATE (BREZTRI AEROSPHERE 160MCG/7.2MCG/5MCG AEROSOL METERED DOSE)

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR** at least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit.

OR

For the treatment of chronic obstructive pulmonary disease (COPD in patients with moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with dual therapy with a long-acting muscarinic antagonist plus a long-acting beta2-agonist (LAMA/LABA) or a long-acting beta2-agonist plus an inhaled corticosteroid (LABA/ICS) for at least 2 months.

Clinical Notes:

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.70. Spirometry reports confirming diagnosis of COPD are recommended. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. mMRC and/or CAT score).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

BUROSUMAB (CRYSVITA 10mg/ml, 20mg/ml, 30mg/ml VIAL)

For the treatment of X-linked hypophosphatemia (XLH) patients who meet all of the following criteria:

- Initiated in pediatric patients who are at least one year of age and in whom epiphyseal closure has not yet occurred;
- A clinical presentation consistent with XLH, including:
    - Fasting hypophosphatemia
    - Normal renal function (defined as fasting serum creatinine below the age-adjusted upper limit of normal);
- Radiographic evidence of rickets with a rickets severity score (RSS) total score of two or greater; and
- Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance.

Discontinuation Criteria

In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred, treatment should be discontinued if:

- there is no demonstrated improvement in the 12-month RSS total score from baseline, or
- the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently.

For adolescent or adult patients in whom epiphyseal closure has occurred and who met the listingcriteria above, treatment should be discontinued if any of the following occur:

- hyperparathyroidism, or
- nephrocalcinosis, or
- evidence of fracture or pseudofracture based on radiographic assessment.

Claim Notes:
A Baseline and annual assessment of the RSS score must be provided for pediatric patients in whom epiphyseal closure has not occurred

Clinical Notes:

- Requests will not be considered for treatment-naïve adults.

- The patient must be under the care of a specialist with expertise in the diagnosis and management of XLH.
- Approvals for children (1-17 years of age) will be up to a maximum of 90 mg every 2 weeks.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2022

Health and Community Services

CABOTEGRAVIR (APRETUDE 30mg tablets, 600mg/3mL VIAL)

For at-risk individuals aged 12 years and older and weighing at least 35 kg for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

Renewal Criteria:

- Confirmation of adherence to treatment.

Claim Note:

- Approval period: 1 year.

Please visit the link below if you require the special authorization request form:
https://www.gov.nl.ca/hcs/files/HIV-Pre-Exposure-Prophylaxis.pdf

Updated July 2025

Health and Community Services

CABOTEGRAVIR/RILPIVIRINE (CABENUVA 400 mg/2 mL-600 mg/2 ml dosing kit, 600 mg/3 mL-900 mg/3 mL dosing kit)

As a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in patients who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL).

Treatment should be discontinued if there is evidence of;

- Sustained loss of virologic suppression (as defined above); OR
- Development of resistance to, adverse events leading to lack of tolerability of, and/or lack of adherence to either component of the drug regimen;

Claim Notes:

- The patient must be under the care of a practitioner experienced in the care of patients with HIV.
- Approval Period: Long term

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Cabenuva.pdf

Updated July 2026

Health and Community Services

CABOTEGRAVIR (VOCABRIA 30mg TABLET)

In combination with rilpivirine tablets, as a complete regimen for short-term treatment of human immunodeficiency virus type 1 (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies/mL) as:

- An oral lead-in to assess tolerability of cabotegravir prior to initiating Cabenuva (cabotegravir/rilpivirine) injections;
- oral bridging therapy for missed Cabenuva injections.

Claim Notes:

- The patient must be under the care of a practitioner experienced in the care of patients with HIV.
- Cabotegravir 30mg tables must be prescribed in conjunction with rilpivirine 25mg tablets.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated July 2026

Health and Community Services

CABOZANTINIB (CABOMETYX) 20 MG, 40 MG, 60 MG TABLET

Metastatic Renal Cell Carcinoma

1. In combination with nivolumab for the treatment of adult patients with advanced (not amendable to curative surgery or radiation) or metastatic renal cell carcinoma who have not had prior systemic therapy for advanced RCC.

2. As monotherapy for the second-line treatment of patients with advanced (not amenable to curative therapy) or metastatic RCC following disease progression on:
   - vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) (i.e., sunitinib or pazopanib); or
   - pembrolizumab in combination with either axitinib or lenvatinib.

3. As monotherapy for the third-line treatment of patients with advanced (not amenable to curative therapy) or metastatic RCC following disease progression on:
   - first-line VEGFR TKI (i.e., sunitinib or pazopanib) and second-line nivolumab monotherapy; or
   - first-line nivolumab in combination with ipilimumab and second-line VEGFR TKI (i.e., sunitinib or pazopanib)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression.

Clinical Notes:

- Patients must have a good performance status and no active CNS metastases.
- Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.
- If nivolumab or cabozantinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.

Claim Notes:

- Patients who experience disease progression during or within 6 months of completing pembrolizumab in the adjuvant setting are not eligible for cabozantinib in combination with nivolumab for advanced RCC.
- Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy.
- Approval period: 1 year.

Differentiated Thyroid Carcinoma

For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) who meet all of the following criteria:

- Disease progression following treatment with one or two prior vascular endothelial growth factor receptor (VEGFR)-targeted tyrosine kinase inhibitors (TKI).
- Refractory to prior radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression.

Clinical Note:

- Patients must have a good performance status.
- Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.
- Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy.

Claim Notes:

- Patients with anaplastic or medullary thyroid cancer are not eligible.
- Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib
- Approval period: 1 year

Advanced Hepatocellular Carcinoma

For the second-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all of the following criteria:

- Disease progression on sorafenib or lenvatinib
- Child-Pugh class status of A
- ECOG performance status of 0 or 1

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and continues to experience clinical benefit.

Clinical Note:

- Treatment should continue until the patient no longer experiences clinical benefit or experiences unacceptable toxicity.

Claim Notes:

- Requests for cabozantinib will not be considered for patients who experience disease progression on regorafenib or immunotherapy (atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab).
- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2025

Health and Community Services

CANAGLIFLOZIN (INVOKANA 100mg, 300mg TABLET)

For the treatment of type 2 diabetes mellitus when added to metformin for patients with inadequate glycemic control on metformin, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after INVOKANA is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

CANNABIDIOL (EPIDIOLEX 100mg/ml oral solution)

Lennox-Gastaut syndrome (LGS)

As adjunctive therapy for the treatment of seizures associated with Lennox-Gastaut syndrome (LGS) in patients who are 2 years or older who:

- Are currently taking 1 or more anti-seizure medications at stable doses for at least 4 weeks before initiation AND
- Have experienced at least 2 drop seizures per week over a 28-day period before initiation of cannabidiol AND
- Have experienced treatment failure on at least 2 anti-seizure medications.

Renewal

- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement.

Discontinuation

- Treatment with cannabidiol should be discontinued upon the occurrence of severe toxicity, lack of beneficial treatment effect, or intolerance.

Clinical Notes:

- Must be prescribed by a physician with expertise in the diagnosis and management of patients with LGS.
- Coverage will not be provided for patients concurrently using cannabis products or other cannabinoid based medications.
- Initial Approval: 6 months
- Renewal: 1 year

Tuberous Sclerosis Complex (TSC)

As adjunctive therapy for the treatment of seizures associated with tuberous sclerosis complex (TSC) in patients aged 2 years and older who:

- Have been taking 1 or more anti-seizure medication at stable doses for at least 4 weeks before initiation AND
- Have had at least 8 seizures per 28 days before initiation of cannabidiol AND
- Have inadequately controlled seizures despite previously or currently receiving treatment with at least 2 anti-seizure medications.

Renewal

- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement.

Discontinuation

- Treatment with cannabidiol should be discontinued due to lack of beneficial clinical effect, severe toxicity, or treatment intolerance.

Clinical Notes:

- Must be prescribed by a physician with expertise in the diagnosis and management of TSC.
- Coverage will not be provided when given in the following instances:
    - in patients concurrently using mTOR inhibitors
    - in patients concurrently using recreational or medicinal cannabis or other cannabinoid based medications.
- Initial Approval: 6 months
- Renewal: 1 year

Dravet Syndrome (DS)

For the adjunctive therapy of seizures associated with DS in patients aged 2 years or older who:

- Have at least 4 convulsive seizures per month AND
- Have inadequately controlled seizures despite previously or currently receiving treatment with at least 2 anti-seizure medications.

Renewal

- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement.

Discontinuation

- Treatment with cannabidiol should be discontinued for lack of beneficial clinical effect after an initial maximum of 6 months of treatment, severe toxicity, or treatment intolerance.

Clinical Notes:

- Must be prescribed by a physician with expertise in the diagnosis and management of patients with DS.
- Coverage will not be provided for patients concurrently using cannabis or other cannabinoid-based medications.
- Initial Approval: 6 months
- Renewal: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2025

Health and Community Services

CAPIVASERTIB (TRUQAP) 160MG AND 200MG TABLETS

In combination with fulvestrant for the treatment of patients with hormone receptor positive, HER2-negative locally advanced or metastatic breast cancer with one or more PIK3CA / AKT1 / PTEN alterations following disease progression on at least one endocrine based therapy in the metastatic setting, or recurrence during or within 12 months of completing adjuvant endocrine therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who have progressed on prior treatment with fulvestrant, received more than 2 lines of hormone therapy, or received more than 1 line of chemotherapy in the metastatic setting.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2025

Health and Community Services

CAPTOPRIL (NOYADA 5mg/5ml, 25mg/5ml oral solution)

- For patients who require administration through a feeding tube.
- For patients 19 years of age and younger, who cannot use a tablet or capsule.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2026

Health and Community Services

Carbamazepine (Tegretol 20mg/ml suspension & generics)

For patients who are fed via gastric tube.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

CARIPRAZINE (VRAYLAR 1.5mg, 3mg, 4.5mg, 6mg capsule)

For the treatment of adult patients with schizophrenia.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated February 2025

Health and Community Services

CENOBAMATE (XCOPRI 12.5mg, 25mg, 50mg, 100mg, 150mg, 200mg, 12.5-25mg started kit, 50-100mg started kit, 150-200mg started kit, 100-150mg maintenance kit, 150-200mg maintenance kit)

As adjunctive therapy in the treatment of patients with partial onset seizures (POS) who have had an inadequate response or have significant intolerance to at least 2 other less costly anticonvulsant therapies (prior or current use).

Note: Less costly anticonvulsant therapies may include the following: Phenytoin, Carbamazepine, Gabapentin, Lamotrigine, Vigabatrin, Topiramate, etc.

- The maximum daily dose is 400 mg once daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

CERITINIB (ZYKADIA) 150MG CAPSULES

As monotherapy treatment for patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer who experience disease progression on, or intolerance to, crizotinib.
Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

Clinical Note:

- Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests for ceritinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib.
- No further ALK inhibitor will be reimbursed following disease progression on ceritinib.
- Initial approval: 1 year.
- Renewal approval: 1 year.
- Recommended dose: 750mg daily

UPDATED April 2021

Health and Community Services

CERLIPONASE ALFA (BRINEURA 150MG/5ML SOLUTION)

For the treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2) disease, in patients who meet all of the following criteria at the time of treatment initiation:

- Confirmed diagnosis of CLN2 disease based on tripeptidyl peptidase 1 (TTP1) enzyme activity and neuronal ceroid lipofuscinosis type 2 (CLN2) genotype analysis; AND
- Score greater than or equal to 1 in each of the motor and the language domains of the CLN2 Clinical Rating Scale; AND
- Aggregate motor-language score of greater than or equal to 3 on the CLN2 Clinical Rating Scale.

Discontinuation Criteria:

- Reduction of greater than or equal to 2 points in the aggregate motor–language score of the CLN2 Clinical Rating Scale that is maintained over any two consecutive 6 month assessment; OR
- Aggregate motor–language score of 0 on the CLN2 Clinical Rating Scale at two consecutive 6 months assessment.

Clinical Notes:

- Documentation of the most recent motor and language domain scores of the CLN2 Clinical Rating Scale must be provided with all requests.
- Patients must be under the care of a specialist with expertise in the diagnosis and management of CLN2 disease.
- Approval duration: 6 months
- Approval Dose: 300 mg (10 mL solution) administered by intracerebroventricular (ICV) infusion once every 2 weeks.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2026

Health and Community Services

CERTOLIZUMAB (CIMZIA 200 MG/ML PREFILLED SYRINGE, PREFILLED AUTOINJECTOR)

Rheumatoid arthritis (RA):

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Response to be assessed after 16 weeks of treatment and therapy continued only if there is clinical response.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on

patient achieving an improvement in symptoms (ACR) of at least 20%.

- Dosage Approved:
    - Loading dose of 400mg at Weeks 0, 2 and 4. Maximum maintenance dose of 200mg every 2 weeks or alternatively, 400mg every 4 weeks.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ankylosing Spondylitis:

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:

- Decrease of at least 2 points on the BASDAI scale compared with the pre-treatment score,

OR

- An adequate clinical response as indicated by significant functional improvement (e.g., measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- combined use of more than one biologic DMARD will not be reimbursed)

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg every four weeks).
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:

https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis

For patients with active psoriatic arthritis who meet **all** of the following of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 400mg at weeks 0, 2, and 4, then 200mg every two weeks (or 400mg every four weeks).
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response criteria).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Updated October 2023

Health and Community Services

CETIRIZINE 20mg generics

For the treatment of chronic idiopathic urticaria (CIU), defined as having hives, angioedema, or both, lasting longer than 6 weeks.

Clinical Notes:

1. Angioedema is defined as periodic submucosal or subcutaneous swelling affecting the face, eyelids, ears, mouth, tongue, hands, feet, or genitals.
2. Hives are defined as red and raised circular swellings on the skin accompanied by itching and sometimes a sensation of burning typically lasting less than 24 hours.

Claim Notes:

- Requests will require the date of first appearance of CIU symptoms.
- Coverage will be considered from 20mg to 40mg daily (considered as one or two 20mg tablets).
- Approval period: Long term.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

CINACALCET (CINACALCET 30mg, 60mg, 90mg generics)

For the management of secondary hyperparathyroidism in patients with chronic kidney disease who are receiving dialysis, as a bridge to transplant where parathyroid hormone (PTH) levels exceed 1000 pg/mL, and there has been inadequate response to optimal dosing of non-surgical interventions.

Clinical Notes:

- Limited to patients currently on dialysis who are awaiting kidney transplantation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2026

Health and Community Services

CIPROFLOXACIN (CIPRO ORAL SUSPENSION 10g/100ml)

For the treatment of the following indications when oral tablets are not an option:

- **Respiratory Tract infections** likely or proven to be caused by *Pseudomonas aeruginosa* including: ○ Exacerbation of COPD with or without bronchiectasis, with previous *Pseudomonas aeruginosa* colonization.
    - Exacerbation of Cystic Fibrosis.

- **Genitourinary Tract Infections** likely or proven to be caused by *Pseudomonas aeruginosa* including:
    - Bacterial prostatitis
    - Anatomically complicated urinary tract infections without source control ○ Failure of previous therapy for urinary trach infection (persistent culture positive).

- **Skin and Soft Tissue Infections** likely or proven to be caused by *Pseudomonas aeruginosa:*
    - Malignant otitis externa
    - Diabetic foot osteomyelitis

- **Gastrointestinal Infections** likely or proven to be caused by *Pseudomonas aeruginosa:* ○ Typhoid fever
    - Gut perforation without surgical source control

- Outpatient **febrile neutropenia**

- **Allergy or intolerance** to oral agents listed in **Spectrum app** (www.Spectrum.app).

- **Gram negative bacilli** from sterile culture which is resistant to other oral agents.

- **Prophylaxis** of close contacts of **culture positive N. meningitides**, as recommended by public health.

- As recommended by **Infectious Disease specialist**

Note:

- The Spectrum app (www.Spectrum.app) is free to all prescribers and contains provincial guidelines on appropriate antimicrobial use based on local resistance rates, provincial antibiogram trends and dose/duration recommendations.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Ciprofloxacin-Oral.pdf

Updated July 2021

Health and Community Services

CIPROFLOXACIN (CIPRO 250 MG, 500MG, 750 MG TABLET and generics)

For the treatment of:

- **Respiratory Tract infections** likely or proven to be caused by *Pseudomonas aeruginosa* including:
  - Exacerbation of COPD with or without bronchiectasis, with previous *Pseudomonas aeruginosa* colonization ○
  Exacerbation of Cystic Fibrosis.

- **Genitourinary Tract Infections** likely or proven to be caused by *Pseudomonas aeruginosa* including:
  - Bacterial prostatitis
  - Anatomically complicated urinary tract infections without source control ○ Failure of previous therapy for urinary trach infection (persistent culture positive).

- **Skin and Soft Tissue Infections** likely or proven to be caused by *Pseudomonas aeruginosa:*
  - Malignant otitis externa
  - Diabetic foot osteomyelitis

- **Gastrointestinal Infections** likely or proven to be caused by *Pseudomonas aeruginosa:*
  - Typhoid fever
  - Gut perforation without surgical source control

- Outpatient **febrile neutropenia**

- **Allergy or intolerance** to oral agents listed in **Firstline app** (www.firstline.org).

- **Gram negative bacilli** from sterile culture which is resistant to other oral agents.

- **Prophylaxis** of close contacts of **culture positive N. meningitides**, as recommended by public health.

- As recommended by **Infectious Disease specialist**

Note:

- The Firstline app (www.firstline.org) is free to all prescribers and contains provincial guidelines on appropriate antimicrobial use based on local resistance rates, provincial antibiogram trends and dose/duration recommendations.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Ciprofloxacin-Oral.pdf

Updated October 2023

Newfoundland Labrador

Health and Community Services

CLADRIBINE (MAVENCLAD 10MG TABLET and generics)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated April 2026

Health and Community Services

CLINDAMYCIN PHOSPHATE 1.2%/BENZOYL PEROXIDE 3.1%/ ADAPALENE 0.15% (CABTREO 1.2%/3.1%/0.15% topical gel)

For the topical treatment of acne vulgaris in patients 12 years of age and older when conventional therapies with benefit topical agents have failed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Health and Community Services

CLOZAPINE (CLOZARIL 25mg, 50mg, 100mg, 200mg, Gen-CLOZAPINE 25mg, 50mg, 100mg, 200mg, Gen ODT 12.5mg, 25mg, 50mg, 100mg, 200mg, AA-CLOZAPINE 25mg, 50mg, 100mg, 200mg)

For patients diagnosed with treatment resistant schizophrenia who have not obtained a satisfactory clinical response, despite treatment with appropriate courses of maximum tolerated***** therapeutic doses, of at least **two chemically unrelated** anti-psychotic medications.

*****intolerance is defined as the inability to achieve adequate benefit due to dose-limiting intolerable adverse effects such as parkinsonism, dystonia, akathesia and tardive dyskinesia.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2025

COBIMETINIB (COTELLIC) 20MG TABLETS

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used in combination with vemurafenib (Zelboraf).

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity

Claim Notes:

- Cobimetinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Updated March 2023

Health and Community Services

Codeine (Codeine Contin 50mg, 100mg, 150mg , 200mg tablets)

For patients with persistent pain***** who have been stabilized on a titrated dose of an oral short-acting codeine product.

*** Please note**: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

VITAMIN D3 50 000 IU generics

- For the treatment of vitamin D resistant rickets.
- For supplementation in patients with hypoparathyroidism.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated December 2023

Health and Community Services

CRIZOTINIB (XALKORI 200 MG, 250MG TABLET)

1. For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer when used as:
   - first-line therapy, or
   - second-line therapy following chemotherapy.

2. As monotherapy for the first-line treatment of patients with ROS1-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Note:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:
- Requests for crizotinib will not be considered for patients who experience disease progression on an ALK inhibitor.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2025

Health and Community Services

CROVALIMAB (PIASKY 340 mg/2 mL subcutaneous injection/intravenous infusion)

For the treatment of patients 13 years of age and older, weight of at least 40 kg with paroxysmal nocturnal hemoglobinuria (PNH) who meet all the following criteria:

- Flow cytometry/FLAER exam with granulocytes clone or monocyte clone size of ≥ 10% **AND**
- LDH > 1.5 ULN

AND at least ONE of the following features attributed to PNH:

- A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
- Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
- Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70 g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia,
- Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,
- Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73 m2, where causes other than PNH have been excluded.
- Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

Renewal will be considered for patients who:
After the initial approval period, a patient may receive approval for further coverage where:

- There has been relief of the PNH symptoms that had qualified the patient for their initial crovalimab approval; AND
- There is demonstrate clinical improvement in the patient or disease stabilization of PNH compared to baseline clinical results and symptoms, AND
- The patient and treating physician have been adequately adherent to treatment and to measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy
- Requests for renewal should be accompanied by confirmation of clone size (by flow cytometry). Granulocyte and monocyte clone size should be included to compare against the baseline results.

Exclusion criteria for both initial and renewal requests:
Patients meeting any of the following criteria will not be eligible for coverage:

- Small clone size - granulocyte and monocyte clone sizes below 10%; **OR**
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy. OR

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; **OR**
- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

Clinical Notes:

- Must be prescribed by a hematologist with expertise in the treatment of PNH.
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).
- The prescriber should submit relevant bloodwork to support the diagnosis including CBC, transfusion records, bone marrow report, flow cytometry/FLAER exam, LDH levels, and as possible, recent consult notes.
- Prescribers should comply the most current National Advisory Committee on Immunization (NACI) recommendations for meningococcal vaccination in patients with complement deficiencies to reduce the risk of serious infections. Appropriate vaccination for meningococcal disease should be accompanied at least 2 weeks prior to receiving the first dose of crovalimab and if there is not possible, refer to the product monograph for the first dose mitigation instructions.
- Funding will not be considered if the patient and treating physician fails to comply adequately with treatment or measures, including monitoring requirements necessary to evaluate effectiveness of the therapy with ravulizumab.
- Coverage will not be approved when any complement inhibitors are to be used in combination. Patients will not be permitted to switch back to a previously trialed complement inhibitor.
- Patients with insufficient initial response or who have failed treatment with eculizumab, ravulizumab or crovalimab at the Health Canada–recommended dosage are not eligible for reimbursement of crovalimab.
- Initial Approval: 6 months
- Renewal Approval: 1 year
- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99,999.99 per claim**, please contact (709) 729-1780 for billing guidance.

PIASKY Dosing Regimen Based on Body Weight

Body Weight	≥ 40 kg to < 100 kg	≥ 100 kg

Leading Dose		
Day 1	1000 mg (IV)	1500 mg (IV)
Day 2, 8, 15, 22	340 mg (SC)	340 mg (SC)
Maintenance Dose		
Day 29 and Q4 weeks thereafter	680 mg (SC)	1020 mg (SC)

IV = intravenous, SC = subcutaneous, kg = kilograms, Q4W=every 4 weeks

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated August 2026

Newfoundland Labrador

Health and Community Services

CYSTEAMINE (CYSTADROPS 3.8 mg/mL OPHTHALMIC SOLUTION)

For the treatment of corneal cystine crystal deposits (CCCDs) in patients 2 years of age and older with cystinosis:

Clinical Note:
Diagnosis of cystinosis must be confirmed by cystinosin (lysosomal cystine transporter) gene mutation or elevated white blood cell cystine levels. (Documentation must be provided).

Claim Note:
Patient must be under the care of an ophthalmologist experienced in the management of the ocular manifestations of cystinosis

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2021

Health and Community Services

CYSTEAMINE (PROCYSBI 25MG CAPSULE, 75MG CAPSULE)

For use in patients with an established diagnosis of infantile nephropathic cystinosis with documented cystinosin, lysosomal cystine transporter gene mutation.

Claim Note:

- Must be prescribed by, or in consultation with, a physician with experience in the diagnosis and management of cystinosis.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2021

DABRAFENIB (TAFINLAR) 50mg, 75mg capsules

Adjuvant Melanoma
In combination with trametinib (Mekinist) for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (8th edition of American Joint Committee on Cancer [AJCC] staging system)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

Claim Notes:

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Approval period: Up to 12 months.

Metastatic Melanoma
For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with trametinib.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have an ECOG performance status of 0 or 1.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Dabrafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Updated March 2023

Health and Community Services

Dalteparin sodium (Fragmin 2500U, 3500U, 7500U, 10000U, 12500U, 15000U, 16500U, 18000U, 25000U vials & syringe),

- For the prevention of VTE following:
    - total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
    - total knee replacement (TKR) surgery (maximum coverage up to 10 days)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/forms/pdf/Thromboembolism_Prevention_Following_Surgery.pdf

- For treatment of acute Venous Thromboembolism (VTE)
    - coverage is limited to 7 to 10 days while establishing a therapeutic INR
    - extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

- For prophylaxis of VTE, coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.
    - Coverage will be limited to a 3 month period.

Anticoagulation in patients with cancer:

- For the treatment of VTE in cancer patients:
    - acute treatment limited to 10 days (while warfarinizing)
    - extended treatment in symptomatic VTE in cancer patients who have had a recurrent VTE on warfarin therapy. Coverage will be limited to a 3 month period.

- For the secondary prevention of symptomatic VTE:
    - For cancer patients who are on active chemotherapy with agents which interact with warfarin OR in patients who have failed oral anticoagulants as evidenced by an extension or recurrence of DVT.
    - **Maximum treatment duration 6 months.**

Please note that the routine use of LMWH in cancer patients to improve survival was reviewed and NOT recommended as there was no consistent evidence to support use.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2020

Health and Community Services

Darbepoetin (Aranesp 10ug, 20ug, 30ug, 40ug, 50ug, 60ug, 80ug, 100ug, 130ug, 150ug, 300ug, and 500ug)

Chronic Renal Failure:

- For anemia of chronic renal failure* (chronic kidney disease) for patients who:
    - Have a serum creatinine level > 176umol/L (2mg/dL) OR GFR < 1ml/sec/1.73m2 (60 mL/min/1.73m2) for three or more months AND who have an anemia work-up showing hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia.

Written request from a medical specialist required.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematologic malignancy* in transfusion dependent patients:
    - With a baseline Hgb ≤ 90g/L whose transfusion requirements are ≥ 2 units of packed red blood cells (PRBC/month) over a 3 month period.

An initial trial of 12 weeks (2.25ug/kg/week) will be approved with documentation of dose, Hgb and therapeutic outcome (#of transfusions).

Further 12 week cycle can be approved dependent on evidence of clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to ≥ 2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 4.5ug/kg/week).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

DARIFENACIN (ENABLEX 7.5mg & 15mg tablet)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

DAROLUTAMIDE (NUBEQA) 300 MG TABLET

Metastatic Castration-Sensitive Prostate Cancer

For the treatment of patients with metastatic castration-sensitive prostate cancer who have had no prior androgen deprivation therapy (ADT) in the metastatic setting, or initiated ADT within 6 months in the metastatic setting with no disease progression, when used:

- in combination with ADT; or
- in combination with docetaxel and ADT

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who are within 1 year of completing adjuvant ADT in the non-metastatic setting.
- Patients who experience disease progression on apalutamide or enzalutamide are not eligible.
- Approval period: 1 year.

Non-Metastatic Castration-Resistant Prostate Cancer

In combination with androgen-deprivation therapy (ADT) for the treatment of patients with nonmetastatic castration-resistant prostate cancer (nmCRPC) who meet all of the following criteria:

- No detectable distant metastases by either CT, MRI or technetium-99m bone scan
- Prostate-specific antigen (PSA) doubling time of less than or equal to 10 months during continuous ADT (i.e., high risk of developing metastases)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:

1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL.
2. Castrate levels of testosterone must be maintained throughout treatment with darolutamide.

3. Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.
4. Patients should have good performance status.
5. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.
- Patients receiving darolutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on darolutamide.
- Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression.
- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2026

Health and Community Services

DARUNAVIR/COBICISTAT (PREZCOBIX 800 MG-150 MG TABLET)

For treatment of human immunodeficiency virus (HIV) infection in treatment-naïve and treatment-experienced patients without darunavir (DRV) resistance-associated mutation (RAMS).

This drug, as with other antivirals in the treatment of HIV, should be used under the direction of an infectious disease specialist.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Health and Community Services

Darunavir (Prezista 75mg, 150mg, 300mg, 400mg, 600mg & 800mg tablet and generics)

- For use in treatment-experienced pediatric HIV-1 patients.
- For the treatment of HIV-1 in patients who are treatment naïve for whom a protease inhibitor (PI) therapy is indicated.
- As an alternate protease inhibitor (PI) as part of a HIV treatment regimen for the treatment-experienced adult patients who have demonstrated failure to multiple PI's and in whom less expensive PI's are not a treatment option.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2020

Health and Community Services

DASATINIB (SPRYCEL) 20mg, 50mg, 70mg, 80mg, 140mg tablet and generics

1. For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic, accelerated, or blast phase.
2. For the treatment of patients with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Claim Note:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2023

Health and Community Services

DECITABINE / CEDAZURIDINE (INQOVI) 35MG / 100MG TABLETS

For the treatment of adult patients with myelodysplastic syndromes (MDS), including previously treated and untreated, who meet all of the following criteria:

- De novo or secondary MDS including all French-American-British subtypes (i.e., refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia)
- Intermediate-1, intermediate-2, or high-risk MDS, according to the International Prognostic Scoring System; and
- Have not experienced disease progression on a hypomethylating agent

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2023

Newfoundland Labrador

Health and Community Services

DEFERASIROX (JADENU 90mg, 180 mg, 360mg TABLET & generics)

For patients who require iron chelation but in whom desferoxamine is contraindicated.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Health and Community Services

DEFERIPRONE (FERRIPROX 1000MG TABLET, 100 mg/mL oral solution

For the treatment of patients with transfusional iron overload due to thalassemia syndromes when current chelation therapy is inadequate.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2017

Health and Community Services

DENOSUMAB (DENOZA 60mg/ml Prefilled Syringe, JUBBONTI 60mg/ml Prefilled Syringe, STOBOCLO 60mg/ml prefilled syringe, BILDYOS 60mg/mL Prefilled Syringe)

For the treatment of osteoporosis in patients who have:

- a high fracture risk, and
- a contraindication, severe gastrointestinal intolerance, or are refractory to bisphosphonates.

Clinical Notes:

- Refractory is defined as a fragility fracture or evidence of a decline in bone mineral density below pre-treatment baseline levels, despite adherence for one year to osteoporosis therapy.
- High fracture risk is defined as:
  - Moderate 10-year fracture risk (10% to 20%) as defined by the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) tool or the World Health Organization's Fracture Risk Assessment (FRAX) tool with a prior fragility fracture; or
  - High 10-year fracture risk (≥ 20%) as defined by the CAROC or FRAX tool.
- Approval period: Long term.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

November 2026 2026

Health and Community Services

DENOSUMAB (IDENOS 120mg/1.7ml Vial, OSENVELT 120mg/1.7ml Vial, WYOST 120mg/1.7ml Vial, TUZEMTY 120mg/1.7mL Vial)

For the prevention of skeletal related events (SREs) in patients with castrate-resistant prostate cancer (CRPC) with one or more documented bony metastases and good performance status (Eastern Cooperative Oncology Group [ECOG] performance status score of 0, 1, or 2).

Approval Period: Indefinite

Recommended Dose: 1.7 ml every four weeks

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2026

Health and Community Services

Diazepam Rectal Gel (Diazepam 5mg/ml rectal gel)

For the management of patients with epilepsy who have failed to respond to benefit lorazepam formulations (either sublingual tablets or injection administered rectally).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

DIENOGEST (VISANNE 2 MG TABLET and generics)

For the management of pelvic pain associated with endometriosis in patients for whom one or more less costly hormonal options are either ineffective or cannot be used.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2021

Health and Community Services

DIMETHYL FUMARATE (TECFIDERA 120mg, 240mg CAPSULE)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2020

Health and Community Services

DOLUTEGRAVIR /LAMIVUDINE (DOVATO 50 MG/300 MG TABLET)

- As a complete regimen for the treatment of Human Immunodeficiency Virus -Type 1 (HIV-1) infection in adults and adolescents 12 years of age and older and weighing at least 40 kg.

Initiation Criteria:

- The patient must be naïve to any antiretroviral therapy (ART) and have an HIV-1 viral load ≤ 500,000 copies/mL.
- The patient must be under the care of a practitioner experienced in the care of patients with HIV.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2020

Health and Community Services

DOLUTEGRAVIR/RILPIVIRINE (JULUCA 50 MG-25 MG TABLET)

As a complete regimen to replace the current antiretroviral (cARV) regimen for the treatment of human immunodeficiency virus (HIV-1) infection in adults who are virologically stable and suppressed (HIV-1 RNA less than 50 copies per ml).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2019

Newfoundland Labrador

Health and Community Services

DOLUTEGRAVIR (TIVICAY 50 MG TABLET)

For the treatment of HIV in both treatment-naive and treatment-experienced adults andchildren 12 years of age and older weighing at least 40kg, in combination with other antiretrovirals.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2015

Health and Community Services

DORAVIRINE/LAMIVUDINE/TENOFOVIR DISOPROXIL FUMARYE (DELSTRIGO 100-300-300 MG Tablet)

For use as a complete regimen for the treatment of HIV-1 infection in adults without past or present evidence of viral resistance to doravirine, lamivudine, or tenofovir.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2020

Newfoundland Labrador

Health and Community Services

DORAVIRINE (PIFELTRO 100 mg)

For the treatment of adults infected with HIV-1 without past or present evidence of viral resistance to DORAVIRINE.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2020

Health and Community Services

DORNASE ALFA (PULMOZYME 1 MG/ML AMPOULE)

For the treatment of patients with cystic fibrosis with:

- clinical evidence of lung disease (e.g., frequent pulmonary exacerbations OR
- difficulty clearing secretions OR
- FEV1 <90% predicted).

Clinical Note:

- Must be prescribed by a clinician with experience in the diagnosis and treatment of CF.
- Coverage will be limited to once daily dosing.
- Restricted to patients under the Select Needs Program.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2021

Health and Community Services

DUPILUMAB (DUPIXENT 200mg (200mg/1.14ml) single use syringe, 200mg (200mg/1.14ml) single use pen, 300mg (300 mg/2ml) single-dose syringe, 300 mg (300mg/2ml) single-dose pen)

Atopic Dermatitis

For the treatment of patients aged 12 years and older with moderate-to-severe atopic dermatitis (AD) whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable, who meet all of the following:

Who are refractory or intolerant to:

- an adequate trial with maximally tolerated prescription topical therapies (corticosteroid and/or topical calcineurin inhibitors) for atopic dermatitis (combined with phototherapy (where available), and
- an adequate trial of prescription topical therapies (corticosteroid and/or topical calcineurin inhibitors) for atopic dermatitis combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine), and
- Have an Investigator's Global Assessment (IGA) score ≥ 3 and an Eczema Area and Severity Index (EASI) score ≥ 16.

- The physician must provide the Eczema Area and Severity Index (EASI) score and the Investigator's Global Assessment (IGA) score for Atopic Dermatitis (vIGA-AD) at the time of initial request for reimbursement.

Renewal Criteria

- The maximum duration of initial authorization is 6 months.
- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 20 weeks after treatment initiation.
- For subsequent renewal, the physician must provide proof of maintenance of EASI 75 response from baseline every 6 months for subsequent authorizations.

Clinical Notes:

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate-to-severe AD.
- For adolescent patients weighing less than 60 kg, coverage may be approved for an initial loading dose of 400 mg (2 subcutaneous injections of 200 mg) followed by 200 mg every other week.

- For adolescent patients weighing 60 kg or more, and for adult patients, coverage may be approved for initial loading dose of 600 mg (2 subcutaneous injections of 300 mg) followed by 300 mg every other week.
- Following initial assessment, continued coverage may be approved for 200 mg every other week for adolescent patients less than 60 kg, or 300 mg every other week for adults and adolescent patients 60 kg or more. Special Authorization may be granted for 6 months.
- Coverage will not be considered in combination with phototherapy, any immunomodulatory drugs (including biologics) or a Janus kinase [JAK] inhibitor treatment for moderate-to-severe AD.

Please visit the following link if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Special-Authorization-Form-Dupixent.pdf

Asthma

For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype in patients aged 6 to 11 years of age who are inadequately controlled with medium-to high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) or high-dose ICS alone and meet the following criteria:

- Eosinophil count ≥ 150 cells/μL (0.15×10^9/L).
- Uncontrolled asthma with at least one severe exacerbation (defined as hospitalization, ER visit, steroid use) in the past 12 months.

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.

Clinical Notes:

- A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
- Medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
- A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.
- Must be prescribed by a pediatric respirologist or allergist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 200 mg every two weeks or 300 mg every four weeks.

- Approval period: 1 year.

For the adjunctive treatment of severe asthma with a type 2 or eosinophilic phenotype or oral corticosteroid (OCS) dependent severe asthma in patients 12 years of age and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS) and one or more additional asthma controller(s) (e.g., long-acting beta-agonist) and meets one of the following criteria:

- blood eosinophil count ≥ 0.15×10^9 /L within the past 12 months, or
- have OCS dependent asthma.

Initial Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or
- No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Subsequent Discontinuation Criteria:

- Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or
- Reduction in the daily maintenance OCS dose achieved after the first 12 months of treatment is not maintained subsequently, or
- Number of clinically significant asthma exacerbations has increased within the previous 12 months.

Clinical Notes:

- A baseline and annual assessment of asthma symptom control using a validated asthma control questionnaire must be provided.
- A baseline and annual number of clinically significant asthma exacerbations must be provided.
- High-dose ICS is defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
- A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized.
- Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma.
- Combined use of dupilumab with other biologics used to treat asthma will not be reimbursed.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Approval period: 1 year

Please visit the following link if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Asthma-1.pdf

Updated September 2026

Newfoundland Labrador

Health and Community Services

EDARAVONE (RADICAVA 30MG/100ML INTRAVENOUS SOLUTION, RADICAVA 105MG/5ML ORAL SUSPENSION)

For the treatment of patients with probable or definite amyotrophic lateral sclerosis (ALS) who meet all of the following criteria:

- has scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R)
- has a forced vital capacity greater than or equal to 80% of predicted
- has had ALS symptoms for two years or less
- patient is not currently requiring permanent non-invasive or invasive ventilation.

Discontinuation criteria:

- patient becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); or
- patient requires permanent non-invasive or invasive ventilation.

Clinical Notes:

- Baseline and biannual ALSFRS-R scores and FVC must be provided

Claim Notes:

- Patient must be under the care of a specialist with experience in the diagnosis and management of ALS.
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

Efavirenez/emtricitabine/tenofovir (Atripla 600mg/200mg/300mg & generics)
For the treatment of HIV-1 infection where the virus is susceptible to each of tenofovir, emtricitabine and efavirenz **AND**:

- **Efavirenez/emtricitabine/tenofovir** is used to replace existing therapy with its component drugs, **OR**
- The patient is treatment naïve, **OR**
- The patient has established viral suppression but requires antiretroviral therapy modification due to intolerance or adverse effects.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2017

Health and Community Services

EFGARTIGIMOD ALFA (VYVGART 400mg vial)

For the treatment of adult patients with generalized myasthenia gravis (gMG) who meet all of the following criteria:

- The patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies.
- The patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 5 or higher at baseline.
- The patient has a Myasthenia Gravis Foundation of America (MGFA) class of II to IV disease
- The patient is refractory to or intolerant of an adequate trial of rituximab for gMG (note that if rituximab is not appropriate for the patient, an adequate trial of another preventative treatment including but not limited to other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate or other immunosuppressants must have been used).

Exclusion criteria:

Efgartigimod alfa should not be initiated:

- during a gMG exacerbation or crisis, OR
- within 3 months of thymectomy.

Renewal:

- For continued coverage beyond the initial three treatment cycles, the patient must have documented improvement in the MG-ADL score of two points or greater from baseline.
- Following this assessment, continued coverage may be approved for up to 1200 mg once weekly for four weeks (per treatment cycle) (with a minimum of 4 weeks between treatment cycles) for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed every 12 months and has maintained a response to therapy as indicated by no worsening of the MG-ADL.Coverage may be continued after the initial 3 cycles of treatment, if there is documented improvement in the MG-ADL score in 2 points or greater.

Clinical Notes:

- Must be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- The MG-ADL score must be measured and provided by the physician at baseline.
- Coverage cannot be provided for zilucoplan when this medication is intended for use in combination with other biologics (including rituximab) or complement inhibitors for the treatment of gMG.

- Patients will not be permitted to switch back to a previously trialed biologic agent/complement inhibitor if they were deemed unresponsive to therapy.
- Patients will be permitted to switch from one biologic agent/complement inhibitor to another following an adequate trial of the first biologic agent/complement inhibitor if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Approvals will be for a dose of 10mg/kg up to a maximum of 1200 mg per infusion administered once weekly for 4 weeks (one treatment cycle)
- Initial Approval: may be approved for up to 1200 mg intravenous (IV) once weekly for four weeks (one treatment cycle). Coverage may be provided for a maximum of three treatment cycles (with a minimum of 4 weeks between treatment cycles) for a period of 6 months.
- Renewal: After the initial 3 cycles of treatment, reassessment will be every 12 months.
- Subsequent renewals will require the physician reassessment confirming proof of no worsening of MG-ADL score.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Newfoundland Labrador

Health and Community Services

EPLERENONE (INSPRA 25mg, 50 MG TABLET and generics)

For the treatment of patients who have New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as a complement to standard therapy.

Clinical Note:
Patients must be on optimal therapy with an angiotensin-converting enzyme (ACE) inhibitor OR an angiotensin-receptor blocker (ARB), AND a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2022

Health and Community Services

ELEXACAFTOR/TEZACAFTOR/IVACAFTOR/IVACAFTOR (TRIKAFTA 100mg/50mg/75mg/150mg TABLET, 50mg/25mg/37.5 mg/75 mg TABLET, 100 mg/50 mg/75 mg & 75mg granules, 80 mg/40 mg/60 mg & 59.5 mg granules)

For the treatment of cystic fibrosis (CF) in patients age two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to lexacaftor/tezacaftor/ivacaftor and ivacaftor.

Patients should be optimized with best supportive care for their CF at the time of initiation.

For patients aged 2 to 5 years of age:

Initial Renewal Criteria:
The patient must meet one of the following criteria:

- Decrease in the total number of days for which the patient received treatment with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment. OR
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment.

AND

- No decrease in Body Mass Index (BMI) z-score compared with baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit must be provided for at least one of the parameters noted above at the end of each 12-month period.

Clinical Notes:

1. The following baseline measurements must be provided prior to initiation of treatment:
   - Total number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the 6 months prior to initiation of treatment
   - Total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the 6 months prior to initiation of treatment
   - BMI z-score

2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Restricted to patients under the Select Needs Program.
- The patient must be under the care of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.

- Approval period: 1 year.

For patients aged 6 years and older who:

Initial renewal criteria:

For the initial renewal, the patient must meet at least ONE of the following criteria:

- Improvement of lung function by 5% of predicted or more (ppFEV1 compared to baseline (baseline lung function should be measured within a 3-month period prior to beginning treatment with Trikafta); OR
- A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment; OR
- A decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6- month period prior to initiating treatment; OR
- Decreased number of CF-related hospitalizations at 6 months compared with the 6-month period prior to initiating Trikafta treatment; OR
- No decline in BMI (BMI z score in children) at 6 months compared with the baseline BMI assessment; OR
- Improvement by 4 points or more in the CF Questionnaire-Revised (CFQ-R) Respiratory Domain scale compared to baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit from treatment with Trikafta for subsequent renewals (e.g. ppFEV1, CFQ-R, pulmonary exacerbations).

Clinical Notes:

1. The following measurements must be completed prior to initiating treatment with Trikafta:
    - Baseline spirometry measurements of FEV_1 and ppFEV1 within the last 90 days prior to initiating treatment ;
    - Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months;
    - Number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months;
    - Number of CF-related hospitalizations in the previous 6 months;
    - Weight, height, and BMI; and
    - CFQ-R Respiratory Domain score.

2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Restricted to patients under the Select Needs Program.
- The patient must be under the case of a physician with experience in the diagnosis and
  management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Initial approval: 7 months.
- Renewal approval period: Longterm

- Approved dose:
  6 to < 12 years of age weighing < 30kg: Two tablets (each containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) in the morning & one tablet (ivacaftor 75 mg) taken in the evening with fat-containing food, approximately 12 hours apart.
  6 to < 12 years of age weighing ≥ 30kg: 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken with fat-containing food, in the evening approximately 12 hours apart.
  12 years and older: 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken in the evening with fat-containing food, approximately 12 hours apart.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2026

Newfoundland Labrador
Health and Community Services

ELOSULFASE ALFA (VIMIZIM 1MG/ML IV SOLUTION)

For the treatment of mucopolysaccharidosis type IVA (MPS IVA) in patients meeting all the following criteria:

- Diagnosis is confirmed by diagnostic testing through enzymatic assay for N-acetylgalactosamine-6-sulfate sulfatase (GALNS) activity in peripheral blood leukocytes or fibroblasts (excluding multiple sulfatase deficiency) AND mutation analysis of GALNS[1] AND
- Patient is under the care of a specialist with experience in the diagnosis and management of MPS IVA; AND

Initiation Criteria:

The following baseline evaluations prior to initiation of Vimizim (elosulfase alfa) must be provided with the request for coverage:

- Detailed medical history documenting surgeries, medical admissions, subspecialty assessments
- Orthopedic evaluation including spinal and cranial MRI, skeletal x-rays, pain symptoms from bone and joints as appropriate to age and clinical disease.
- Mobility measure: 6MWT and stair climb (if appropriate for age and disease status)
- Respiratory function testing including sleep study testing (if appropriate for age)
- Age appropriate quality of life measure (such as HAQ, PODCI, EQ5D5L or SF36)
- documentation of mobility aide requirement, such as a walker or cane
- documentation of requirement for respiratory aides, including ventilation status and changes in respiratory support requirements;
- Ophthalmologic and ear, nose and throat (ENT) assessment (if appropriate)
- Urine keratin sulfate (KS) determination: specific KS determination is preferred over total glycosaminoglycans (GAGs)
- Cardiac echocardiogram

[1]Note: not all MPS IVA patients will have 2 known pathogenic alleles identified and parental mutation analysis to establish the phase of mutations should be performed.
Exclusion Criteria (Patient will not be started on Vimizim if any of the following are met/apply):

- The patient is diagnosed with an additional progressive life limiting condition where treatment would not provide long term benefit (such as cancer or multiple sclerosis)
- The patient has a forced vital capacity (FVC) of less than 0.3 liters and requires continuous ventilator assistance.
- The patient/family is unwilling to comply with the associated monitoring criteria

- The patient/family is unwilling to attend clinics for assessment and treatment purposes

Approval duration of initials: 1 year
Recommended dose: 2mg/kg IV infusion once a week.

Renewal Criteria:

Patients must demonstrate at least 3 of the 5 following treatment effects for continuation of coverage of treatment with elosulfase alfa:

- 6 MWT or Stair Climb test stabilized at or improved by at least 5% of baseline measure
- Forced Vital Capacity (FVC) or Forced Expiratory Volume in one second (FEV-1) stabilized at or improved by at least 5% of baseline measure or remaining within 2 standard deviations of normal for the patient's age
- Improvement or no change (if minimal effect) in age appropriate quality of life measure
- Reduction of urine KSs of 20%
- Stability of cardiac ejection fraction reduction (within 5% of baseline)

Discontinuation criteria

Patients will not be eligible for coverage of treatment if they:

- Fail to meet 3 of the 5 continuation criteria
- Are unable to tolerate infusions due to infusion related adverse events that cannot be resolved
- Require permanent invasive ventilation
- Miss more than 6 infusions in a 12-month interval, unless for medically related issues.
- Meets any one of the Exclusion Criteria

Approval duration of renewals: 1 year
Recommended dose: 2mg/kg IV infusion once a week

Please visit the link below if you require the NLPDP special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated April 2024

Health and Community Services

Elvitegravir/Cobicistat/Emtricitabine/Tenofovir alafenamide (GENVOYA 150mg/150mg/200mg/10mg tablet (EVG/COBI/FTC/TAF))

As a complete regimen for the treatment of HIV-1 infection in adult and pediatric patients 12 years of age and older (and weighing ≥ 35kg) and with no known mutations associated with resistance to the individual components of GENVOYA

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2017

Health and Community Services

ELVITEGRAVIR/COBICISTAT/EMTRICITABINE/TENOFOVIR (STRIBILD 150-150-200-300MG tablet)

As a complete regimen for antiretroviral treatment-naive HIV-1 infected patients in whom efavirenz is not indicated.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2015

Health and Community Services

EMPAGLIFLOZIN (JARDIANCE 10mg, 25mg)

Diabetes Mellitus

For the treatment of type 2 diabetes mellitus when added to metformin for patients with inadequate glycemic control on metformin, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after JARDIANCE is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Cardiovascular Disease

As an adjunct to diet, exercise, and standard care therapy to reduce the incidence of cardiovascular (CV) death in patients with type 2 diabetes mellitus (T2DM) and established cardiovascular disease who have inadequate glycemic control, if the following criteria are met:

- Patients have inadequate glycemic control despite an adequate trial of metformin
- Patients have established cardiovascular disease

NOTE: Established CV disease is defined on the basis of one of the following (details must be provided):

- History of myocardial infarction (MI).
- Multi-vessel coronary artery disease in two or more major coronary arteries (irrespective of revascularization status).
- Single-vessel coronary artery disease with significant stenosis and either a positive non-invasive stress test or discharged from hospital with a documented diagnosis of unstable angina within 12 months prior to selection.
- Last episode of unstable angina > 2 months prior with confirmed evidence of coronary multi-vessel or single-vessel disease.

- History of ischemic or hemorrhagic stroke.
- Occlusive peripheral artery disease.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Diabetes-Mellitus-Type-2-High-Cardiovascular-Risk.pdf

Updated September 2024

Health and Community Services

EMPAGLIFLOZIN / METFORMIN (SYNJARDY 500mg/5mg, 850mg/5mg, 1000mg/5mg, 500mg/12.5mg, 850mg/12.5mg, 1000mg/12.5mg)

For the treatment of type 2 diabetes mellitus in patients with inadequate glycemic control on metformin and who are not using insulin. Patients must be already stabilized on therapy with metformin and empagliflozin. Coverage will be provided to replace the individual components of empagliflozin and metformin in these patients.

Clinical Note:

- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after SYNJARDY is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

EMTRICITAB/RILPIVIRINE/TENOFOVIR (COMPLERA 200 MG-25MG-300MG TAB)

For the treatment of human immunodeficiency virus type 1 (HIV-1):

- in antiretroviral treatment-naïve patients, or
- to replace the three components given as dual or triple therapy for patients stabilized on appropriate doses.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2012

Newfoundland Labrador

Health and Community Services

EMTRICITABINE/RILPIVIRINE/TENOFOVIR (ODEFSEY 200 MG-25 MG-25 MG TABLET)

As a complete regimen for the treatment of adults infected with HIV-1 with no known mutations associated with resistance to the non-nucleoside reverse-transcriptase inhibitor (NNRTI) class, tenofovir or FTC, and with a viral load ≤ 100,000 copies/mL

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2018

Health and Community Services

EMTRICITABINE/TENOFOVIR (TRUVADA 200mg/300mg tablets & generics)

HIV-1 treatment

As a dual nucleoside/nucleotide option for the treatment of HIV patients where the virus is susceptible to both agents and efavirenez is not indicated due to adverse effects or antiretroviral resistance.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Pre-Exposure Prophylaxis (PrEP)

For at-risk adult individuals for pre-exposure prophylaxis (PrEP) to reduce the risk of HIV-1 infection.

Renewal Criteria:

- Confirmation of adherence to treatment.

Claim Note:

- Approval period: 1 year.

Please visit the link below if you require the special authorization request form:
https://www.gov.nl.ca/hcs/files/HIV-Pre-Exposure-Prophylaxis.pdf

Updated July 2025

Health and Community Services

ENCORAFENIB (BRAFTOVI) 75MG CAPSULE

Melanoma
In combination with binimetinib for treatment of patients with locally advanced unresectable or metastatic melanoma with a BRAF V600 mutation.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients should have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Approval period: 6 months.

Metastatic Colorectal Cancer
In combination with panitumumab for the treatment of patients with metastatic colorectal cancer who meet all of the following criteria:
- Presence of BRAF V600E mutation.
- Disease progression following at least one prior therapy in the metastatic setting.
- No previous treatment with an EGFR inhibitor.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients should have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Encorafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.

- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2023

Newfoundland Labrador

Health and Community Services

ENOXAPARIN (INCLUNOX™ PREFILLED SYRINGE 30mg/0.3ml, 40mg/0.4ml, 60mg/0.6ml, 80mg/0.8ml, 100mg/1ml, HP 120mg/0.8ml PREFILLED SYRINGE, HP 150mg/1ml PREFILLED SYRINGE**, REDESCA** PREFILLED SYRINGE 30 mg/0.3 ml, 40 mg/0.4 ml, 60 mg/0.6 ml, 80 mg/0.8 ml, 100 mg/1 ml, HP 120 mg/0.8 ml, HP 150 mg/1 ml, MULTIPLE DOSE VIAL 300 mg/3 ml**, NOROMBY** PREFILLED SYRINGE 20mg/0.2ml, 30mg/0.3ml, 40mg/0.4ml, 60mg/0.6ml, 80mg/0.8ml, 100mg/1ml, HP 120mg/0.8ml, 150mg/1ml**, ELONOX** 30mg/0.3ml, 40mg/0.4ml, 60mg/0.6ml, 80mg/0.8ml, 100mg/ml, HP 120mg/0.8ml, HP 150mg/ml prefilled syringe**)**

For the **prophylaxis** of thromboembolism (VTE) following:

- total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
- total knee replacement (TKR) surgery (maximum coverage up to 10 days)

- For the prophylaxis of venous thromboembolism (VTE) post abdominal or pelvic surgery for management of a malignant tumor.
    - Approval up to 10 days

OR

- Approval up to 28 days for high risk patients e.g. those with a history of VTE and/or anesthesia lasting > 2 hours and/or bed rest lasting > 4 days following surgery.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/LMWH-for-VTE-Prevention-Following-Surgery-.pdf

For **prophylaxis** of venous thromboembolism (VTE), coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.

- Coverage will be limited to a 3 month period.

For **treatment** of acute Venous Thromboembolism (VTE)

- coverage is limited to 7 to 10 days while establishing a therapeutic INR
- extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated October 2024

Health and Community Services

ENTRECTINIB (ROZLYTREK) 100 mg, 200 mg Capsule

Non-Small Cell Lung Cancer
As monotherapy for the first-line treatment of patients with ROS1-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 1 year

Solid Tumors with NTRK gene fusion
As monotherapy for the treatment of adult patients with unresectable locally advanced or metastatic extracranial solid tumors who meet all of the following criteria:
- Tumors have a NTRK gene fusion without a known acquired resistance mutation.
- No other satisfactory treatment options.
- Not a candidate for surgery and/or radiation due to risk of substantial morbidity.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. If CNS metastases are present, patients must be asymptomatic.
3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:
- Requests will not be considered for patients who experience disease progression on a NTRK inhibitor.
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

ENZALUTAMIDE (XTANDI) 40 MG CAPSULES

Non-Metastatic Castration-sensitive Prostate Cancer
As monotherapy, or in combination with androgen deprivation therapy (ADT), for the treatment of patients with non-metastatic castration-sensitive prostate cancer (nmCSPC) with biochemical recurrence (BCR) at high risk for metastasis after radical prostatectomy (RP) or radiation (RT), who have all the following characteristics:

- Prostate-specific antigen (PSA) doubling time of 9 months or less, and
- Screening PSA level of 1 mcg/L or higher in prior RP (plus or minus postoperative RT) patients, OR PSA level at least 2 mcg/L above nadir in prior RT
- Testosterone level of 150 ng/dL (5.2 nmol/L) or higher
- Not a candidate for salvage radiation therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no risk factors for seizures.
2. There must be no evidence of metastases on conventional imaging.
3. Enzalutamide should be held after 36 weeks if PSA is suppressed to less than or equal to 0.2 mcg/L. Enzalutamide may be restarted if PSA increases to at least 5 mcg/L in patients with no prior RP or if PSA increases to at least 2 mcg/L in patients with prior RP.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Metastatic Castration-sensitive Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must be castration sensitive (i.e., no prior ADT in the metastatic setting or within six months of beginning ADT).
2. Patients must have a good performance status and no risk factors for seizures.

3. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:
- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Non-metastatic Castration-resistant Prostate Cancer
In combination with androgen deprivation therapy (ADT) for the treatment of patients with nonmetastatic castration-resistant prostate cancer (nmCRPC) who have a prostate-specific antigen doubling time (PSADT) of ≤ 10 months during continuous ADT (i.e., high risk of developing metastases).

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Castration-resistance must be demonstrated during continuous ADT and is defined as a minimum of three rises in PSA, measured at least one week apart, with the last PSA greater than 2 mcg/L.
2. Castrate levels of testosterone must be maintained throughout treatment with enzalutamide.
3. Patients must have a good performance status and no risk factors for seizures.
4. Treatment should be discontinued upon radiographic disease progression or unacceptable toxicity.

Claim Notes:
- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Metastatic Castration-resistant Prostate Cancer
For the treatment of patients with metastatic castration-resistant prostate cancer.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status and no risk factors for seizures.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for enzalutamide will not be considered for patients who experience disease progression on apalutamide.

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2025

Health and Community Services

EPINEPHRINE (EPIPEN 0.15mg/0.3ml, 0.3mg/0.3ml, EMERADE 0.3mg/0.3ml, 0.5 mg/0.5 mL, ALLERJECT 0.15 mg/0.15 mL, 0.3 mg/0.3 mL)

For the emergency treatment of anaphylactic reactions, when out of reach of immediate medical attention.
Note:

- A limit of one per year can be filled without Special Authorization. Special Authorization is required for higher quantities and/or subsequent fills.
- Approval will be provided to replace used or expired units as needed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2021

Health and Community Services

EPLONTERSON (WAINUA 45mg/0.8mL autoinjector)

For the treatment of adult patients with a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis with polyneuropathy ((hATTR-PN)) who meet the following criteria:

- Patients are symptomatic with early-stage neuropathy, defined by one of the following:
    - Polyneuropathy disability (PND)[1] stage I to ≤ IIIB, OR
    - Familial amyloidotic polyneuropathy (FAP)[2] stage I or II

AND

- Do not exhibit severe heart failure symptoms (defined as New York Heart Association (NYHA) class III or IV) AND
- Have not previously undergone liver transplant.

Initial approval:

- Initial approval will be for 45mg administered subcutaneously once a month for a period of nine months.

Renewal:

- patients must show continued benefit from treatment with eplontersen and must NOT be:
    - permanently bedridden and dependent on assistance for basic activities of daily living, NOR
    - receiving end-of-life care[3].

Clinical Notes:

- Patients must be under the care of a specialist with experience in the diagnosis and management of hATTR-PN.
- Duration of Approval of Initial approval: 9 months
- Duration of Approval of first renewal: 6 months
- Duration of Approval of 2nd and subsequent renewals: 1 year
- Coverage cannot be provided for use in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR.
- Approved will be for 45mg administered subcutaneously once a month.
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99999.99 per claim, please contact (709) 729-1780 for billing guidance.

Notes:

[1]PND is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Sensory disturbances but preserved walking capability
- Stage II – Impaired walking capacity but ability to walk without a stick or crutches

- Stage IIIA – Walking with the help of one stick or crutch
- Stage IIIB – Walking with the help of two sticks or crutches
- Stage IV – Confined to a wheelchair or bedridden.

[2]FAP is classified according to the following stages:

- Stage 0 – No symptoms
- Stage I – Unimpaired ambulation; mostly mild sensor, motor, and autonomic neuropathy in the lower limbs
- Stage II – Assistance with ambulation required mostly moderate impairment progression to the lower limbs, upper limbs, and trunk
- Stage III – Wheelchair bound or bedridden; severe sensory, motor, and autonomic involvement of all limbs.

[3]End-of-life care is defined as care in the late stages of a terminal illness, where life expectancy is measured in months, and treatment aimed at cure or prolongation of life is no longer deemed appropriate, but care is aimed at improving or maintaining the quality of remaining life (e.g., management of symptoms such as pain, nausea and stress).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

Epoprostenol sodium (CARIPUL & FLOLAN 0.5mg, 1.5mg vials for injection)

- For the treatment of patients with pulmonary arterial hypertension (primary (idiopathic) or scleroderma-associated) with NYHA functional class III or IV unresponsive to therapy with vasodilators and bosentan.

- For the treatment of severe/advanced (NYHA functional class IV) pulmonary arterial hypertension.

Written request from a medical specialist required.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Newfoundland Labrador

Health and Community Services

EPTINEZUMAB (VYEPTI 100MG/ML solution for intravenous infusion, 300mg/3ml solution for intravenous infusion)

For the prevention of migraine headaches in patients with a confirmed diagnosis of episodic or chronic migraine who at baseline are refractory or intolerant to at least two oral prophylactic migraine medications of different classes.

Renewal:

- a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- At subsequent renewals the physician must provide proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

Clinical Notes:

- The average number of headache and migraine days per month must be provided on initial and renewal requests.
- According to the International Headache Society criteria, episodic or chronic migraine are defined as:
    - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
    - Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

Claim Notes:

- The patient should be under the care of a physician expertise in the management of patients with migraine headaches.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Migraine-1.pdf

Updated March 2025

Health and Community Services

Erythropoietin Alpha (Eprex 1000 U, 2000 U, 3000 U, 4000 U, 5000U, 6000 U, 8000 U, 10,000U, 20,000 U, 30,000 U, 40,000 U)

Chronic Renal Failure:

- For anemia of chronic renal failure* (chronic kidney disease) for patients who:
    - Have a serum creatinine level > 176umol/L (2mg/dL) OR GFR < 1ml/sec/1.73m2 (60 mL/min/1.73m2) for three or more months AND who have an anemia work-up showing hemoglobin < 100g/L (10g/dL) or hematocrit < 30% and normochromic normocytic anemia.

Written request from a medical specialist required.

Anemia in hematologic malignancy:

- For the treatment of anemia in hematological malignancy* for those patients who:
    - are transfusion dependent with a baseline Hgb ≤ 90g/L and whose transfusion requirements are ≥ 2 units of packed red blood cells per month (PRBC/month) over a 3 month period.

Initial approval will be for a 12 week period only. Further consideration beyond this period (for 12 week approvals) can be considered dependent on evidence of satisfactory clinical response or reduced treatment requirements to < 2 units of PRBC/month. If transfusion requirements increase to ≥ 2 units/month (over a 3 month period), one dose increase may be attempted (maximum dose 60,000 iu per week).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ESLICARBAZEPINE (APTIOM 200mg, 400mg, 600mg, 800mg tablet)

For the treatment of patients with refractory partial-onset seizures as adjunctive therapy who meet **all** of the following criteria:

- Are under the care of a neurologist or physician experienced in the treatment of epilepsy **AND**
- Are currently receiving two or more antiepileptic drugs **AND**
- In whom all other antiepileptic drugs are ineffective or not appropriate.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2015

Newfoundland Labrador

Health and Community Services

ETANERCEPT (BRENZYS 50 MG/ML (0.98 ML) SYRINGE, BRENZYS 50 MG/ML (0.98 ML) PEN, ERELZI 25 MG/0.5 ML SYRINGE, 50 MG/ML SYRINGE, 50 MG/ML PEN, RYMTI 50 MG/ML SYRINGE, RYMTI 50 MG/ML PEN INJECTOR)

Rheumatoid Arthritis (RA):

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approval period: Long term
- Maximum Dosage Approved: Etanercept: 25mg twice a week or 50mg once a week with no dose escalation permitted.

Please visit the link below if you require our special authorization form:

https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ankylosing Spondylitis:

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- Combined use of more than one biologic DMARD will not be reimbursed)

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 50mg per week.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Polyarticular Juvenile Idiopathic Arthritis (pJIA):

For the treatment of moderate to severely active, polyarticular juvenile rheumatoid arthritis in children (age 4-17) who have not responded to adequate treatment with one or more DMARDs for at least 3 months or who have intolerance to DMARDs, and do not have a contraindication to etanercept.

Claim Notes:

- Must be prescribed by, or in consultation with, a rheumatologist, who is familiar with the use of biologic DMARDs in children.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 0.8mg/kg, up to 50mg per week.
- Approval period: Long term

Please visit the link below if you require our special authorization form:

https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet all of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 50mg per week.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Chronic Plaque Psoriasis:

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approved for 50mg twice weekly for 12 weeks then 50mg weekly for maintenance.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Updated April 2025

Health and Community Services

ETRANACOGENE DEZAPARVOVEC (HEMGENIX 1 x 1013 genome copies/mL)

For the treatment of adults (aged 18 years of age or older) with Hemophilia B (congenital factor IX deficiency) who require routine prophylaxis to prevent or reduce the frequency of bleeding episodes only if the following conditions are met:

- Adults (≥ 18 years of age) who meet all of the following criteria:
    - Documented moderately severe to severe hemophilia B based on circulating coagulation factor IX (FIX) ≤ 2% and bleeding requiring ongoing prophylactic treatment.
    - AAV5 neutralizing antibodies below a threshold of 1:900 titer.

Coverage will not be considered in patients who meet any of the following criteria:

- Presence of factor IX inhibitors.
- Previous receipt of gene therapy for the treatment of hemophilia

Clinical Notes:

- Coverage is limited to one lifetime administration of etranacogene dezaparvovec.
- Must be prescribed by specialists who have expertise in treating hemophilia B.
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2026

Health and Community Services

ETRASIMOD (VELSIPITY 2mg TABLET)

For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- Combined use of etrasimod with a biologic DMARD or JAK inhibitor will not be reimbursed.
- Approvals will be for a maximum dose of 2 mg daily
- Initial Approval: 6 months
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated February 2026

Health and Community Services

EVEROLIMUS (AFINITOR) 2.5 MG, 5 MG, 10 MG TABLET and generics

Metastatic Renal Cell Carcinoma (MRCC)

For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Advanced Breast Cancer

For the treatment of hormone-receptor positive, HER2 negative advanced breast cancer, in postmenopausal women after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI), when used in combination with exemestane.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients previously approved for CDK4/6 and whose disease has progressed are not eligible for coverage of Afinitor (everolimus) + exemestane.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Neuroendocrine Tumors (pNET or GILNET)

1. For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumours (pNET).
2. For the treatment of patients with unresectable, locally advanced or metastatic, well-differentiated, non-functional neuroendocrine tumours (NETs) of gastrointestinal or lung origin (GIL) with documented radiological disease progression within six months.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for everolimus will not be considered for patients who experience disease progression on sunitinib for pNET.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2021

Health and Community Services

EVINACUMAB (EVKEEZA 150MG/ML IV SOLUTION single dose vial)

For the treatment of homozygous familial hypercholesterolemia (HoFH) in adult and pediatric patients aged 5 years and older with a clinically or genetically confirmed diagnosis if the following criteria are met:
Clinical criteria:

- Untreated total cholesterol (TC) > 12.93 mmol/L and triglycerides (TGs) < 3.39 mmol/L, AND
- Both parents with documented TC > 6.47 mmol/L, indicative of HeFH (heterozygous familial hypercholesterolemia), or patient with cutaneous or tendinous xanthoma before the age of 10 years

Genetic criteria:

- Documented functional mutation or mutations in both low-density lipoprotein receptor (LDLR) alleles, OR
- Documented homozygous or compound heterozygous mutations in apolipoprotein B (Apo B) or proprotein convertase subtilisin/kexin type 9 (PCSK9), or low-density lipoprotein receptor adaptor protein 1 (LDLRAP1), or at least 2 such variants at different loci

AND

- Patients must have elevated LDL-C despite an adequate trial of other accessible lipid-lowering therapies; “elevated LDL-C” is defined as LDL-C greater than 1.8 mmol/L at baseline for adult patients and greater than 3.4 mmol/L for children.

Initial and Subsequent Renewals:

- the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as reduction in LDL-C from baseline that is considered clinically beneficial by the treating physician.

Clinical Notes:

- Must be prescribed by specialists with qualifications and experience in the diagnosis and management of HoFH (e.g., [pediatric] endocrinologists, cardiologists, lipidologists).
- The physician must provide the baseline LDL-C when the initial request for reimbursement occurs after all other treatment options of lipid-lowering therapies have been exhausted.
- Initial Approval: 24 weeks.
- Renewal Approval: 1 year
- Approvals will be for a maximum of 15 mg/kg every 4 weeks

- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2026

Newfoundland Labrador
Health and Community Services

EVOLOCUMAB (REPATHA 140 MG/ML PREFILLED AUTOINJECTOR)

Atherosclerotic cardiovascular disease (ASCVD):
For the reduction of elevated low-density lipoprotein cholesterol (LDL-C) in adult patients with primary hyperlipidemia (atherosclerotic cardiovascular disease [ASCVD]) if certain conditions are met:

- The patient has had a recent acute coronary syndrome (ACS) event defined as a being hospitalized for a heart attack or unstable angina in the past 52 weeks; AND

- The patient has an elevated LDL-C levels, defined as an LDL-C ≥ 1.8 mmol/L, non–HDL-C ≥ 2.6 mmol/L, or ApoB ≥ 0.7 g/L, despite receiving maximally tolerated dose of statins (defined as at least atorvastatin 20mg daily or equivalent for at least 4 weeks before treatment OR document intolerance to at least two statins OR contraindication to statins).

    - If LDL-C is ≤ 2.2 mmol/L, non–HDL-C is ≤ 2.9 mmol/L, or ApoB is ≤ 0.8 g/L, an adequate trial of ezetimibe (for at least four weeks) is required before initiation of evolocumab.
    - Evolocumab can be initiated with or without ezetimibe [Patients on a stable (≥ 4 weeks), optimized lipid lowering background therapy consisting of an effective statin dose (i.e., high–to–moderate intensity; at least atorvastatin 20 mg daily or equivalent) if LDL-C is > 2.2 mmol/L, non–HDL-C is > 2.9 mmol/L, or ApoB is > 0.8 g/L].

Clinical Notes:
- Optimized lipid-lowering background therapy is defined as treatment with an effective statin of high to moderate intensity (at least atorvastatin 20 mg daily or equivalent) for at least 4 weeks before treatment, with or without ezetimibe.
- Must be prescribed by a cardiologist or internal medicine specialist with expertise in the post-ACS setting.
- An adequate trial for a statin will be for at least 4 weeks (at least atorvastatin 20mg daily or equivalent).
- An adequate trial for ezetimibe will be for at least 4 weeks.
- Coverage will not be considered for use in combination with other PCSK9 inhibitors.

Claim Notes:
- Maximum dose approved: 140mg every 2 weeks.
- Initial approval period: 6 months (26 weeks).
- Renewal approval period: 1 year.

Heterozygous familial hypercholesterolemia (HeFH):

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (LDL-C less than 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite confirmed adherence to at least 3 months of continuous treatment with:
    - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
    - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial renewal criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent renewal criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatine kinasegreater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance have been ruled out.
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- Must be prescribed by a cardiologist or physician with expertise in the diagnosis and treatment of heterozygous familial hypercholesterolemia (HeFH).

Claim Notes:

- Maximum dose approved: 140mg every 2 weeks.
- Initial approval period: 6 months (26 weeks).
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2026

Health and Community Services

FARICIMAB (VABYSMO 6 mg/0.05 mL VIAL, VABYSMO 6 mg/0.05 mL Pre-filled Syringe)

For patients with Neovascular (wet) age-related macular degeneration (AMD), Diabetic Macular edema (DME), and RVO who meet the following criteria:

- have failed to respond to three consecutive injections of Avastin, OR
- have contraindications to the use of Avastin, OR
- are unable to tolerate Avastin; AND
- provide written confirmation from an ophthalmologist detailing the contraindication (s) as noted below.

Neovascular (wet) age-related macular degeneration (AMD):

A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
o Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;

- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
  - A corrected Visual acuity between 6/12 and 6/96;
- Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea;

Criteria for Exclusion:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%

Macular edema secondary to retinal vein occlusion:

For the treatment of visual impairment due to macular edema secondary to retinal vein occlusion in patients meeting one of the following criteria:

- clinically significant macular edema secondary to branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO)

Contraindications to use of (Avastin) bevacizumab:

- Allergy or hypersensitivity to bevacizumab
- Documented acute intra-ocular inflammation or endophthalmitis following intravitreal bevacizumab
- History of recent (within 6 months) thromboembolic event (stroke, myocardial infarction, etc)
- Thromboembolic event during treatment with bevacizumab
- Patient deemed very high risk for thromboembolic event
    - Multiple previous events with or without permanent deficits

- Documented treatment failure with intravitreal bevacizumab
    - No response (no reduction in central foveal thickness or no improvement in visual acuity) following 3 monthly bevacizumab treatments
    - Disease progression (increase in central foveal thickness, decrease in visual acuity or new hemorrhage) despite monthly bevacizumab treatments

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Ophthalmic-VEG-F-inhibitor-Form-1.pdf

Updated March 2026

Newfoundland Labrador

Health and Community Services

FEBUXOSTAT (ULORIC 80 MG TABLET and generics)

For the treatment of symptomatic gout in patients who are refractory, intolerant or have a contraindication to allopurinol.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2021

Health and Community Services

FEDRATINIB (INREBIC) 100 mg capsule

For the treatment of splenomegaly and/or disease-related symptoms in adult patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis, who have a contraindication or intolerance to ruxolitinib.

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by a reduction in spleen size or symptom improvement.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued in patients who have progressive increase in spleen size, return of constitutional symptoms or development of serious adverse events.

Claim Notes:

- Requests will not be considered for patients who experience disease progression following treatment with ruxolitinib or momelotinib.
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2026

Health and Community Services

Fentanyl (Duragesic 12.5ug, 25mcg/hr, 50mcg/hr, 75mcg/hr, 100mcg/hr transdermal system and generics)

For the treatment of malignant or chronic non-malignant pain* in **adult patients** who were previously receiving **continuous opioid administration (long-acting opioids)** or who are unable to take oral therapy.

*** Please note**: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie., surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

FERRIS CARBOXYMALTOSE (FERINJECT 50 MG/ML VIAL)
IRON DEFICIENCY ANEMIA

For the treatment of iron deficiency anemia (IDA) in adult and pediatric patients 1 year of age and older who meet the following criteria:

- are intolerant to oral iron replacement products, OR
- have not responded to an adequate trial of oral iron.

Clinical Notes:

- Given the safety concerns associated with IV iron, it is expected that the patients will be carefully screened and will have tried various oral iron options before being eligible for IV iron.
- Details regarding oral iron tried, length of therapy, and outcome must be provided.

IRON DEFICIENCY IN HEART FAILURE

For the treatment of iron deficiency in adult patients with heart failure who meet ALL of the following criteria:

- New York Heart Association (NYHA) class II or III

AND

- Documented left ventricular ejection fraction (LVEF) of ≤ 40% determined by echocardiography

AND

- Ferritin ≤ 300 mcg/L with a T transferrin saturation (SAT) < 15%.

Initial and Subsequent Renewal:

- If a patient requires iron repletion again after receiving the full dose of ferric carboxymaltose, the physician must provide proof that the patient meets initial approval criteria (NYHA class II or III, LVEF ≤ 40%, and ferritin ≤ 300 mcg/L with a TSAT < 15%).

Clinical Notes:

- Must be prescribed by a Cardiologist or clinician experienced in the management of chronic HF
- Initial and renewal approval: 24 weeks

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Newfoundland Labrador

Health and Community Services

FESOTERODINE FUMARATE (TOVIAZ 4 MG, 8MG TABLET and generics)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2022

Health and Community Services

FIDAXOMICIN (DIFICID 200mg TABLET)

For treatment of Clostridioides difficile infection (CDI) in adult persons who:
have an initial episode or first recurrence of CDI:

AND

- At least one of the following risk factors for recurrence:
  - Age > 65
  - Severe immunosuppression

OR

- An allergy to vancomycin.

Claim Notes:

- Should be prescribed by, or in consultation with, an infectious disease specialist or gastroenterologist.
- Requests will be approved for 200mg twice a day for 10 days.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2026

Health and Community Services

FILGRASTIM (GRASTOFIL 300MCG/0.5ML, 480MCG/0.8ML SYRINGE, NIVESTYM 300 MCG/0.5ML SYRINGE, 300 MCG/ML VIAL, 480 MCG/0.8ML SYRINGE, 480 MCG/1.6 ML VIAL, NYPOZI 300MCG/0.5ML Pre-filled Syringe, 480MCG/0.8ML Prefilled Syringe)

Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy for:

Primary prophylaxis:

- When given as an integral part of an aggressive chemotherapy regimen with curative intent in order to maintain dose intensity in compressed interval or dose dense treatment, as specified in a chemotherapy protocol.
  - Chemotherapy protocol must be supplied with request

- For use in patients ≥65 years who are receiving CHOP.

Secondary prophylaxis:
Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy with curative intent who:

- have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **OR**
- For use in patients who have experienced a dose reduction or treatment delay longer than one week due to neutropenia.

Dosing for chemotherapy support:

- The Supplier recommends an initial dose of 5ug/kg/day.
- Patients ≤ 70kg use 1ml vial (300ug).
- Patients > 70kg use 1.6ml vial (480ug).

Clinical Notes:

- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for either primary or secondary G-CSF prophylaxis.
- Profound neutropenia is defined as an ANC ≤ 0.1 x 109 per litre.

Stem Cell Transplantation Support

- For mobilization of peripheral blood progenitor cells for the purpose of stem cell transplantation.
- To enhance engraftment following stem cell transplantation.

Claim Notes:

- All requests for coverage of filgrastim will be approved for biosimilar only. Neupogen is no longer considered for coverage by NLPDP.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2024

Health and Community Services

FINERENONE (KERENDIA 10mg, 20mg TABLET)

For use as an adjunct to standard of care therapy to reduce the risk of end-stage kidney disease or cardiovascular death, nonfatal myocardial infarction or hospitalization for heart failure in adult patients with chronic kidney disease (CKD) and Type 2 diabetes (T2D), if all of the following criteria:

- Estimated glomerular filtration rate (eGFR) level of at least 25 mL/min/1.73 m^2 AND
- Urine albuminuria-creatinine ratio (UACR) greater than 30 mg/g (or 3 mg/mmol)
- Does not have New York Heart Association [NYHA] class II to IV heart failure.

Claim Notes:

- eGFR and UACR lab values must be provided
- Coverage cannot be provided for use in combination with another mineralocorticoid receptor antagonist (MRA).
- Must be prescribed by a physician who has experience in the diagnosis and management of patients with CKD and T2D.
- Approvals will be for a maximum of 20 mg daily.
- Approval period: Initial approval period: 6 months. Subsequent renewals will be annually.
- Treatment should be discontinued if the patient has an eGFR less than 15 mL/min/1.73 m^2 or urinary albumin-to-creatinine ratio (UACR) increase from baseline level while receiving finerenone.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated February 2024

Newfoundland Labrador

Health and Community Services

FINGOLIMOD (GILENYA 0.5 MG CAPSULE and generics)

For the treatment of patients with Relapsing Remitting Multiple Sclerosis (RRMS) who meet all of the following criteria:

- Failure to respond to full and adequate courses[1] of at least one at least one disease modifying therapy publicly listed on the NLPDP Formulary ; **OR** documented intolerance[2] to at least 2 therapies
- Have experienced one or more clinically disabling relapses in the previous year
- Demonstrate a significant increase in T2 lesion load compared with that from a previous MRI scan **OR** have at least one gadolinium enhancing lesion
- Request is being made by and followed by a neurologist experienced in the management of RRMS
- Patient has a recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

[1] Failure to respond to full and adequate courses is defined as a trial of at least 6 months of one disease modifying therapy publicly listed on the NLPDP Formulary **AND** experienced at least one disabling relapse (attack) while on therapy.
(MRI report does NOT need to be submitted with the request)

[2] Intolerance is defined as documented serious adverse effects or contraindications that are incompatible with further use of that class of drug. (Note that skin reactions at the site of the injection do NOT qualify as a contraindication to interferon or glatiramer therapy.)

<u>Requirements for Initial Requests:</u>
• The patient's physician must provide documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings.

<u>Renewal requests will be considered:</u>
• Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within that last 90 days);

AND

• Patient must be stable or have experienced no more than 1 disabling attack/relapse in the past year;

AND

• The recent Expanded Disability Status Scale (EDSS) score must be less than or equal to 5.5 (i.e. patients must be able to ambulate at least 100 meters without assistance)

Dosage: 0.5 mg once daily

Approval period: 1 year

Exclusion Criteria:

- Combination therapy of Fingolimod with other disease modifying therapies (e.g. *Avonex, Betaseron, Copaxone, Rebif, Extavia, Tysabri, Aubagio, Tecfidera*) will not be funded.
- Combination therapy of fingolimid with Fampyra will not be funded.
- Patients with EDSS > 5.5 will not be funded
- Patients who have experienced a heart attack or stroke within the 6 months prior to the funding request will not be considered.
- Patients with a history of sick sinus syndrome, atrioventricular block, significant QT prolongation, bradycardia, ischemic heart disease, or congestive heart failure will not be considered.
- Patients younger than 18 years of age will not be considered.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2022

Health and Community Services

FLUCONAZOLE (DIFLUCAN 50 MG/5 ML SUSPENSION)

For the treatment of oropharyngeal candidiasis when nystatin has failed, or for systemic infections when oral tablets are not an option.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2019

Health and Community Services

FLUDARABINE (FLUDARA 10 MG TABLET)

For the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL) when used in combination with rituximab.

Usual Dose: 40mg/m^2 po daily Days 1 to 5 every 28 days for a total of six cycles unless disease progression or unacceptable toxicity occurs

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

Fluorouracil 1% Eye Drops (compounded using Fluorouracil injection)

On request of an ophthalmologist or oncologist for the treatment of:

- Malignant melanoma of the conjunctiva
- Ocular surface squamous neoplasia (OSSN), also known as conjunctival-cornea intraepithelial neoplasia (CCIN)

Clinical Notes:

1. Coverage is considered for treatment 3 to 4 times daily for 4 to 5 days each week for 4-6 weeks OR 4 times daily for one week, then three weeks off, for 4-6 cycles total.

Claim Notes:

1. Amounts reimbursed for this compound will be in accordance with NLPDP's Program Claiming Policies with respect to compounded preparations. Details of this policy can be found at: Program-Claiming-Policies.pdf (gov.nl.ca)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2024

Newfoundland Labrador

Health and Community Services

FLUTICASONE/SALMETEROL (ADVAIR DISKUS 100MCG, 250MCG, 500MCG, ADVAIR MDI 125MCG, 250MCG and generics)

Asthma

For the treatment of asthma in patients who are using optimal doses of inhaled corticosteroids but remain poorly controlled.

- Poorly controlled is defined as require additional symptom control because of asthma symptoms (e.g., cough, awakening at night, missing activities such as school, work or social activities) and resulting in increased amounts of short-acting beta2-agonists.

Clinical Note:

- Patients who have a diagnosis of both asthma and COPD do not need to have a trial of inhaled corticosteroids before requesting special authorization of a Advair.

Limitations to coverage:

- LAMA inhalers will not be reimbursed concurrently with LABA/ICS inhalers. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control (see Triple Therapy criteria below).

LABA/ICS as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL (TRELEGY ELLIPTA 100MCG/62.5MCG/25MCG)

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who have experienced two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR** at least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit.

OR

For the treatment of chronic obstructive pulmonary disease (COPD in patients with moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with dual therapy with a long-acting muscarinic antagonist plus a long-acting beta2-agonist (LAMA/LABA) or a long-acting beta2-agonist plus an inhaled corticosteroid (LABA/ICS) for at least 2 months.

Clinical Notes:

- COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio less than 0.70. Spirometry reports confirming diagnosis of COPD are recommended. Spirometry reports from any point in time will be accepted. If spirometry cannot be obtained, reasons must be clearly explained, and other evidence of COPD severity provided (i.e. mMRC and/or CAT score).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Newfoundland Labrador

Health and Community Services

FLUTICASONE FUROATE/VILANTEROL (BREO ELLIPTA *100MCG/25MCG and 200MCG/25MCG dry powder for inhalation*)

Asthma

For the treatment of asthma in patients who are using optimal doses of inhaled corticosteroids but remain poorly controlled.

- Poorly controlled is defined as require additional symptom control because of asthma symptoms (e.g., cough, awakening at night, missing activities such as school, work or social activities) and resulting in increased amounts of short-acting beta2-agonists.

Clinical Note:

- Patients who have a diagnosis of both asthma and COPD do not need to have a trial of inhaled corticosteroids before requesting special authorization of a Breo Ellipta.

Limitations to coverage:

- LAMA inhalers will not be reimbursed concurrently with LABA/ICS inhalers. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control (see Triple Therapy criteria below).

LABA/ICS as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.
- When used as triple therapy (LAMA/LABA/ICS) for COPD, **BREO ELLIPTA 100MCG/25MCG** will not be considered in combination with open benefit INCRUSE ELLIPTA 62.5MCG under any circumstances. Beneficiaries who meet the criteria for this triple therapy combination will be considered for TRELEGY ELLIPTA 100MCG-62.5MCG-25MCG.
- **BREO ELLIPTA 200MCG/25MCG** may be considered as part of triple therapy for COPD in patients with concurrent uncontrolled asthma, requiring a higher corticosteroid dose. Special authorization will also be required for the LAMA inhaler.
    - TRELEGY ELLIPTA 200MCG-62.5MCG-25MCG is not considered by NLPDP.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

FOSFOMYCIN TROMETHAMINE (MONUROL 3 GRAM PACKET and generics)

For the treatment of uncomplicated urinary tract infections in adult female patients where:

- The infecting organism is resistant to other oral agents **OR**
- Other less costly treatments are not tolerated.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2022

Health and Community Services

FOSLEVODOPA, FOSCARBIDOPA (VYALEV 240MG/ML, 12MG/ML)

For the treatment of motor fluctuations in patients with advanced levodopa-responsive Parkinson's disease who do not have satisfactory control of severe, debilitating motor fluctuations and hyper-/dyskinesia despite optimized treatment with available combinations of Parkinson's medicinal products only if all of the following criteria are met:

Initiation:

- Have not been able to achieve satisfactory control of severe, debilitating motor fluctuations and hyperkinesia or dyskinesia despite optimized treatment with available combinations of Parkinson's disease treatments, including maximally tolerated doses of levodopa in combination with carbidopa, a COMT inhibitor, a dopamine agonist, a MAO-B inhibitor, and amantadine, if not contraindicated AND
- Have severe disability associated with at least 25% of the waking day in the off state and/or ongoing, bothersome levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least 5 doses per day) AND
- Have received an adequate trial of maximally tolerated doses of levodopa, with previously demonstrated clinical response AND
- The patient does not have severe psychosis or severe dementia AND
- Patient or caregiver are able to demonstrate correct understanding and use of the delivery system.

Renewal:

- The patient has significant reduction in the time spent in the "off" state and/or in ongoing levodopa-induced dyskinesias, along with an improvement in the related disability.

Clinical Notes:

- Time in the "off" state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist or neurologist with expertise in managing advanced Parkinson's disease, and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
- Must be prescribed by neurologists who are movement disorder subspecialists or who have expertise in managing advanced Parkinson's disease.
- Approval period: 1 year

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated September 2024

Health and Community Services

FREMANEZUMAB (AJOVY 225mg/1.5ml single dose prefilled syringe, 225mg/1.5ml prefilled autoinjector)

For the prevention of migraine headaches in patients with a confirmed diagnosis of episodic or chronic migraine who at baseline are refractory or intolerant to at least two oral prophylactic migraine medications of different classes.

Renewal:

- a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- At subsequent renewals the physician must provide proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

Clinical Notes:

- The average number of headache and migraine days per month must be provided on initial and renewal requests.
- According to the International Headache Society criteria, episodic or chronic migraine are defined as:
    - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
    - Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

Claim Notes:

- The patient should be under the care of a physician expertise in the management of patients with migraine headaches.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Migraine-1.pdf

Updated November 2024

Health and Community Services

FRUQUINTINIB (FRUZAQLA) 1MG and 5MG CAPSULE

For the treatment of adult patients with metastatic colorectal adenocarcinoma (mCRC) who have been previously treated with or are not considered candidates for the following therapies:

- fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- anti-VEGF therapy
- anti-EGFR therapy (if RAS wild-type)
- trifluridine-tipiracil-based therapy
- immune checkpoint inhibitor (if MSI-H or dMMR tumour)
- BRAF inhibitor (if BRAF-mutant tumour)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no active CNS metastases.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will be considered for patients with small bowel or appendiceal adenocarcinoma.
- Patients who experience disease progression during or within 6 months of completing neoadjuvant/adjuvant chemotherapy may be considered as having received one prior chemotherapy regimen for advanced disease.
- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2026

Health and Community Services

FULVESTRANT (FASLODEX & generics) 250MG/5ML SYRINGE

1. For monotherapy treatment of postmenopausal women with non-visceral locally advanced or metastatic estrogen-receptor positive, HER2 negative breast cancer, who have not been previously treated with endocrine therapy.

2. For monotherapy treatment of postmenopausal women with locally advanced or metastatic breast cancer who have disease progression following prior anti-estrogen therapy.

3. In combination with palbociclib or ribociclib for the treatment of hormone receptor positive, HER2-negative locally advanced or metastatic breast cancer as initial therapy or following disease progression on previous endocrine therapy, who:
   - may have received up to one prior chemotherapy treatment for advanced or metastatic disease, and
   - do not have active or uncontrolled metastases to the central nervous system

4. In combination with capivasertib for the treatment of hormone receptor positive, HER2-negative locally advanced or metastatic breast cancer with one or more PIK3CA / AKT1 / PTEN alterations, who:
   - have disease progression after at least one endocrine-based therapy in the metastatic setting, or
   - have disease recurrence during or within 12 months of completing adjuvant hormone therapy.
   - do not have active or uncontrolled metastases to the central nervous system

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Note:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2025

Health and Community Services

GALCANEZUMAB (EMGALITY 120mg/1.0 mL single-dose prefilled pen, 120mg/1.0 mL single-dose prefilled syringe)

For the prevention of migraine headaches in patients with a confirmed diagnosis of episodic or chronic migraine who at baseline are refractory or intolerant to at least two oral prophylactic migraine medications of different classes.

Renewal:

- a reduction of at least 50% in the average number of migraine days per month at the time of first renewal compared with baseline.
- At subsequent renewals the physician must provide proof that the initial 50% reduction in the average number of migraine days per month has been maintained.

Clinical Notes:

- The average number of headache and migraine days per month must be provided on initial and renewal requests.
- According to the International Headache Society criteria, episodic or chronic migraine are defined as:
    - Episodic migraine: migraine headaches on at least 4 days per month and less than 15 headache days per month for more than 3 months.
    - Chronic migraine: headaches for at least 15 days per month for more than 3 months of which at least eight days per month are with migraine.

Claim Notes:

- The patient should be under the care of a physician expertise in the management of patients with migraine headaches.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Migraine-1.pdf

Updated November 2024

Health and Community Services

GARADACIMAB (ANDEMBRY 200mg/1.2mL pre-filled syringe, ANDEMBRY 200MG/1.2ML PRE-FILLED PEN)

For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age or older who have experienced at least three HAE attacks within any four-week period and required injectable treatment.

Renewal criteria:

- An assessment of a response to treatment should be conducted three months after initiating treatment with garadacimab.
- A response to treatment is defined as a reduction in the number of HAE attacks for which acute injectable treatment was received within the initial three months of treatment with garadacimab compared to the rate of attacks observed before initiating treatment with garadacimab.
- Following the initial three-month assessment, patients should be assessed for continued response to garadacimab every six months.
- Continued response is defined as no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to initiating treatment with garadacimab.

Discontinuation criteria:

Treatment should be discontinued in patients who either respond inadequately or exhibit a loss of response, defined as follows:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with garadacimab compared to number of attacks observed before initiation treatment with garadacimab.
- An increase in the observed number of HAE attacks for which acute injectable treatment was received before initiating treatment with garadacimab.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients already receiving long-term prophylactic treatment for HAE and intent to transition to garadacimab.

Claim Notes:

- The patient must be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.
- Garadacimab should not be used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH).

- Approvals will be for a maximum of 400mg (two 200mg injections) on the first day of treatment followed by a monthly dose of 200mg.
- Initial approval period: 3 months
- Renewal approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

GILTERITINIB (XOSPATA 40 MG TABLET)

As monotherapy for the treatment of adult patients who have relapsed or refractory FMS-like tyrosine kinase 3 (FLT3)- mutated acute myeloid leukemia who meet all of the following criteria:

- Confirmed positive for FLT3 mutation at the time of relapse or determination of refractory disease
- Presence of FLT3-ITD, FLT3-TKD/D835 or FLT3-TKD/I836 mutation

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
3. In the absence of disease progression or unacceptable toxicity, treatment may be given for a minimum of six months to determine clinical benefit as a delay in clinical response can occur.

Claim Notes:

- Initial approval period: 7 months.
- Renewal approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2021

Health and Community Services

GIVOSIRAN SODIUM (GIVLAARI 189MG/ML SINGLE-USE VIAL)

For the treatment of acute hepatic porphyria (AHP) in adults:

Initiation

- Must have had 4 or more porphyria attacks requiring either hospitalization, or IV hemin (other than for the purpose of prophylaxis) in the previous year (i.e. baseline annualized attack rate of 4 or more)
- Initial coverage may be approved for one 2.5 mg/kg dose of givosiran each month for 12 months.

Renewal

- For coverage beyond 12 months, a patient must have a reduction in the annualized attack rate after 12 months of therapy compared to baseline.

Clinical Noted:

- Prescription should be restricted to a clinician experienced in the management of AHP
- Coverage will not be provided for use in combination with prophylactic hemin.

Please visit the link below if you require the standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated October 2023

Newfoundland Labrador

Health and Community Services

GLATIRAMER ACETATE (GLATECT 20 MG/ML SYRINGE, MYLAN-GLATIRAMER ACETATE INJECTION 20MG/ML)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria.
- Has experienced one or more disabling relapses or new MRI activity in the past two years.
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2026

Health and Community Services

GLECAPREVIR/PIBRENTASVIR (MAVIRET 100 MG-40 MG TABLET, MAVIRET 50-20 MG GRANULES PACK)

For treatment-naïve and treatment-experienced* adult patients and pediatric patients 3 years of age and older and weighing ≥12 kg with hepatitis C infection:

	Approval Period
Genotype 1, 2, 3, 4, 5, or 6 • Treatment-naïve	8 weeks
Genotype 1, 2, 3, 4, 5, or 6 • Treatment-experienced with regimens containing peginterferon/ribavirin (PR) and/or sofosbuvir (SOF)	8 weeks (12 weeks with cirrhosis)

Genotype 1
- NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing:
  - Boceprevir/PR; or
  - Simeprevir (SMV)/SOF; or
  - Telaprevir/PR
	12 weeks

Genotype 1 - NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing: - DCV/PR; or - Ledipasvir/SOF	16 weeks
Genotype 3 • Treatment-experienced with regimens containing PR and/or SOF	16 weeks

Patients must meet all of the following criteria:

- Quantitative HCV RNA value within the last 12 months **OR**
- TWO Quantitative HCV RNA values ≥ 12 months ago
    - tests must have been completed within 6 months apart)

Treatment-experienced is defined by the Health Canada Product Monograph based on the genotype treated and the scenario in which the previous drug(s) have been used.

- Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6
- Genotype report must be provided if requesting Maviret for treatment experienced patients in the following circumstances:
    - NS5A inhibitor treatment-naïve and treatment-experienced with regimens containing:
        - Boceprevir/PR; or
        - Simeprevir (SMV)/SOF; or
        - Telaprevir/PR
    - NS3/4A inhibitor treatment-naïve and treatment-experienced with regimens containing:
        - DCV/PR; or
        - Ledipasvir/SOF
    - Treatment-experienced with regimens containing PR and/or SOF

Claim Notes:

- Please note: A single professional fee will be paid per 30 day supply.
- Special Authorization requests must include the most recent HCV RNA test performed in the last 12 months **OR** TWO positive HCV RNA results ≥ 12 months ago (tests must have been completed within 6 months apart).

Please visit the link below if you require the special authorization request form:
https://www.gov.nl.ca/hcs/files/Hepatitis-C-Treatment.pdf

Updated March 2026

Health and Community Services

GLYCEROL PHENYLBUTYRATE (RAVICTI ORAL LIQUID 1.1G/ML)

For the chronic management of urea cycle disorders (UCDs).

- Medication should be prescribed in consultation with a specialist in this area.

Clinical Note :
Diagnosis must be confirmed by blood, enzymatic, biochemical or genetic testing.

Please visit the following link if you require our standard special authorization form:
https://www.health.gov.nl.ca/prescription/standard_specauth_form.pdf

Updated March 2019

Health and Community Services

GOLIMUMAB (SIMPONI 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector, ±100mg/1.0mL Prefilled syringe, ±100mg/1.0mL Autoinjector)

Rheumatoid Arthritis (RA): 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

Or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved:
  - Golimumab: 50mg once a month with no dose escalation permitted

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ankylosing Spondylitis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:

- Decrease of at least 2 points on the BASDAI scale compared with the pre-treatment score,

OR

- An adequate clinical response as indicated by significant functional improvement (e.g., measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- combined use of more than one biologic DMARD will not be reimbursed)

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg per month.
- Initial Approval: 4 months.
- Renewal Approval: 1 year.
- Maximum Dosage Approved:
- Maximum Dosage Approved:
    - Golimumab: 50mg once a month with no dose escalation permitted

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 50mg per month.
- Initial Approval: 4 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (*20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).*
- Maximum Dosage Approved:
    - Golimumab: 50mg once a month with no dose escalation permitted

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ulcerative Colitis: 50mg/0.5ml Prefilled syringe, 50mg/0.5ml Autoinjector, 100mg/1.0mL Prefilled syringe, 100mg/1.0mL Autoinjector

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.

- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial dose: 200 mg initially administered by subcutaneous injection at Week 0, followed by 100 mg at Week 2 and then 50 mg every 4 weeks, thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

± **Please note:** The 100mg/1mL dosage forms are indicated for the treatment of ulcerative colitis only.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated October 2023

Health and Community Services

GRANISETRON HCL (KYTRIL and generics) 1 MG TABLET

The following Anti-emetics are covered by the Program as open benefits, with limitations, for chemo induced nausea and vomiting only:
Ondansetron 4mg and 8mg tab: up to 3 tablets in a 24 hour period
Granisetron 1mg tab: up to 2 tablets in a 24 hour period

The quantity limits above may only be filled as an open benefit for the first fill of any chemo antiemetic drug. A special authorization is required for a higher quantity dispensed than noted above for a first fill or for any subsequent fills of any chemo anti-emetic drug.

Coverage is considered for the treatment of emesis in patients who:

- are receiving moderate to highly emetogenic anticancer therapy OR
- are receiving mildly emetogenic anticancer therapy and have experienced episodes of nausea and vomiting related to such treatment, not responding to therapeutic doses of benefit antiemetics (metoclopramide, dexamethasone and prochlorperazine), or where these agents are not tolerated or contraindicated OR
- Post radiation therapy

Duration of therapy:

- Coverage will be provided for a maximum of 2mg on the day of anticancer therapy.
- Coverage will be limited to 2mg one hour before radiation therapy.

In order to accurately assess requests for coverage, we require the following information:
For Anticancer therapy:

- anticancer agents (including dose)
- number of days per cycle for each agent
- cycle frequency
- expected treatment duration (total number of cycles)
- previous antiemetic trials and the outcome

For Radiotherapy:

- targeted area
- number of days per cycle
- cycle frequency
- expected treatment duration (total number of cycles)
- previous antiemetic trials and the outcome

Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

GUSELKUMAB (TREMFYA® 100mg/ml Pre-filled Syringe, 100 mg/mL AUTO-INJECTOR, 100mg/ml Pre-filled Pen (200mg), 10mg/mL Vial (200mg), 100mg/ml Pre-filled Pen (100mg))

Ulcerative Colitis (UC)

For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week) **OR**
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Consideration will be given for an induction dosage is 200mg IV infusion at week 0, week 4, and week 8 or 400mg SC at week 0, week 4 and week 8. For maintenance, the dosage is 100 mg SC at week 16 and every 8 weeks thereafter or 200mg every four weeks starting at week 12.
- Initial Approval: 24 weeks
- Renewal Approval: 1 year.
- Coverage will not be considered when combined with biological or other JAK inhibitor treatments for UC. Combined use of more than one biologic DMARD will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Crohn's Disease

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approved will be considered for an induction dosage of 200mg IV infusion at weeks 0, 4, and 8 or 400 mg SC injection at weeks 0, 4, and 8. For maintenance therapy, consideration will be for 100 mg SC at week 16 and every 8 weeks thereafter or 200 mg a SC at week 12 and every 4 weeks thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to be assessed at 12 weeks then yearly using criteria such as a 100-point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less, or a decrease in score of 4 or more.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet all of the following criteria:

- Have at least three active and tender joints **AND**
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 100mg to be given at week 0 and at week 4, followed by maintenance dosing every 8 weeks.
- Initial Approval: 24 weeks.
- Renewal Approval: 1 year.
  Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

***Chronic Plaque Psoriasis*:**

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 AND Dermatology Life Quality Index (DLQI) >10 AND Body Surface Area (BSA) involvement of at least 10% **OR** involvement of the face, hands, feet or genital regions **AND**
- Refractory or intolerant to or unable to access phototherapy **AND**
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is 65 years of age or older) for a minimum of 12 weeks **OR** cyclosporine (6 weeks treatment).

Response to the biologic must be assessed after 16 weeks and therapy continued only in patients who have responded to therapy as defined below:

An adequate response defined below:

- Greater than or equal to 75% reduction in PASI score, **OR**
- Greater than or equal to 50% reduction in PASI and greater than or equal to 5 points in the DLQI **OR**
- A quantitative reduction in BSA affected with qualitative consideration of specific regions such as face, hands, feet or genital region and situations such as itch and recalcitrant plaques.

Clinical notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approved for 100mg at week 0 and at week 4, followed by maintenance dosing every 8 weeks thereafter.
- The initial approval: 12 weeks.
- Renewal approval: 1 year

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

UPDATED June 2026

Health and Community Services

HALOBETADOL (BRYHALI 0.01 % LOTION)

For the topical treatment of corticosteroid-responsive dermatoses and the topical treatment of plaque psoriasis.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated December 2023

Health and Community Services

HALOBETASOL PROPION/TAZAROTENE (DUOBRII 0.01% - 0.045% LOTION)

Initiation Criteria

For improving the signs and symptoms of plaque psoriasis in adult patients with moderate-to-severe plaque psoriasis only if the following conditions are met:

1. Patients must have a clinical diagnosis of plaque psoriasis with all of the following characteristics:
   - An Investigator's Global Assessment (IGA) score of 3 (moderate) or 4 (severe) and
   - An area of plaque psoriasis appropriate for topical treatment covering a body surface area (BSA) of 3% to 12%

   AND

2. For use in patients whom have not adequately responded to a topical high-potency corticosteroid and for whom the addition of a second topical medication would be appropriate. Patients meeting the first initiation criterion would be considered to have had an inadequate response to a topical high-potency corticosteroid.

Renewal Criteria:
For continued coverage beyond 12 weeks, the patient must meet the following criteria:
- The patient must be assessed by the prescriber after the initial 8-12 weeks of therapy to determine response.
- The prescriber must confirm, in writing, that the patient is a 'responder' with an IGA score of 'clear' or 'almost clear' (0 or 1).

Initial approval: 12 weeks.
Renewals: 1 year

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Topical-Antipsoriatic-Agents.pdf

Updated February 2025

Health and Community Services

HYDROMORPHONE HCL (HYDROMORPH CONTIN 3mg, 4.5mg, 6mg, 9mg, 12mg, 18mg, 24mg, 30mg and generics)

For patients with persistent pain* who have been stabilized on a titrated dose of an oral short-acting hydromorphone product OR whose pain is not adequately controlled or who are intolerant to oral sustained-release morphine or oxycodone products despite dose titration and adjuvant antiemetics and laxatives.

*** Please note**: In order to assess requests for coverage in the treatment of non-malignant pain the Department will require the following information:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (ie surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Current analgesic uses, current dosage, and assessment of current level of pain control.
- Use of antidepressants and/or anticonvulsants if pain is neuropathic.
- Any other information you feel is pertinent to the request.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2022

Health and Community Services

IBRUTINIB (IMBRUVICA) 140 MG CAPSULE

Chronic Lymphocytic Leukemia/Small Cell Lymphoma

1. In combination with venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL).

   Clinical Notes:
   1. Patients must have a good performance status and no CNS involvement or Richter's transformation.
   2. Combination treatment should be initiated following three months of ibrutinib monotherapy and continued for a total of 12 months, or until disease progression or unacceptable toxicity, whichever occurs first.
   3. If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued.

   Claim Notes:
   - Requests for re-treatment with venetoclax in combination with ibrutinib will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
   - Approval period: 15 months

2. As monotherapy for adult patients with previously untreated CLL/SLL for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, del 11q or unmutated IGHV).

   Renewal Criteria:
   - Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

   Clinical Notes:
   1. Patients must have a good performance status.
   2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

   Claim Note:
   - Approval period: 1 year

3. As monotherapy for the treatment of adult patients with CLL / SLL who have received at least one prior therapy.

   Renewal Criteria:
   - Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase inhibitor or idelalisib.
- Patients who experience disease progression during or within one year of completing ibrutinib in combination with venetoclax are not eligible for ibrutinib in the relapsed setting.
- Approval period: 1 year.

Mantle Cell Lymphoma

As monotherapy or in combination with venetoclax for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least one prior line of therapy.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment may be continued until disease progression or unacceptable toxicity, or up to a maximum of two years when used in combination with venetoclax.

Claim Notes:

- Requests will not be considered for patients who experience disease relapse during or within six months of stopping prior Bruton's tyrosine kinase inhibitor (BTKi) therapy.
- Requests for re-treatment with ibrutinib, alone or in combination with venetoclax, will be considered for patients if there is a relapse-free interval of 6 months or longer following prior ibrutinib exposure.
- Approval period: 1 year

Waldenström Macroglobulinemia

For the treatment of adult patients with previously treated relapsed or refractory Waldenström macroglobulinemia as monotherapy or in combination with rituximab, and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Note:

1. Patients must meet at least one criterion for treatment as per IWWM consensus panel.
2. Patients must have a good performance status and no evidence of disease transformation.

3. Patients who relapse during or within 6 months of completing rituximab-based therapy are eligible for ibrutinib monotherapy.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

ICATIBANT (FIRAZYR 30MG/ML pre-filled syringes)

For the treatment of acute attacks of hereditary angioedema (HAE) in adults with lab confirmed c1-esterase inhibitor deficiency (type I or type II) under the following conditions:

- Treatment of non-laryngeal attacks of at least moderate severity, **or**
- Treatment of acute laryngeal attacks

Clinical Notes:

- Coverage is limited to a single dose for self-administration per attack
- Must be prescribed by physicians with experience in the treatment of HAE

Claim Notes:

- Maximum of two doses on hand at any time.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

IDELALISIB (ZYDELIG) 100mg, 150mg tablets

Idelalisib (Zydelig) in combination with rituximab for the treatment of patients with relapsed chronic lymphocytic leukemia (CLL). Treatment should continue until unacceptable toxicity or disease progression.

Approval period: 12 months

Dosing: 150mg twice daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of idelalisib.

Patients previously approved for Imbruvica (Ibrutinib) coverage and whose disease has progressed are not eligible for coverage of Zydelig (idelalisib).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Health and Community Services

Imiquimod (Aldara 5% cream & generics)

- For the treatment of external genital and perianal warts and condyloma acuminata in adults.

- For the treatment of actinic keratosis on the head and neck in patients who have failed treatment with 5FU and cryotherapy.

- For treatment of biopsy-confirmed primary superficial basal cell carcinoma:

    - with a tumor diameter of ≤ 2 cm **AND**
    - located on the trunk, neck or extremities (excluding hands and feet) **AND**
    - where surgery or irradiation therapy is not medically indicated
        - Recurrent lesions in previously irradiated area OR
        - Multiple lesions, too numerous to irradiate or remove surgically.

    Approval Period: 6 weeks (renewals for the same tumor will not be considered).
    Note: Surgical management should be considered first-line for superficial basal cell carcinoma in most patients, especially for isolated lesions.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2014

Health and Community Services

INCLISIRA (LEQVIO 284mg/1.5ml single dose prefilled syringe)

For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met:

- Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and
- Patient is unable to reach LDL-C target (LDL-C less than 2.0 mmol/L for secondary prevention or at least a 50% reduction in LDL-C from untreated baseline for primary prevention) despite confirmed adherence to at least 3 months of continuous treatment with:
    - high-dose statin (e.g. atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or
    - ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance.

Initial renewal criteria:

- A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Subsequent renewal criteria:

- The patient continues to maintain a reduction in LDL- C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.

Clinical Notes:

- LDL-C levels must be provided.
- Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and
    - for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and
    - at least one statin was initiated at the lowest daily starting dose; and
    - other known causes of intolerance have been ruled out.
- For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided.
- For patients who cannot take a statin due to an intolerance or contraindication, details must be provided (ie. confirmed rhabdomyolysis, active liver disease, unexplained persistent elevations of serum transaminases exceeding three times the upper limit of normal).
- Must be prescribed by a cardiologist or physician with expertise in the diagnosis and treatment of heterozygous familial hypercholesterolemia (HeFH).

- Initial approval: 6 months
- Renewal approval: 1 year
- Maximum dose approved: 284 mg initially, at 3 months, then every 6 months thereafter
- Inclisiran and PCSK9 inhibitors will not be insured in combination.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

INDACATEROL/GLYCOPYRRONIUM/MOMETASONE (ENERZAIR BREEZHALER 150MCG-50MCG-160MCG)

For the treatment of asthma in patients who are inadequately controlled with a medium or high dose inhaled corticosteroid (ICS) and a long-acting beta-2 agonist (LABA) and have experienced one or more asthma exacerbations in the previous 12 months.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

INDACATEROL/GLYCOPYRRONIUM (ULTIBRO BREEZHALER 110MCG-50MCG)

- For the treatment of moderate to severe COPD (CAT score ≥ 10 or mMRC ≥ 2) **OR**
- For patients who have experienced an exacerbation of COPD in the previous 12 months while on a LAMA or LABA inhaler.

Clinical Notes

- Coverage of a LABA and LAMA as two separate inhalers will not be considered.
- mMRC Grade 2 is described as: walking on level ground slower than people of same age because of breathlessness or having to stop for breath when walking at your own pace on the level.
- The COPD assessment test (CAT) is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at https://www.catestonline.org/patient-site-test-page-english.html

Limitations to coverage:

- ICS inhalers will not be reimbursed concurrently with a LAMA/LABA inhaler. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control.

LAMA/LABA inhaler as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.

- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

INDACATEROL ACETATE/MOMETASONE (ATECTURA BREEZHALER 150-80 mcg, 150 mcg-160 mcg, 150 mcg-320 mcg)

Asthma

For the treatment of asthma in patients who are aged 12 years and older who are using optimal doses of inhaled corticosteroids but remain poorly controlled.

- Poorly controlled is defined as require additional symptom control because of asthma symptoms (e.g., cough, awakening at night, missing activities such as school, work or social activities) and resulting in increased amounts of short-acting beta2-agonists.

Clinical Note:

- Patients who have a diagnosis of both asthma and COPD do not need to have a trial of inhaled corticosteroids before requesting special authorization of Atectura Breezhaler.

Limitations to coverage:

- LAMA inhalers will not be reimbursed concurrently with LABA/ICS inhalers. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control (see Triple Therapy criteria below).

LAMA/ICS inhaler as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment

with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated October 2026

Health and Community Services

INEBILIZUMAB (UPLIZNA 100mg/10mL (10 mg/mL) single use vial)

For the treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who meet all of the following:

- The patient is anti-aquaporin-4 immunoglobulin G (AQP4-IgG) seropositive AND
- The patient has had at least 1 relapse of NMOSD in the prior 12 months or at least 2 attacks in the prior 2 years AND
- The patient has experienced an inadequate response or intolerance following a trial of rituximab for NMOSD, or has a contraindication to rituximab; (Note: if rituximab is not appropriate for the patient, an adequate trial of another preventative treatment including but not limited to other monoclonal antibodies, azathioprine, mycophenolate or other immunosuppressants must have been used) AND
- Patients must have an EDSS score of 8 points or less.

Renewal after the initial 12 months, the following criteria must be met:

- The physician should measure and provide EDSS scores (measured annually).
- The patient must have an EDSS score of less than or equal to 8.0 at each renewal.

Discontinuation

- Reimbursement of inebilizumab treatment should be discontinued if the patient's EDSS score is greater than 8 points.

Clinical Notes:

- Must be prescribed by a neurologist with expertise in treating NMOSD.
- Inebilizumab should not be initiated during a NMOSD relapse episode.
- Inebilizumab should not be reimbursed when used in combination with rituximab, satralizumab, eculizumab, or ravulizumab.
- Initial: 12 months
- Approvals will be for a maximum of 300 mg at 0 and 2 weeks and 300 mg every 6 months thereafter.
- Patients will be permitted to switch from one biologic agent to another following an adequate trial of the previous drug if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Patients will not be permitted to switch back to inebilizumab if they were deemed unresponsive to therapy.
- Coverage cannot be provided for inebilizumab when intended for use in combination with a biologic agent (including rituximab) for treatment of NMOSD.
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99999.99 per claim, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

INFLIXIMAB (IXIFI 100MG Vial, RENFLEXIS 100MG Vial, AVSOLA 100MG VIAL, REMDANTRY 100MG VIAL)

Rheumatoid arthritis (RA):

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:
- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch from Ixifi, Renflexis, Avsola or Remdantry to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
- Approval period: Long term

- Maximum Dosage Approved:
  - Infliximab: 3mg/kg/dose at 0, 2 and 6 weeks followed by maintenance therapy of 3mg/kg/dose every 8 weeks.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ankylosing Spondylitis:

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Clinical Notes:
- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- Combined use of more than one biologic DMARD will not be reimbursed).

Claim Notes:
- Must be prescribed by a rheumatologist or physician with expertise in treating ankylosing spondylitis.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approval Period: Long term
- Approvals will be for a maximum of 5mg/kg at weeks 0, 2 and 6, then every 6 to 8 weeks thereafter.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Chronic Plaque Psoriasis

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:
- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approved for 5mg/kg induction (0, 2, 6 weeks) then every 8 weeks.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 5mg/kg at weeks 0, 2 and 6, then every 6 to 8 weeks thereafter.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Crohn's disease:
For the treatment of pediatric and adult patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with

corticosteroids and other immunosuppressants.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Concurrent use of other biologic DMARDS not approved.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey Bradshaw Index Assessment (HBI) score.
- Approved for 3 infusions of infliximab 5mg/kg at week 0, 2 & 6.
- The maximum approved dose is 5mg/kg every 8 weeks.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Ulcerative colitis (UC):

For the treatment of pediatric adult patients with moderately to severely active ulcerative colitis who has a partial Mayo score > 4, and a rectal bleeding sub-score ≥ 2 and are:
- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Clinical Notes:
- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approval period: Long term
- **Maximum Quantity Reimbursed:**
  Infliximab: 5 mg/kg at weeks 0, 2 and 6, then every 8 weeks thereafter.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated April 2025

Health and Community Services

SUBCUTANEOUS INFLIXIMAB (REMSIMA SC 120 mg/mL Pre-filled Pen, SC 120 mg/mL Pre-filled syringe)

Rheumatoid arthritis (RA):

For the treatment of moderately to severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: Long term
- Maximum Dosage Approved:
  - Remsima 120 mg subcutaneous injection at week 0 followed by additional subcutaneous injections at 1, 2, 3 and 4 weeks after the first injection, then every 2 weeks thereafter for maintenance.
  - If intravenous loading doses of infliximab are given to initiate treatment, 2 intravenous infusions of infliximab 3 mg/kg should be given 2 weeks apart, at

week 0 and week 2. The first treatment with Remsima SC should be initiated as maintenance therapy 4 weeks after the second intravenous administration

OR

- patients who have been on maintenance therapy with IV and are switching to SC maintenance therapy, the first dose of SC may be administered 8 weeks after the last IV dose.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf

Crohn's disease:

For the treatment of adult patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Concurrent use of other biologic DMARDS not approved.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey Bradshaw Index Assessment (HBI) score.
- For patients who have completed an induction regimen with intravenously administered Infliximab. The recommended maintenance dosing regimen of Remsima SC is 120 mg (given as one subcutaneous injection) once every 2 weeks, starting 4 weeks following completion of an induction regimen.
- For patients who have been on maintenance therapy with IV and are switching to SC maintenance therapy, the first dose of SC may be administered 8 weeks after the last IV dose.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Ulcerative colitis (UC):

For the treatment of adult patients with moderately to severely active ulcerative colitis who has a partial Mayo score > 4, and a rectal bleeding sub-score ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Clinical Notes:

- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- For patients who have completed an induction regimen with intravenously administered
  Infliximab. The recommended maintenance dosing regimen of Remsima SC is 120 mg (given as one subcutaneous injection) once every 2 weeks, starting 4 weeks following completion of an induction regimen.
- For patients who have been on maintenance therapy with IV and are switching to SC maintenance therapy, the first dose of SC may be administered 8 weeks after the last IV dose

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated October 2025

Newfoundland Labrador

Health and Community Services

INSULIN DETEMIR (LEVEMIR 100 UNIT/ML PENFILL, LEVEMIR FLEXTOUCH 100 unit/ml)

1. For the treatment of patients with type 1 or type 2 diabetes who have taken other long-acting insulin analogues (insulin glargine and insulin degludec), and have:
    - experienced unexplained nocturnal hypoglycemia at least once a month despite optimal management; or
    - documented severe or continuing systemic or local allergic reaction.

2. For the treatment of pediatric and adolescent patients (under 18 years of age) with type 1 diabetes.

3. For the treatment of pregnant individuals with type 1 or type 2 diabetes requiring insulin.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Insulin-Detemir.pdf

Updated October 2023

Newfoundland Labrador

Health and Community Services

INSULIN GLARGINE/LIXISENATIDE (SOLIQUA 100 UNITS-33 mcg/mL PEN)

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) in combination with metformin.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2022

Health and Community Services

INSULIN REGULAR (ENTUZITY KWIKPEN 500 UNIT/ML)

For the treatment of patients with diabetes mellitus with unacceptable glycemic control who require more than 200 units of insulin per day, with or without other therapies

- Treatment should be initiated by a specialist with experience in treating severe insulin resistance

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2022

Health and Community Services

INTERFERON BETA-1A (AVONEX 30mcg Prefilled Syringe, AVONEX 30mcg AUTOINJECTOR, REBIF 22mcg/0.5ml prefilled syringe, 44mcg/0.5ml prefilled syringe, 66mcg/1.5ml Multi-dose cartridge, 132mcg/1.5ml Multi-dose cartridge, PLEGRIDY Starter pack 63mcg/0.5mL, 94mcg/0.5mL prefilled pen and prefilled syringe, Admin pack 125mcg/0.5mL prefilled pen and prefilled syringe)

INTERFERON BETA-1B (BETASERON 0.3 mg)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2026

Newfoundland Labrador

Health and Community Services

IRON ISOMALTOSIDE 1000 (MONOFERRIC 100 MG/ML VIAL)

For the treatment of iron deficiency anemia in patients who:

- are intolerant to oral iron replacement products, or
- have not responded to an adequate trial of oral iron.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2021

Health and Community Services

ISAVUCONAZONIUM (CRESEMBA 100mg CAPSULE, 200 mg VIAL)

- For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole.
- For the treatment of adult patients with invasive mucormycosis.

Claim Notes:

- Must be prescribed by an infectious disease specialist or medical microbiologist.
- Initial requests will be approved for a maximum of 3 months.
- Recommended dose: 200mg administered intravenously or orally every 8 hours for 6 doses followed by a maintenance dose of 200mg daily starting 12 to 24 hours after the last loading dose.
- Oral therapy should be considered as a preferred option when clinically appropriate. A loading dose is not required when switching from intravenous to oral treatment or vice versa.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2020

Health and Community Services

ITRACONAZOLE (SPORANOX 100 MG CAPSULE and generics)

- For the treatment of severe or resistant systemic fungal infections.
- For the treatment of topical fungal infections not responding to alternative therapy.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2022

Newfoundland Labrador

Health and Community Services

IVABRADINE (LANCORA 5mg, 7.5mg TABLET)

For the treatment of stable chronic heart failure with reduced left ventricular ejection fraction (LVEF) (<35%) in adult patients with New York Heart Association (NYHA) classes II or III who are in sinus rhythm with a resting heart rate >77 beats per minute (bpm), to reduce the incidence of cardiovascular mortality and hospitalizations for worsening heart failure, administered in combination with standard chronic heart failure therapies if the following are met:

- Patients with NYHA class II to III symptoms despite at least four weeks of treatment with a stable dose of an angiotensin converting enzyme inhibitor (ACEI) or an angiotensin II receptor blocker (ARB) in combination with a beta blocker and, if tolerated, a mineralocorticoid receptor antagonist (MRA) AND
- Patients with at least one hospitalization due to heart failure in the last year AND
- Resting heart rate must be documented as ≥ 77 bpm on average using either an ECG on at least three separate visits or by continuous monitoring AND
- Patients should be under the care of a specialist experienced in the treatment of heart failure for patient selection, titration, follow-up and monitoring.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2018

Newfoundland Labrador

Health and Community Services

IVACAFTOR (KALYDECO 150mg TABLET, 50mg sachet, 75mg sachet)

For the treatment of cystic fibrosis (CF) in patients:

- age six (6) years and older who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R; or
- age eighteen (18) and older with an R117H mutation in the CFTR gene.

Renewal criteria:

Renewal requests will be considered in patients with documented response to treatment as evidenced by the following:

In cases where the baseline sweat chloride levels were greater than 60 mmol/L:

- The patient's sweat chloride test falls below 60 mmoL/L; OR
- The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60 mmoL/L,

- The patient's sweat chloride test falls by at least 30%; OR
- The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance, FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

Clinical Notes:

- The patient's sweat chloride level and FEV_1 must be provided with each request.
- A sweat chloride test must be performed within a few months of starting ivacaftor therapy to determine if sweat chloride levels are reducing.
    - If the expected reduction occurs, a sweat chloride test must be performed again 6 months after starting therapy to determine if the full reduction has been achieved. Thereafter, sweat chloride levels must be checked annually.
    - If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, coverage will be discontinued.

Claim Notes:

- The drug is prescribed by a clinician with experience in the diagnosis and treatment of CF.
- Restricted to patients under the Select Needs Program.
- Maximum Dose: 150mg every 12 hours

- Patients will be limited to receiving a one-month supply per prescription.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2021

Health and Community Services

IVOSIDENIB (TIBSOVO) 250MG TABLET

In combination with azacitidine for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (IDH1) R132 mutation who are not eligible to receive intensive induction chemotherapy. Patients must meet at least one of the following criteria:

- Age 75 years or older;
- ECOG PS of 2 or greater,
- severe cardiac disorder;
- severe pulmonary disorder;
- CrCl less than 45 mL/min; or
- Bilirubin level greater than 1.5 times ULN; or
- any other comorbidity incompatible with intensive induction chemotherapy.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Note:

1. Patients must not have prior treatment for AML, except for treatments aimed at stabilizing disease (e.g., hydroxyurea or leukapheresis).
2. Treatment should be for a minimum of 6 cycles and should be discontinued upon disease progression or intolerable toxicity.
3. Ivosidenib must be given in combination with azacitidine; it cannot be given as monotherapy. Patients with IDH1 R132 mutation may be candidates to be switched to ivosidenib + azacitidine when experiencing intolerance or toxicity with venetoclax + azacitidine.
4. Patients who are initiated on venetoclax + azacitidine prior to receiving the mutational test results, may consider switching to ivosidenib + azacitidine once the IDH-1 R132 test results are confirmed.
5. On a time-limited basis ivosidenib may be added to patients who have confirmed IDH1 R132 mutation status and have started treatment with azacitidine monotherapy prior to ivosidenib + azacitidine becoming available.

Claim Notes:

• Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2025

Health and Community Services

IXEKIZUMAB (TALTZ 80 MG/ML SYRINGE, 80 MG/ML AUTOINJECTOR)

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- The recommended dose is 160 mg by subcutaneous injection (two 80 mg injections) at Week 0, followed by 80 mg every 4 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).

Please visit the link below if you require our special authorization form:
https://www.health.gov.nl.ca/health/prescription/ra_meds_initiation.pdf
https://www.health.gov.nl.ca/health/prescription/ra_meds_continuation_request.pdf

Chronic Plaque Psoriasis

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:
For continued coverage, patients must meet the following criteria:

- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- The recommended dose of ixekizumab is a 160 mg subcutaneous injection (SC) at week 0; followed by 80 mg SC at weeks 2, 4, 6, 8, 10, and 12; followed by 80 mg SC every 4 weeks.
- Approved for maintenance therapy not exceeding 80mg every four weeks.
- Initial approval: 6 months
- Renewal approval period: 1 year.
    - Ongoing coverage for maintenance therapy should only be provided for responder, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Updated April 2025

Health and Community Services

LACOSAMIDE (VIMPAT 50mg, 100mg, 150mg & 200mg tablets and generics)

For the treatment of patients with refractory partial-onset seizures who meet the following criteria:

- Are under the care of a neurologist or physician experienced in the treatment of epilepsy

AND

- Who have had an inadequate response or intolerance to at least two other antiepileptic drugs.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2026

Health and Community Services

Lactulose (generics)

- For the prophylaxis and treatment of portal-systemic encephatopathy (PSE).
- In combination with rifaximin, for patients unable to achieve adequate control of overt hepatic encephalopathy (HE) recurrence with maximal tolerated doses of lactulose alone.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2016

Health and Community Services

LAMIVUDINE (HEPTOVIR 100 MG TABLET and generics)

Chronic Hepatitis B:

- For the treatment of hepatitis B.

Note: Must be prescribed by a hepatologist, gastroenterologist, infectious disease specialist or other prescribers with expertise in the treatment of hepatitis B.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2019

Health and Community Services

LANADELUMAB (TAKHZYRO 300MG/2ML PRE-FILLED SYRINGE, 300 MG/2 ML Vial)

For prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age or older who have experienced at least three HAE attacks within any four-week period and required injectable treatment.

Renewal criteria:

- An assessment of a response to treatment should be conducted three months after initiating treatment with lanadelumab.
- A response to treatment is defined as a reduction in the number of HAE attacks for which acute injectable treatment was received within the initial three months of treatment with lanadelumab compared to the rate of attacks observed before initiating treatment with lanadelumab.
- Following the initial three-month assessment, patients should be assessed for continued response to lanadelumab every six months.
- Continued response is defined as no increase in the number of HAE attacks for which acute injectable treatment was received compared with the number of attacks observed prior to initiating treatment with lanadelumab.

Discontinuation criteria:

Treatment should be discontinued in patients who either respond inadequately or exhibit a loss of response, defined as follows:

- No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to number of attacks observed before initiation treatment with lanadelumab.
- An increase in the observed number of HAE attacks for which acute injectable treatment was received before initiating treatment with lanadelumab.

Clinical Note:

- The pre-treatment attack rate must be provided for those patients already receiving long-term prophylactic treatment for HAE and intent to transition to lanadelumab.

Claim Notes:

- The patient must be under the care of a specialist experienced in the diagnosis and management of patients with angioedema.
- Lanadelumab should not be used in combination with other medications used for long-term prophylactic treatment of angioedema (e.g., C1-INH).
- Approvals will be for a maximum of 300 mg every two weeks.
- Initial approval period: 3 months
- Renewal approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2021

Health and Community Services

LANSOPRAZOLE (PREVACID 15mg, 30mg capsule and generic brands, PREVACID FASTAB 15mg, 30mg)

Requests for lansoprazole will be considered for patients:

- In whom there has been therapeutic failure of 8 week trials of regular benefit PPIs (i.e. omeprazole 20mg, rabeprazole 20mg daily, pantoprazole sodium 40mg daily and pantoprazole magnesium 40mg daily).
- When compounded as an oral suspension for patient 12 years and younger, who require the use of a proton pump inhibitor and cannot use a tablet or capsule.

Clinical Note:

- Requests for lansoprazole 30mg BID will only be considered if there has been inadequate response to an 8 week trial of lansoprazole 30mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID

		Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Prevacid 15mg, 30mg FasTabs are considered for patients who meet the indications

above **and** who require delivery of medication through a feeding tube.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2020

Health and Community Services

LAROTRECTINIB (VITRAKVI) 25 mg capsule, 100 mg capsule, and 20 mg/mL

As monotherapy for the treatment of adult and pediatric patients with unresectable locally advanced, or metastatic solid tumors who meet all of the following criteria:

- Presence of a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation.
- No other satisfactory treatment options.
- Is not a candidate for surgery and/or radiation due to risk of substantial morbidity.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of radiographic disease progression.

Clinical Notes:

1. Patients must have a good performance status*.
2. If brain metastases are present, patient must be asymptomatic.
3. Treatment should be discontinued upon radiographic progression or unacceptable toxicity.

*Good performance status is defined as: ECOG performance status of 0 to 2 for adults and ECOG performance status of 0 to 3 for pediatrics

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a NTRK inhibitor.
- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2023

Health and Community Services

LEBRIKIZUMAB (EBGLYSS 250 mg/2mL single use prefilled pen, 250 mg/2 mL single use prefilled syringe).

For the treatment of patients 12 years of age and older with moderate to severe atopic dermatitis (AD), who meet all of the following criteria:

Who are refractory or intolerant to:

- an adequate trial with maximally tolerated prescription topical therapies (corticosteroid and/or topical calcineurin inhibitors) for atopic dermatitis (combined with phototherapy (where available), and
- an adequate trial of prescription topical therapies (corticosteroid and/or topical calcineurin inhibitors) for atopic dermatitis combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine), and
- Have an Investigator's Global Assessment (IGA) score ≥ 3 and an Eczema Area and Severity Index (EASI) score ≥ 7.1.
- The physician must provide the Eczema Area and Severity Index (EASI) score and the Investigator's Global Assessment (IGA) score for Atopic Dermatitis (vIGA-AD) at the time of initial request for reimbursement.

Renewal Criteria:

- The maximum duration of initial authorization is 6 months.
- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 20 weeks after treatment initiation.
- For subsequent renewal, the physician must provide proof of maintenance of EASI-75 response from baseline every 6 months for subsequent authorizations.

Clinical Notes:

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe atopic dermatitis.
- Initial Approval: 6 months at a dose of 500 mg (two 250 mg injections) injected subcutaneously at Week 0 and Week 2, followed by 250 mg (one injection) every two weeks until Week 16, followed by maintenance dosing of 250 mg every four weeks thereafter starting at week 16.
  Renewal: 6 months at a dose of 250 mg every four weeks.
- Coverage will not be considered in combined with phototherapy, any immunomodulatory agents (including biologics) or other JAK inhibitor treatment for moderate to severe AD.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Special-Authorization-Form-Dupixent.pdf

Updated October 2026

Health and Community Services

LEDIPASVIR/SOFOSBUVIR (HARVONI 90mg/400mg TABLET)

For treatment-naïve or treatment-experienced adult patients with hepatitis C virus (HCV) who meet all of the following criteria:

- Lab-confirmed hepatitis C genotype 1
- Quantitative HCV RNA value within the last 12 months **OR**
- TWO laboratory confirmed quantitative HCV RNA values ≥ 12 months ago
    - tests must have been completed within 6 months apart)

	Approval Period and Regimen
Genotype 1 • Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level < 6 million IU/mL and mono-HCV infected only	8 weeks
Genotype 1 • Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level ≥ 6 million IU/mL • Treatment-naïve with compensated cirrhosis • Treatment-naïve with advanced liver fibrosis (Fibrosis stage F3-F4) • Treatment-experienced without cirrhosis • HCV/HIV co-infected without cirrhosis or with compensated cirrhosis	12 weeks
Genotype 1 • Treatment-experienced with compensated cirrhosis	24 weeks
Genotype 1 • Decompensated cirrhosis • Liver transplant recipients without cirrhosis or with compensated cirrhosis	12 weeks in combination with ribavirin

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

Clinical Notes:

1. Treatment-experienced is defined as a patient who has been previously treated with peginterferon/ribavirin regimen, including regimen containing HCV protease inhibitors, and who has not experienced an adequate response.
2. For this population cohort, evidence has shown that the SVR rates with 8-week and 12-week treatment regimens are similar. Treatment regimens of up to 12 weeks are recognized by Health Canada as an approved treatment option. 12-week treatment regimens may be considered for patients with advanced liver fibrosis.
3. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Special Authorization requests must include the genotype report from the latest post-treatment course.
- Special Authorization requests must include the most recent HCV RNA test performed in the last 12 months **OR** TWO laboratory confirmed quantitative HCV RNA values ≥ 12 months ago
    - tests must have been completed within 6 months apart)
- Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require the special authorization request form:
https://www.gov.nl.ca/hcs/files/Hepatitis-C-Treatment-Request-.pdf

Updated April 2025

Health and Community Services

LENALIDOMIDE (REVLIMID and generics) 2.5 MG, 5 MG, 10 MG, 15 MG, 20 MG AND 25 MG CAPSULES

Multiple Myeloma

1. For the first line treatment of newly diagnosed multiple myeloma, in patients who are not candidates for autologous stem cell transplant (TNE) when used:
   - in combination with dexamethasone, with or without bortezomib; or
   - in combination with daratumumab and dexamethasone; or
   - in combination with daratumumab, bortezomib and dexamethasone.

2. For the treatment of patients with newly diagnosed multiple myeloma who are eligible for ASCT when used:
   - in combination with bortezomib and dexamethasone; or
   - in combination with daratumumab, bortezomib and dexamethasone.

3. For the treatment of relapsed or refractory multiple myeloma, whose disease is not refractory to lenalidomide, when used:
   - In combination with dexamethasone; OR
   - In combination with carfilzomib and dexamethasone; OR
   - In combination with daratumumab and dexamethasone.

4. For the maintenance treatment of patients with multiple myeloma who have stable or improved disease following ASCT and no evidence of disease progression when used as monotherapy or in combination with daratumumab.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:

1. Treatment should be discontinued upon disease progression or unacceptable toxicity.
2. Patients must have a good performance status.

Claim Notes:

- Approval period: 1 year.

Myelodysplastic Syndrome (MDS)

For the treatment of patients with anemia due to myelodysplastic syndrome (MDS) in patients who meet all of the following:

- Presence of deletion 5q cytogenetic abnormality
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1

- Transfusion-dependent symptomatic anemia

Renewal criteria:
- Patients who are transfusion-dependent must demonstrate a reduction in transfusion requirements of at least a 50%.
- Renewal requests for all other patients will be considered on a case-by-case basis. Information describing the results of serial CBC (pre- and post lenalidomide) and any other objective evidence of response should be included.

Clinical Notes:
- Requests for patients who are not transfusion-dependent may be considered. Clinical evidence of symptomatic anemia affecting the patient's quality of life, rationale for why transfusions are not being used, and details pertaining to other therapies prescribed to manage anemia is required.

Claim Notes:
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

LENVATINIB (LENVIMA) 4MG, 8MG, 10MG, 12MG, 14MG, 20MG and 24MG per dose Compliance Pack

Advanced Endometrial Carcinoma
In combination with pembrolizumab for the treatment of adult patients with advanced, recurrent, or metastatic endometrial carcinoma or carcinosarcoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), and who meet all the following criteria:

- Disease progression following prior platinum-based therapy.
- Are not candidates for curative surgery or radiation.
- No active or uncontrolled brain metastases.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- Patients must have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).
- Confirmation that patient does not have MSI-H or dMMR disease must be done prior to initiating treatment.
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib may also be given at the discretion of the treating physician.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Advanced and Metastatic Renal Cell Carcinoma
In combination with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma who have not had prior systemic therapy for metastatic disease.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- Patients must have a good performance status.

- Patients must not have active CNS metastases.
- Treatment should be discontinued upon disease progression or unacceptable toxicity (can be continued as monotherapy after completing 2 years of combination therapy with pembrolizumab).
- If pembrolizumab or lenvatinib is discontinued for toxicity, the other agent can be continued at the discretion of the physician.
- If patient requires and qualifies for re-treatment with pembrolizumab, lenvatinib may also be given at the discretion of the treating physician.

Claim Notes:
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

LENVATINIB (LENVIMA) 4 MG, 8 MG and 12 MG per dose Compliance Pack

Advanced Hepatocellular Carcinoma
For the treatment of unresectable hepatocellular carcinoma, as first-line or second-line therapy after progression on immunotherapy (atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab), for patients who meet all of the following criteria:
- Child-Pugh class status of A
- ECOG performance status of 0 or 1
- Less than 50% liver involvement and no invasion of the bile duct or main portal vein
- No prior liver transplant
- No brain metastases

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for lenvatinib will not be considered for patients who have progressed on sorafenib.
- Initial approval period: 6 months.
- Renewal approval period: 6 months

LENVATINIB (LENVIMA) 10MG, 14MG, 20MG and 24MG per dose Compliance Pack

Differentiated Thyroid Cancer
For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet the following criteria:
- Pathologically confirmed papillary or follicular thyroid cancer, and
- Disease that is refractory or resistant to radioactive iodine therapy, and
- Radiological evidence of disease progression within the previous 13 months, and
- Previous treatment with no more than one tyrosine kinase inhibitor (TKI)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

- Patients must have a good performance status.
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2025

Health and Community Services

LETERMOVIR (PREVYMIS 240mg, 480mg TABLET)

For the prophylaxis therapy of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) who have undetectable CMV viremia at baseline and who meet one of the following criteria:

- umbilical cord blood as stem cell source or
- patient is a haploidentical recipient, or
- recipients of T-cell depleted grafts, or
- recipients treated with antithymocyte globulin (ATG) for conditioning, or
- recipients requiring high-dose steroids (defined as the use of ≥ 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid) or other immunosuppression for acute graft versus host disease (GVHD), or
- recipients treated with ATG for steroid-refractory acute GVHD treatment, or
- recipients with documented history of CMV disease prior to transplantation.

Claim Notes:

- Must be prescribed by clinicians with expertise in the management of HSCT such as medical oncologists, hematologists, or infectious disease specialists.
- Approvals will be for a maximum dose of 480 mg per day.
- Approval period: 100 days, per patient, per HSCT procedure.

UPDATED June 2021

Health and Community Services

LEVETIRACETAM 100 MG/ML SOLUTION (LEVETIRACETAM 100 MG/ML ORAL SOLUTION)

For use in patients who are unable to swallow the tablet formulation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

LEVOCARNITINE (CARNITOR 100mg/ml solution, 330mg tablet)

- For the treatment of primary systemic carnitine deficiency.
- For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

CARBIDOPA/LEVODOPA (DUODOPA 20 mg/mL levodopa/ 5 mg/mL carbidopa intestinal gel cassette)

For the treatment of patients with advanced levodopa-responsive Parkinson's disease who meet all of the following criteria:

- Experiences severe, debilitating motor fluctuations and dyskinesia, with at least 25% of the waking day in the "off" state and/or ongoing levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day)
- Received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response
- Failed an adequate trial of each of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgment of the prescriber: amantadine, a dopamine agonist, entacapone, and a monoamine oxidase (MAO-B) inhibitor
- Must be able to administer this medication and care for the administration port and infusion pump. Alternatively, trained personnel or care partner must be available to perform these tasks reliably.

Exclusion Criteria:

- Patients with a contraindication to the insertion of a PEG-J tube.
- Patients with severe psychosis or dementia

Renewal Criteria:

- The patient has significant reduction in the time spent in the "off" state and/or in ongoing levodopa-induced dyskinesias, along with and an improvement in the related disability.

Clinical Note:

- Time in the "off" state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal specialist care, clinical interview of a patient and/or care partner, or motor symptom diary.
- Must be prescribed by a movement disorder subspecialist who has appropriate training in the use of Duodopa and is practicing in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2021

Health and Community Services

LEVOFLOXACIN HEMIHYDRATE (QUINSAIR 240MG/2.4ML INHALATION SOLUTION)

For the treatment of chronic pulmonary Pseudomonas aeruginosa infections, when used as a cyclic treatment, in patients 18 years of age or older with cystic fibrosis who have experienced treatment failure with inhaled tobramycin (Tobi or Tobi Podhaler or generics)[1].

Please note:
[1] failure of inhaled tobramycin therapy should include at least one of the following:
(i) growth of resistant pseudomonas strains (to tobramycin), OR
(ii) increased symptoms, OR
(iii) increased frequency of exacerbations

Clinical Note:
- The drug is prescribed by a clinician with experience in the diagnosis and treatment of CF.
- The drug is not used in combination with another inhaled antibiotic(s) to treat pulmonary P. aeruginosa infections, either concurrently or for antibiotic cycling during off-treatment periods.
- QUINSAIR is taken in alternating cycles of 28 days on treatment followed by 28 days off treatment
- Restricted to patients under the Select Needs Program.

Please visit the following link if you require our standard special authorization form:
https://www.health.gov.nl.ca/prescription/standard_specauth_form.pdf

Updated August 2019

Newfoundland Labrador

Health and Community Services

LEVOFLOXACIN (LEVAQUIN 250mg, 500mg, 750mg tablet & generics)

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).

- For the treatment of severe pneumonia in nursing home patients.

- For the treatment[1] of CAP in patients
    - with co-morbidity[2] upon radiographic confirmation of pneumonia, *or*
    - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).

- For the treatment[1] of AECB in complicated patients[3] who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

[1] If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

[2] Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.

[3] Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea **AND**

- FEV_1 < 50% predicted
  OR
- FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2023

Health and Community Services

LINAGLIPTIN / METFORMIN (JENTADUETO 2.5mg/500mg, 2.5mg/850mg, 2.5mg/1000mg TABLET)

For the treatment of type 2 diabetes mellitus in patients with inadequate glycemic control on metformin and who are not using insulin. Patients must be already stabilized on therapy with metformin and linagliptin. Coverage will be provided to replace the individual components of linagliptin and metformin in these patients.

Clinical Note:

- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after JENTADUETO is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

LINAGLIPTIN (TRAJENTA 5 MG TABLET)

For the treatment of type 2 diabetes mellitus when added to metformin for patients with inadequate glycemic control on metformin, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after TRAJENTA is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

Linezolid (Zyvoxam 600mg tablet & generics)

- For treatment of VRE (Vancomycin resistant enterococcus) proven infections.
- For the treatment of MRSA/MRSE (Methicillin resistant s.aureus/ methicillin resistant s.epidermidis) proven infections in those patients who are unresponsive to, or intolerant of vancomycin.

Upon the request of an infectious disease specialist only.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

LISDEXAMFETAMINE DIMESYLATE (Vyvanse 10mg, 20mg, 30mg, 40mg, 50mg, 60mg chewable tablet and generics)

For treatment of attention deficit hyperactivity disorder (ADHD) in patients who are unable to be treated with the regular oral lisdexamfetamine demesylate capsule formulation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2025

Health and Community Services

LORLATINIB (LORBRENA) 25mg and 100mg tablets

As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer (NSCLC).

Renewal Criteria:

- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
3. Patients must not have had any prior systemic therapy for advanced or metastatic NSCLC.
4. Patients may switch to lorlatinib if chemotherapy was initiated before confirmation of ALK status.
5. Patients may be switched to an alternate ALK inhibitor in the case of intolerance without disease progression.

Claim Notes:

- Approval period: 1 year
- Coverage will not be considered for subsequent ALK inhibitor therapy following disease progression on lorlatinib.

Please visit the link below if you require our special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2024

Health and Community Services

LUMASIRAN SODIUM (OXLUMO 94.5 mg/0.5 mL subcutaneous injection)

For the treatment of primary hyperoxaluria type 1 (PH1) to lower urinary oxalate levels in pediatric and adult patients only if the following conditions are met:

Initiation

- Patients must have a genetically confirmed diagnosis of primary hyperoxaluria type 1 (PH1) AND
- Patients in whom urinary oxalate can be measured must be unable to normalize urine oxalate excretion while staying compliant with standard of care therapy, including vitamin B6 for a duration of 3 to 6 months.

For initial coverage, the following pre-treatment information must be provided:

- 24-hour urinary oxalate level of 1.5 times the upper limit of normal (ULN) or greater, in patients where a urinary oxalate can be measured, or
- Spot urine oxalate:creatinine ratio, in patients who are not continent, or
- Predialysis plasma oxalate level, in patients with end-stage kidney disease (ESKD) or those who are on dialysis.

Renewal:
Coverage can be continued in patients who have evidence of response as defined below:

- a lowering of 24-hour urine oxalate to less than 1.5 times the ULN, for patients in whom urinary oxalate can be measured, or
- a 30% reduction in spot urine oxalate: creatinine ratio in non-continent patients, or
- a 15% reduction in plasma oxalate level in patients with ESKD or who are on dialysis.

Clinical Notes:

- Must be prescribed by a nephrologist or metabolic diseases specialist with experience in the diagnosis and management of PH1;
- Subsequent renewal of prescriptions following the initial prescription can be through a pediatrician instead of nephrologist or metabolic diseases physician.
- Coverage cannot be renewed once the patient has received a liver transplant with or without a kidney transplant.
- Approval: Coverage may be approved for 12 months.
- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99,999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Please visit the following link if you require our special authorization form:

https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated June 2025

Health and Community Services

LUSPATERCEPT (REBLOZY 25mg VIAL, 75mg VIAL)

Beta-Thalassemia anemia:

Initiation:

For the treatment of adults with RBC transfusion-dependent anemia associated with beta-thalassemia who meet all of the following criteria:

The patients has “transfusion-dependent” beta-thalassemia associated anemia, defined as:

- Requiring 6 to 20 RBC units in the 24 weeks prior to initiating treatment with luspatercept, and
- Has not had a transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment with luspatercept.

Renewal:

- Patients should be assessed for a response to luspatercept every 6 months.
- Renewals will be considered for patients who are able to achieve or maintain at least a 33% reduction in transfusion burden (RBC units/time) compared to pre-treatment baseline RBC transfusion burden and do not meet the discontinuation criteria.
- At each renewal, RBC transfusion burden over 24 weeks will be compared against the baseline RBC transfusion burden measured in the 24 weeks prior to initiation of treatment with luspatercept.
- At each subsequent assessment, a reduction in transfusion burden of ≥33% compared to the pre-luspatercept transfusion burden must be maintained.

Discontinuation:

Luspatercept should be discontinued if a patient does not achieve a reduction in RBC transfusion burden after nine weeks of treatment (three doses) at the maximum dose (1.25mg/kg).

Prescribing:

- The patient should be under the care of a specialist with experience in managing patients with beta-thalassemia.
- The patient’s RBC transfusion record within the 24 weeks prior to treatment initiation with luspatercept must be provided.

- Renewal requests must include the patient's RBC transfusion record within the 6 months (approximately 24 weeks) of the coverage period in order to compare baseline and on-treatment RBC transfusion burden and other relevant laboratory/bloodwork results.
- The maximum dose of luspatercept should not exceed 1.25 mg/kg (or 120 mg total dose) per administration every three week in accordance with the product monograph

Myelodysplastic syndromes (MDS) associated anemia:

For the treatment of adult patients with red-blood cell (RBC) transfusion dependent anemia associated with myelodysplastic syndromes (MDS) who meet all of the following criteria:

- Diagnosed with very low- to intermediate-risk MDS with ringed sideroblasts in accordance with the Revised International Hematological Response Criteria and has 'transfusion-dependent' MDS associated anemia defined as requiring at least 2 RBC units over 8 weeks; **AND**
- Has failed or are not suitable for erythropoietin-based therapy for their MDS-associated anemia (see notes for more info).

Renewal:

- Initial renewals will be approved for patients who achieve RBC transfusion independence over a minimum of 16 consecutive weeks within the first 24 weeks of treatment initiation with luspatercept AND who do not meet the discontinuation criteria.
- Subsequent renewals will be approved for patients who maintain their transfusion independence while on treatment and who have not developed unacceptable toxicities to luspatercept.
- CBCs, other relevant bloodwork, and transfusion records during the coverage period should be included with the application.

Discontinuation:

- Luspatercept should be discontinued in patients who have not achieved a reduction in RBC transfusion burden after using 3 consecutive escalated doses (9 weeks) at 1.75 mg/kg in accordance with the product monograph
- Progression of MDS to a higher risk category or transformation to AML

Clinical Notes:

- Treatment should be initiated by a specialist with expertise in managing and treating patients with MDS.
- The patient's RBC transfusion record within the 24 weeks prior to treatment initiation with luspatercept must be provided.
- Renewal requests must include the patient's RBC transfusion record within the 6 months (approximately 24 weeks) of the coverage period in order to compare

baseline and on-treatment RBC transfusion burden and other relevant laboratory/bloodwork results.

-
- Initial request should include details of the Erythropoietin Stimulating Agents (ESAs) that have been used (i.e. Name of treatment, dose(s), duration of use, response).
- Patients considered inappropriate for ESA therapy may include those who are predicted to have less than a 25% chance of responding to an ESA, or those with contraindications, or have a history of unacceptable toxicities to an ESA.
- The maximum dose of luspatercept should not exceed 1.75 mg/kg (or 168 mg total dose) per administration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2023

Health and Community Services

MECASERMIN (INCRELEX 40MG/4ML)

For the treatment of growth failure in children and adolescents from 2 to 18 years with confirmed severe primary insulin-like growth factor-1 deficiency (SPIGFD) only if the following conditions are met:

Initiation:
Treatment can be initiated in patients who are at least two years of age and in whom epiphyseal closure has not yet occurred, and with confirmed diagnosis of SPIGFD defined by:

- The patient has a known genetic mutation recognized as a cause of SPIGFD; and/or
- The patient has clinical and biochemical features of SPIGFD.

Discontinuation:
Treatment with mecasermin must be discontinued upon occurrence of any of the following:

- Height velocity is less than 1 cm per 6 months or less than 2 cm per year, or
- Bone age is more than 16 years in boys and 14 years in girls.

Clinical Notes:

- Patient must be under the care of a pediatric endocrinologist.
- Mecasermin must not be prescribed concomitantly with recombinant growth hormone treatment.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2022

Health and Community Services

MACITENTAN (OPSUMIT) 10 MG TABLET

For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with World Health Organization (WHO) functional class II, III or IV.

Clinical Note:

- The diagnosis of PAH should be confirmed by right heart catheterization.

Claim Notes:

- Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.
- Combined use of more than one endothelin receptor antagonists will not be reimbursed.
- The maximum dose of macitentan that will be reimbursed is 10 mg daily.
- Approval period: Long term.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2022

Health and Community Services

MARALIXIBAT (LIVMARLI 9.5mg/ml, 19mg/ml, 10mg tablet, 15mg tablet, 20mg tablet, 30mg tablet)

Alagille syndrome (ALGS)

For the treatment of patients aged 12 months and older with a diagnosis of Alagille syndrome (ALGS) who have demonstrated the following:

- Evidence of cholestasis (must include at least 1 of the following):
  - total serum bile acids (sBA) > 3 × upper limit of normal (ULN) for age
  - conjugated bilirubin > 1 mg/dL
  - fat-soluble vitamin deficiency otherwise unexplainable
  - gamma glutamyltransferase (GGT) > 3 × ULN for age
  - intractable pruritus explainable only by liver disease

AND

- Moderate to severe itch defined as an average daily score of 2 or more on the Itch Reported Outcome (ItchRO) or Clinician Scratch Scale (CSS) for 2 consecutive weeks.

AND

- Currently treated with, or who have received an adequate trial with, a systemic treatment for pruritus before initiating maralixibat.

Exclusions:

- Patients with biliary diversion, previous liver transplant, decompensated cirrhosis, or history or presence of other concomitant liver disease.

Renewal:

- Requests for renewal must provide proof of beneficial clinical effect, defined as an improvement in pruritus to minimal or no itch (a score of 1 or less) on the ItchRO or CSS.
- Subsequent renewals: Ongoing coverage will be considered in patients who maintains the improvement in ItchRO or CSS demonstrated at the initial renewal.

Discontinuation:

- Reimbursement of maralixibat will be discontinued if the patient receives liver transplantation or biliary diversion surgery.

Clinical Notes:

- Should be under the care of a hepatologist or gastroenterologist with experience in the diagnosis and management of ALGS.
- Initial coverage: 6 months
- Renewal coverage: 6 months
- An adequate trial for systemic treatment of pruritus is defined as a trial of 1 to 3 months with appropriate dosing of a systemic treatment for pruritus based on

usual care. This may include ursodeoxycholic acid (UDCA), rifampicin, sertraline, naltrexone, cholestyramine, or antihistamines.
- Approvals will be for a maximum of 28.5 mg (3 mL) daily.
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.

Progressive familial intrahepatic cholestasis (PFIC):

For the treatment of cholestatic pruritus in patients aged 12 months or older with progressive familial intrahepatic cholestasis (PFIC) who meet the following:

- Have a confirmed diagnosis of biallelic PFIC of the following subtypes (gene mutations): PFIC1 (ATP8B1), non-truncated-PFIC2 (ABCB11), PFIC3 (ABCB4), PFIC4 (TJP2) and PFIC10 (MYO5B).

AND

- Have experienced severe pruritus for 6 months or longer with average Itch Reported Outcome (Observer reported) [ItchRO(Obs)] score of ≥1.5 in past 4 weeks while receiving usual care with at least one therapy used for symptomatic relief of pruritus used for symptomatic relief of pruritic.

AND

- Total serum bile acid (sBA) > 3 × ULN.

AND

The patient does NOT have:
- Mutation in the ABCB11 gene that leads to a nonfunctional or absent bile salt export pump (BSEP), such as a truncated form OR
- Heterozygous PFIC mutation.

Renewal:

- ItchRO(Obs) should demonstrate 1 point or more reduction after 6 months from initiation.
- For subsequent renewals, the physician must provide proof of maintenance of the change in pruritus severity from baseline every 6 months.

Discontinuation:
- Maralixibat should be discontinued upon liver transplant or biliary surgery.

Clinical Notes:
- Should be prescribed by, or in consultation with a clinician with experience in managing PFIC.
- Coverage will not be considered in combination with another ileal bile acid transporter (IBAT) inhibitor.
- Initial approval: 6 months (inclusive of titration period).
- Renewal approval: 6 months
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2026

Health and Community Services

Maracirov (Celsentri 150mg, 300mg tablets)

For the treatment of HIV-1 infection given in combination with other antiretroviral medications in patients:

- Who have CCR5 tropic viruses **and**
- Who have documented resistance to at least one agent from each of the three main classes of antiretroviral agents (nucleoside reverse transcriptase inhibitors, non- nucleoside reverse transcriptase inhibitors, protease inhibitors).

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

MARIBAVIR (LIVTENCITY 200mg TABLET)

For the treatment of adults with post-transplant cytomegalovirus infection/disease who are refractory[1] (with or without genotypic resistance) to 1 or more of the following antiviral drugs: valganciclovir, ganciclovir, foscarnet, or cidofovir.

Renewal and/or Retreatment:

- Subsequent treatment may be approved for patients who have a recurrence of CMV viremia after a previous successful course of therapy with maribavir.

Treatment should be discontinued if any of the following occurs:

- No change or an increase in CMV viral load after at least 2 weeks of maribavir treatment
- Confirmed CMV genetic mutation associated with resistance to maribavir

Clinical Notes:

- Must be prescribed by clinicians with experience and expertise in transplant medicine, transplant infectious disease, or infectious diseases.
- [1] Refractory to antiviral treatment is defined as: a lack of change in CMV viral load or increase in CMV viral load after at least 2 weeks of appropriately dosed treatment."
- Approval period: 6 months

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated January 2025

Health and Community Services

MAVACAMTEN (CAMZYOS 2.5mg, 5mg, 10mg, 15mg CAPSULES)

For the treatment of symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of NYHA class II to III in adult patients who meet all the following:

- documented left ventricular ejection fraction (LVEF) ≥ 55% at rest determined by echocardiography AND
- left ventricular (LV) wall thickness ≥ 15 mm (or ≥ 13 mm with a family history of hypertrophic cardiomyopathy (HCM) AND
- left ventricular outflow tract (LVOT) peak gradient ≥ 50 mm Hg at rest, after Valsalva maneuver, or postexercise, as confirmed by echocardiography.
- Patients must be receiving beta-blockers (BB) or calcium channel blockers (CCB) therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments.

For renewal, the physician must document that the patient must NOT have:

- LVEF ≤ 30% NOR
- received septal reduction therapy (SRT)

Clinical Notes:

- The patient should be under the care of a cardiologist.
- LVEF must be measured via echocardiography**.**

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated October 2024

Newfoundland Labrador
Health and Community Services

MEPOLIZUMAB (NUCALA 100 mg/mL auto-injector, 100 mg/mL prefilled syringe)

Severe chronic rhinosinusitis

For add-on maintenance treatment with intranasal corticosteroids in adult patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) inadequately controlled by intranasal corticosteroids alone only if the following conditions are met:

Initiation:

Patients must have all the following:

- endoscopically or CT-documented bilateral nasal polyps
- have undergone at least 1 prior surgical intervention for nasal polyps or have a contraindication to surgery.
- be tolerant and able to continue use of inhaled nasal corticosteroids but have refractory symptoms despite use of inhaled corticosteroids for 3 months at maximally tolerated doses.

Prescribing clinician must submit a baseline SNOT-22 or endoscopic NPS.

Renewal:

- Patients must exhibit a clinically meaningful response on the Sino-nasal Outcome Test (SNOT-22) or endoscopic NPS relative to their baseline score.
- Response to treatment should be assessed after every 52 weeks.

Prescribing:

- Must be prescribed by physicians with expertise in managing severe CRSwNP such as an otolaryngologists (ENT) or allergist.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Chronic-Rhinosinusitis-with-Nasal-Polyps.pdf

Asthma

As an add-on maintenance treatment for adult patients with severe eosinophilic asthma, if the following conditions are met:

Initiation Criteria:

- Patient must have a documented diagnosis of asthma.

- Patient is inadequately controlled with high-dose inhaled corticosteroids, defined as greater or equal to 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., long-acting beta agonists).
- Patient has one of the following:
    - blood eosinophil count of ≥ 300 cells/μL AND has experienced two or more clinically significant asthma exacerbations in the past 12 months
    - blood eosinophil count of ≥ 150 cells/μL AND is receiving maintenance treatment with oral corticosteroids (OCS).

Clinical Notes:

- Mepolizumab should not be used in combination with other biologics used to treat asthma.
- A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of mepolizumab treatment.
- Patients should be managed by a physician with expertise in treating asthma

Renewal Criteria:

- The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue.
- Reimbursement of treatment should be discontinued if:
    1. the 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment, OR
    2. the asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, OR
    3. the number of clinically significant exacerbations has increased within the previous 12 months, OR
    4. in patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment, OR
    5. in patients on maintenance treatment with OCS, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained subsequently.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Asthma-1.pdf

Updated January 2025

Health and Community Services

METHADONE (METADOL 1mg, 5mg, 10mg, 25mg tablet and generics)

Palliative analgesia:

For use as a replacement for other narcotic analgesics in palliative care patients who are requiring frequent and continuous dosing of short-acting opiates.

Chronic Non-Malignant Pain:

For use as a replacement for other narcotic analgesics in chronic non-malignant pain patients who have been thoroughly investigated and in whom alternate treatments (including treatment with lower potency opioids) have been unsuccessful, or are not feasible and are, therefore, requiring frequent and continuous dosing of higher potency narcotics.*

*** Please note: in order to assess requests for coverage in the treatment of non-malignant pain, the Department will require the following information**:

- Results of any xrays/CT scans/MRIs.
- Information relating to any consultations completed and their recommendations (i.e., surgical, orthopedic and/or physiotherapy consultations).
- Surgical history.
- Past analgesic use and response; current analgesic use, dosage, and assessment of current level of pain control.
- Any other information you feel is pertinent to the request.

Requests are only considered for those physicians holding a valid license to prescribe methadone.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated May 2024

Health and Community Services

METHYLPHENIDATE (BIPHENTIN 10mg, 15mg, 20mg, 30mg, 40mg, 50mg 60mg, 80mg capsule and generics)

For treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients who:

- Have experienced unsatisfactory results due to poor symptom control, side effects, administrative barriers and/or societal barriers.

AND

- Have been tried on open benefit extended release methylphenidate*, dextroamphetamine, or mixed salts amphetamine with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 80mg daily.
- Reimbursement will not be considered for Biphentin and/or Vyvanse concurrently with methylphenidate (immediate release or sustained/controlled/extended release formulation), dextroamphetamine (immediate or sustained release formulation), or mixed salts amphetamine.

*Foquest, Concerta and generics are open benefit. Please note claims for Concerta brand will be reimbursed up to the cost of generic methylphenidate ER.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2024

Newfoundland Labrador

Health and Community Services

METRELEPTIN (MYALEPTA 3mg vial, 5.8mg vial, 11.3mg vial)

As an adjunct to diet as a replacement therapy to treat the complications of leptin deficiency in lipodystrophy (LD) patients with either of the following:

For the treatment of patients with either of the following:

- with confirmed congenital generalized LD (Berardinelli-Seip syndrome) OR acquired generalized LD (Lawrence syndrome) in adults and children 2 years of age and above.
- with confirmed familial partial lipodystrophy (PL) or acquired PL (Barraquer-Simons syndrome), in adults and children 12 years and older with persistent significant metabolic abnormalities (as defined by baseline hemoglobin A1C ≥ 6.5% and/or fasting TGs ≥ 5.65 mmol/L) for whom standard treatments have failed to achieve adequate metabolic control after at least 12 months since initiating standard treatments.

Genetic testing must be conducted and:

- If genetic testing is positive, then diagnosis is confirmed and treatment with metreleptin can be initiated.
- If after conducting genetic testing lipodystrophy is not confirmed, treatment can be initiated in patients with confirmed clinical diagnosis based on a comprehensive clinician assessment and if fasting leptin levels are < 12.0 ng/mL in females and < 8.0 ng/mL in males older than 5 years of age or < 6 ng/mL in children aged 6 months to 5 years.

Exclusions:

- Patients should not be pregnant or lactating or have HIV-associated LD.

Initial Renewal Criteria:

The prescriber must provide proof of beneficial metabolic effect defined as 1 or both of the following:

- Actual hemoglobin A1C reduction of at least 0.5% from baseline.
- Percent fasting TG reduction of at least 15% from baseline.

Subsequent Renewal Criteria:

- The prescriber must provide proof of maintenance of reduction in hemoglobin A1C and/or fasting TG from baseline every 12 months for subsequent authorizations.

Clinical Notes:

- A1C and/or fasting TG levels must be provided.
- Initial and renewal approval duration: 12 months
- Prescribing should be limited to endocrinologists or pediatric endocrinologists with expertise in treating lipodystrophy.

- Approvals will be for a maximum dose of 0.13 mg/kg daily for patients ≤40kg and 10mg daily for patients >40 kg.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated March 2026

Health and Community Services

MIDOSTAURIN (RYDAPT) 25MG CAPSULES

For the treatment of adult patients with newly diagnosed FMS-like tyrosine kinase 3 (FLT3)-mutated acute myeloid leukemia (AML) when used in combination with standard cytarabine and daunorubicin (7+3) induction and cytarabine consolidation chemotherapy.

Claim Notes:

- Requests for midostaurin will not be considered when used as maintenance therapy, or as part of re-induction and/or re-consolidation.
- Requests for midostaurin in combination with idarubicin containing 7+3 induction and cytarabine consolidation chemotherapy will be considered.
- Approval period: Up to 6 cycles (maximum of 2 cycles of induction and 4 cycles of consolidation).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2020

Health and Community Services

MIGALASTAT (GALAFOLD 123mg capsule)

For the treatment of Fabry Disease in adult patients with lab confirmed alpha-galactosidase (alpha-Gal A) mutation, determined to be amenable by an in vitro assay.

Clinical Note:

- Eligibility for the treatment of Fabry Disease is determined by the Canadian Fabry Disease Initiative.

Claim Notes:

- Combined use of more than one disease specific therapy (i.e. enzyme replacement therapy or chaperone therapy) will not be reimbursed
- Initial approval period: 1 year.
- Renewal approval period: 1 year. Confirmation of continued response is required
- Not for use in pediatrics (i.e. patients < 18 years of age)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2021

Health and Community Services

MIRABEGRON (MYRBETRIQ ER 25mg, 50mg TABLET)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Newfoundland Labrador

Health and Community Services

MIRIKIZUMAB (OMVOH 300mg/15mL Vial for infusion, 100 mg/mL (2 x 100mg/mL), 100 mg/mL (2 x 100mg/mL), 100mg/mL (100mg/mL & 200mg/2mL), 100mg/mL (100mg/mL & 200mg/2mL))

Ulcerative Colitis (UC)

For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Initial Approval: Initial coverage may be approved for a total of 6 doses administered every 4 weeks: 3 doses of 300 mg intravenous (IV) followed by either 3 doses of 200 mg subcutaneous (SC) **OR** an additional 3 doses of 300 mg IV (for patients who do not have adequate therapeutic response at Week 12).
- Maintenance: 200 mg every 4 weeks after completion of induction dosing.
- Renewal Approval: 1 year.
- Coverage will not be considered when combined with biological or other JAK inhibitor treatments for UC. Combined use of more than one biologic DMARD will not be reimbursed.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Crohn's Disease

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approved for 900 mg infused intravenously at week 0, week 4, and week 8 followed by 300 mg (given as 2 consecutive subcutaneous injections of 100 mg and 200 mg in any order) every 4 weeks starting at week 12 upon completion of induction dosing.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to be assessed at 12 weeks then yearly using criteria such as a 100-point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less, or a decrease in score of 4 or more.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated April 2026

Health and Community Services

MIRTAZAPINE RD (REMERON RAPID TABLETS 15mg, 30mg, 45mg and generics)

For the treatment of depression in patients 18 years of age or older who are unable to be treated with the regular oral mirtazapine formulation.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2021

Health and Community Services

Mitomycin Eye Drops (compounded using Mitomycin injection)

On request of an ophthalmologist or oncologist for the treatment of:

- Malignant melanoma of the conjunctiva **OR**
- Ocular surface squamous neoplasia (OSSN), also known as conjunctival-corneal intraepithelial neoplasia (CCIN)

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Treatment should be repeated every 7 days for 2-3 cycles and discontinued if there is no response after 3 cycles.

Claim Notes:

- Initial approval period: 3 weeks
- Renewal approval period: 6 months
- Amounts reimbursed for this compound will be in accordance with NLPDP's Program Claiming Policies with respect to compounded preparations. Details of this policy can be found at: Program-Claiming-Policies.pdf (gov.nl.ca)

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2023

Health and Community Services

MOMELOTINIB (OJJAARA) 100MG, 150MG, AND 200MG TABLET

For the treatment splenomegaly and/or disease-related symptoms in adult patients with primary myelofibrosis, post-polycythemia vera myelofibrosis or post essential thrombocythemia myelofibrosis with moderate to severe anemia who have:

- high-risk or intermediate-2 risk myelofibrosis, or intermediate-1 risk associated with symptomatic splenomegaly and/or hepatomegaly;
- palpable splenomegaly of at least 5 cm or confirmed splenomegaly on imaging;
- hemoglobin less than 100 g/L.

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by a reduction in spleen size or symptom improvement.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued in patients if no response to treatment has been demonstrated after 6 months of treatment, if there is splenic progression, or development of serious adverse events.

Claim Notes:

- Patients are eligible regardless of prior JAK inhibitor use; however ruxolitinib and fedratinib are not funded as a subsequent line of therapy after disease progression or lack of response to momelotinib.
- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2026

Health and Community Services

MOMETASONE/FORMOTEROL (ZENHALE 100MCG-5MCG, 200MCG-5MCG INHALER

Asthma

For the treatment of asthma in patients who are using optimal doses of inhaled corticosteroids but remain poorly controlled.

- Poorly controlled is defined as require additional symptom control because of asthma symptoms (e.g., cough, awakening at night, missing activities such as school, work or social activities) and resulting in increased amounts of short-acting beta2-agonists.

Clinical Note:

- Patients who have a diagnosis of both asthma and COPD do not need to have a trial of inhaled corticosteroids before requesting special authorization of a Zenhale.

Limitations to coverage:

- LAMA inhalers will not be reimbursed concurrently with LABA/ICS inhalers. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control (see Triple Therapy criteria below).

LABA/ICS as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

Moxifloxacin (Avelox 400mg tablet & generics)

- For step-down therapy after hospital discharge for the treatment of nosocomial pneumonia, community acquired pneumonia (CAP) or acute exacerbation of chronic bronchitis (AECB).

- For the treatment of severe pneumonia in nursing home patients.

- For the treatment[1] of CAP in patients:

    - with co-morbidity[2] upon radiographic confirmation of pneumonia,

OR

    - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).

- For the treatment[1] of AECB in complicated patients[3] who have failed treatment with one of the following (amoxicillin, doxycycline, TMP-SMX, cefuroxime, macrolide, ketolide or amoxicillin-clavulanate).

[1] If treated with an antibiotic within the past 3 months choose an antibiotic from a different class.

[2] Co-morbidity includes chronic lung disease, malignancy, diabetes, liver, renal or congestive heart failure, use of antibiotics or steroids in the past 3 months, suspected macroaspiration, hospitalization within last 3 months, HIV/AIDs, smoking, malnutrition or acute weight loss.

[3] Complicated AECB defined as increased cough and sputum, sputum purulence and increased dyspnea, **AND**

- FEV_1 < 50% predicted

    OR

- FEV 50-65% and one of the following:
    - ≥ 4 exacerbations per year
    - Ischemic heart disease
    - Chronic oral steroid use
    - Antibiotic use in the past 3 months

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

NABILONE (CESAMET 0.25mg, 0.5mg, 1mg TABLETS and generics)

For the management of severe nausea and vomiting associated with cancer chemotherapy.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Health and Community Services

Naratriptan (Amerge 1mg and 2.5mg tablet and generics)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

NATALIZUMAB (TYSABRI 300mg/15ml SINGLER USE VIAL)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Experienced one or more disabling relapses or new MRI activity in the past year
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)
- Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab).

Renewal Criteria:

- Evidence of continued benefit must be provided (i.e. stability or reduction in the number of relapses in the past year or stability or improvement of EDSS score obtained within the previous 90 days).

Clinical Notes:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.
- A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist.

Claim Notes:

- Must be prescribed by a neurologist.
- Combined use with other disease modifying therapies to treat RRMS will not be reimbursed.
- Initial approval period: 1 year.
- Renewal approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2022

Health and Community Services

NETUPITANT/PALONOSETRON (AKYNZEO 300 MG-0.5MG CAPSULE)

In combination with dexamethasone for the prevention of acute and delayed nausea and vomiting in patients receiving:

- highly emetogenic chemotherapy, OR
- moderately emetogenic chemotherapy who have had inadequate symptom control using a 5-HT3 antagonist and dexamethasone in a previous cycle.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

Nilotinib (Tasigna capsule)

Written request from an oncologist/hematologist required.

Initial approval period: one year

Request for renewal must specify that the patient has benefited from therapy and is expected to continue to do so. Renewal: one year

Tasigna 150mg

For the first-line treatment of adult patients with Philadelphia chromosome positive chronic myeloid leukemia in chronic phase.

Tasigna 200mg

For the treatment of adult patients with accelerated phase (AP) or chronic phase (CP) Philadelphia chromosome positive (Ph+) CML who are resistant to or intolerant of imatinib AND either have a mutational resistance to dasatinib predicted by mutational analysis OR uncontrolled pleural effusions on dasatinib.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2012

Health and Community Services

NINTEDANIB (OFEV 100mg, 150mg capsule)

For the treatment of adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests)

Initial renewal criteria (at 6 months):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% from initiation of therapy until renewal (initial 6 month treatment period). IF a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):

Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥ 10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion criteria:
Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

Notes:
Patients who have experienced intolerance or failure to Ofev (nintedanib) or Esbriet (pirfenidone) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

For the treatment of patients with chronic fibrosing interstitial lung disease with progressive phenotype:

- With a progressive phenotype confirmed by a respirologist and
- The patient has a forced vital capacity greater than or equal to 45% of predicted and
- The patient is under the care of a physician with experience in interstitial lung diseases.

Renewal criteria:

- The patient must not experience a more severe progression of disease, defined as an absolute decline in percent predicted forced vital capacity of 10% or greater over the preceding year of treatment with nintedanib.
- The patient's clinical status should be evaluated every 12 months.

Exclusion criteria:
Combination use of Ofev (nintedanib) and Esbriet (pirfenidone) will not be funded.

Please visit the link below if you require the special authorization form:
https://www.gov.nl.ca/hcs/files/Atrial-Fibrillation-Medication-Request.pdf

Updated October 2023

Health and Community Services

NIRAPARIB/ABIRATERONE ACETATE (AKEEGA) 50MG/500MG and 100MG/500MG TABLET

In combination with prednisone for the first-line treatment of adult patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who meet all of the following criteria:

- Presence of deleterious or suspected deleterious germline and/or somatic mutation in BRCA1 or BRCA2 genes; and
- Have not received prior treatment with an androgen-receptor-axis-targeted (ARAT) therapy (e.g., apalutamide, darolutamide, enzalutamide) for metastatic castration-sensitive prostate cancer or non-metastatic castration-resistant prostate cancer.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients should have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients receiving abiraterone and prednisone as first-line therapy for mCRPC for less than 4 months may be switched to Akeega with prednisone once BRCA mutation is confirmed provided there has been no disease progression on treatment.
- Requests will not be considered for patients previously treated with a PARP inhibitor or who experience disease progression on abiraterone in any setting.
- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2025

Health and Community Services

NIRAPARIB (ZEJULA) 100 MG TABLET

Newly-Diagnosed

As monotherapy maintenance treatment for adult patients with newly-diagnosed, high-grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the
following criteria:

- Complete or partial response after 6 to 9 cycles of first-line platinum-based chemotherapy
- Last cycle of platinum-based chemotherapy completed within the previous 12 weeks
- High-grade serous or endometrioid tumours classified as stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients should have a good performance status and no active or uncontrolled metastases in the central nervous system.
2. Maintenance therapy with niraparib should continue until unacceptable toxicity, disease progression, or completion of 3 years of therapy, whichever occurs first.

Claim Notes:

- Patients are eligible to receive first-line maintenance treatment with only one of olaparib or niraparib, and cannot have received bevacizumab in the maintenance setting. Switching is only permitted if there is intolerance but no progression.
- Requests for niraparib in combination with bevacizumab will not be considered. Patients already on bevacizumab maintenance at the time of niraparib funding may be switched to niraparib, as long as there is no evidence of progression on imaging and is within 12 weeks of completion of chemotherapy.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Relapsed

As monotherapy maintenance treatment for adult patients with platinum-sensitive, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:

- Completed at least two previous lines of platinum-based chemotherapy
- Received at least four cycles of the most recent platinum-based chemotherapy regimen and in complete or partial radiologic response

- Last cycle of platinum-based chemotherapy was completed within the last 8-12 weeks
- Have high-grade serous or endometrioidal tumours

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no active or uncontrolled metastases in the central nervous system.
2. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
3. Patients should be clinically evaluated for disease progression every 3-4 months and if clinically indicated, evaluation should include CA 125 and/or radiologic imaging.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for niraparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

NIRMATRELVIR/RITONAVIR (PAXLOVID 150MG/100MG)

Treatment with nirmatrelvir-ritonavir should be initiated as soon as possible after a diagnosis of COVID-19 has been made, and within 5 days of symptom onset in adult patients who have either of the following:

Severe immunosuppression, such as:

- recipient of solid organ transplant
- treatment for a malignant hematologic condition
- bone marrow, stem cell transplant, or transplant-related immunosuppressant use
- receipt of an anti-CD20 drugs or B-cell depleting drugs (such as rituximab) in the past 2 years
- Severe primary immunodeficiencies

Moderate immunosuppression, such as:

- treatment for cancer, including solid tumors
- treatment with significantly immunosuppressing drugs (e.g., a biologic in the past 3 months, oral immune-suppressing medication in the past month, oral steroid [20 mg/day of prednisone equivalent taken on an ongoing basis] in the past month, or immune-suppressing infusion or injection in the past 3 months).
- advanced HIV infection (treated or untreated)
- moderate primary immunodeficiencies
- renal conditions (i.e., hemodialysis, peritoneal dialysis, glomerulonephritis and dispensing of a steroid)

Clinical notes:

- Treatment should not be offered to patients who are taking a medication that may result in a serious drug interaction with nirmatrelvir/ritonavir.
- Treatment should not be offered to patients who have a medical condition that would make treatment with nirmatrelvir/ritonavir inappropriate.
- Treatment is not to be offered to hospitalized patients as nirmatrelvir-ritonavir is intended for outpatient use. Patients in hospital under Alternate Level of Care (ALC) are eligible for treatment.
- An individual must have a positive COVID-19 test (PCR or RAPT) within the past 5 days

<u>Claiming Paxlovid:</u>

- Individual must be a beneficiary of NLPDP
- The Screening and Prescribing Form has been updated and will continue to serve as the official prescription for Paxlovid for NLPDP beneficiaries. This can be sent to a pharmacy of the individual's choice for the purposes of dispensing.

- In order for a pharmacist to dispense and claim NLPDP for Paxlovid written by a physician or nurse practitioner, the Screening and Prescribing form must be completed in full.

The updated Screening and Prescribing form can be found at:
https://www.gov.nl.ca/hcs/files/NLPDP-Paxlovid-Form-for-Coverage.pdf

Updated August 2024

Health and Community Services

NORFLOXACIN (NOROXIN 400mg TABLETS)

For prevention of recurrent spontaneous bacterial peritonitis.

Updated May 2021

Health and Community Services

NUSINERSEN SODIUM (SPINRAZA 2.4MG/ML INTRATHECAL SOLUTION)

For the treatment of Sq spinal muscular atrophy (SMA), if the following criteria are met:

- Genetic documentation of Sq SMA homozygous gene deletion, homozygous mutation , or compound heterozygous mutation; **AND**

- Patient who:

    - Are pre-symptomatic with genetic documentation of two or three copies of the survival motor neuron 2 (SMN2) gene, OR
    - has had disease duration less than 6 months, two copies of the SMN2 gene, and symptom onset after the first week of birth and on or before 7 months of age, O
    - is 18 years of age or younger with symptom onset after 6 months of age.

AND

- Patient is not requiring permanent invasive ventilation*; AND
- A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale- Expanded [HFMSE]) **must** be completed prior to initiation of nusinersen treatment.

* Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.

<u>Discontinuation Criteria: For continued coverage, the patient must meet the following criteria:</u>
Prior to the fifth dose or every subsequent dose

- There is demonstrated achievement or maintenance of motor milestone function as assessed using age-appropriate scales since treatment initiation in patients who were pre-symptomatic at the time of treatment initiation; OR
- There is demonstrated maintenance in motor milestone function as assessed using age-appropriate scales: HINE Section 2, CHOP INTEND, or HFMSE) since treatment initiation in patients who were symptomatic at the time of treatment initiation; or
- The patient does not require permanent invasive ventilation*.

Treatment should be discontinued if, prior to the fifth dose or every subsequent dose of nusinersen, the above renewal criteria are not met.

Claim Notes:

- The patient must be under the care of a specialist experienced in the treatment of SMA.
- Approval Period: 1 year.
- Requests for patients who do not meet the criteria may be considered on a case-by-case basis as outlined in the Exceptional Review Process.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2020

Health and Community Services

OBETICHOLIC ACID (OCALIVA 5MG, 10MG TABLETS)

For the treatment of primary biliary cholangitis (PBC) in adult patients who meet the following criteria:

A confirmed diagnosis of PBC, defined as:

- Positive antimitochondrial antibodies (AMA); **OR**
- Liver biopsy results consistent with PBC

AND

- Used in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response[1] to a minimum of 12 months of treatment with UDCA, **OR**
- As monotherapy in adults who have experienced unmanageable intolerance to UDCA

AND

- The patient is under the care of a gastroenterologist or hepatologist (An internal medicine clinician with an interest in gastroenterology / hepatology may also be acceptable if the patient resides in a rural area).

[1]Note that an inadequate response is defined as a patient who has used UDSA to treat PBC for a minimum of 12 months and demonstrates the following:

- alkaline phosphatase (ALP) ≥ 1.67 x upper limit of normal (ULN) **and/or**
- bilirubin > ULN and < 2 x ULN **and/or**
- evidence of compensated cirrhosis

(Documentation of lab work should be submitted with the special authorization request)

Duration of approval for initial request: 1 year

Renewal Criteria:

Requests for renewal will be considered in patients who continue to benefit from treatment as evidenced by any one of the following:

- A reduction in the ALP level to less than 1.67 x ULN; **or**
- A 15% reduction in the ALP level compared with values before beginning treatment with obeticholic acid.

Duration of approval for renewals: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2019

Health and Community Services

OCRELIZUMAB (OCREVUS 300mg/ml iv infusion)

For the management of patients with relapsing-remitting multiple sclerosis (RRMS), who meet all of the following criteria:

- Written request from a neurologist.
- Age over 18 years.
- Confident diagnosis of relapsing-remitting MS.
- Two relapses in the previous 24 months (Relapse defined as the appearance of symptoms and signs compatible with MS, lasting greater than 24 hours and not due to a rise in temperature.)
- Kurtzke EDSS score of 6.5 or less (assistance needed to walk about 20m without resting).

Initial dose: 300 mg intravenous infusion, followed 2 weeks later by a second 300 mg intravenous infusion. Subsequent doses: single 600 mg intravenous infusion every 6 months

For the management of primary progressive multiple sclerosis (PPMS) in adult patients with early PPMS who meet **all** of the following criteria:

- Written request from a neurologist
- Age over 18 years.
- Diagnosis confirmed based on McDonald criteria 2017
- An Expanded Disability Status Scale (EDSS) score between 3.0 and 6.5
- A score of at least 2.0 on the Functional Systems scale for the pyramidal system due to lower extremity findings
- A disease duration of less than 15 years for those with an EDSS greater than 5.0 or less than 10 years for those with an EDSS of 5.0 or less.

Treatment should be discontinued for patients with an EDSS score of equal to or greater than 7.0.

Initial dose: 300 mg intravenous infusion, followed 2 weeks later by a second 300 mg intravenous infusion. Subsequent doses: single 600 mg intravenous infusion every 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

October 2019

Health and Community Services

ODEVIXIBAT (BYLVAY 200mcg capsule, 400mcg capsule, 600mcg capsule, 1200mcg capsule)

Progressive familial intrahepatic cholestasis (PFIC):

For the treatment of pruritus in patients aged 6 months or older with progressive familial intrahepatic cholestasis (PFIC) who meet all the following criteria:

- Have a genetic diagnosis of PFIC1 or PFIC2; AND
- Have severe pruritus with an observer-reported outcome (ObsRO) scratching score of ≥ 2; AND
- Are receiving at least 1 therapy used for symptomatic relief of pruritus prior to initiating odevixibat; AND
- Have a serum bile acid (sBA) levels ≥ 100 µmol/L; AND
- Have not received a liver transplant.

Note: Genetic testing should be conducted to confirm patients' PFIC subtype.

Initial Renewal Criteria:

- The prescriber must document response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline.
- If no response is observed after 3 months following the initial authorization, renewal of odevixibat will be for a 3-month trial of up to 120 mcg/kg per day dose (maximum of 7,200 mcg per day) and the patient will be required to then demonstrate response in pruritus, defined as an ObsRO scratching score of ≤ 1 or at least a 1-point decrease from baseline.

Subsequent Renewal Criteria:

- Subsequent renewals require documentation of continued maintenance of pruritus response (ObsRO scratching score demonstrated at the initial renewal).

Clinical Notes:

- Genetic testing must be conducted to confirm patients' PFIC subtype.
- Systemic treatment of pruritus may include ursodeoxycholic acid (UDCA), rifampicin, cholestyramine, sertraline, or Naltrexone.
- Must be prescribed by a physician with expertise in the treatment and management of PFIC.
- Initial approval: 3 months
- Renewal approval: 6 months
- The maximum duration of initial authorization is 3 months of treatment with a dose of 40mcg/kg per day.

- Odevixibat will be renewed at the 40 mcg/kg per day dose only if patients experience a documented response in pruritus after 3 months of treatment.
- Eligible dose: 40 mcg/kg/day for the first three months, with an increase in patients not responding after three months to up to 120 mcg/kg/day (maximum of 7,200 mcg/day).

Alagille syndrome (ALGS):

For the treatment of patients aged 12 months or older with a diagnosis of Alagille Syndrome (ALGS) who have demonstrated the following:

- Significant pruritus defined as an itching or scratching score of 2 or higher on the PRUCISION PRO or ObsRO scale; AND
- Serum bile acid (sBA) level greater than the upper limit of normal (ULN).
- The patients must be either currently receiving systemic therapy for pruritus or have previously undergone an adequate trial[1] of such treatment before initiating odevixibat.

[1]An adequate trial is defined as a trial of at least 1 month at appropriate dosing of ursodeoxycholic acid (UDCA), rifampicin, sertraline, naltrexone, cholestyramine, or antihistamines. (Please provide drug, dose, duration and outcome of each trial).

Renewal:
- The physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as an improvement in pruritus to minimal or no itch.

Exclusions:
- Patients with any of the following should not be eligible for reimbursement:
- biliary diversion,
- previous liver transplant,
- decompensated liver disease, or
- history or presence of other concomitant liver disease.

Discontinuation:
Coverage should be discontinued if 1 or both of the following occurs:
- Patients receive a liver transplant or
- Patients have biliary diversion surgery.

Clinical Notes:
- Must be prescribed by a hepatologist or specialist with experience in the treatment and management of ALGS.
- Initial treatment: 6 months
    - the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as an improvement in pruritus to minimal or no itch.
- Subsequent renewals: 6 months

- the physician must provide proof of maintenance of the change in pruritus severity from baseline every 6 months.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated March 2026

Health and Community Services

OFATUMUMAB (KESIMPTA 20 mg/0.4 mL Pen)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all of the following criteria:

- Confirmed diagnosis based on McDonald criteria;
- Has experienced one or more disabling relapses or new MRI activity in the past two years; and
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5).

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2022

Health and Community Services

OLAPARIB (LYNPARZA) 100MG AND 150MG TABLETS

Breast Cancer

1. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who have had upfront surgery followed by adjuvant chemotherapy and who meet one of the following criteria:
   - Triple negative breast cancer and either axillary node-positive or axillary node-negative with invasive primary tumor pathological size of at least 2 cm (> pT2 cm).
   - Hormone receptor positive, HER2-negative breast cancer with at least 4 pathologically confirmed positive lymph nodes.

2. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who received neoadjuvant chemotherapy followed by surgery and who meet one of the following criteria:
   - Triple negative breast cancer with residual invasive disease in the breast and/or resected lymph nodes (non-pCR).
   - Hormone receptor positive, HER2-negative breast cancer with residual invasive disease in the breast, and/or the resected lymph nodes, and a CPS + EG score of 3 or higher.

Clinical Notes:

1. Patients must have completed neoadjuvant or adjuvant chemotherapy containing an anthracycline and/or taxane.
2. Treatment should be initiated within 12 weeks of completion of the last treatment (i.e., surgery, chemotherapy, or radiation therapy).
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 1 year of therapy, whichever occurs first.

Claim Notes:

- Requests for patients determined to be at high-risk for relapse using a disease scoring system other than CPS + EG will be considered.
- Approval period: 1 year.

Metastatic Castration-Resistant Prostate Cancer

1. As monotherapy for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who meet all of the following criteria:
   - Deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM; and
   - Disease progression on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year.

2. In combination with abiraterone and prednisone for the first-line treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) in whom chemotherapy is not clinically indicated and who meet all of the following criteria:
   - Presence of deleterious or suspected deleterious germline and/or somatic mutation in BRCA1 or BRCA2 genes; and
   - Have not received prior treatment with an androgen receptor pathway inhibitor for metastatic castration-sensitive prostate cancer or non-metastatic castration-resistant prostate cancer.

   Renewal Criteria:

   - Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

   Clinical Notes:

   1. Patients must have a good performance status.
   2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

   Claim Notes:

   - Patients receiving abiraterone and prednisone as first-line therapy for mCRPC for less than 4 months may have olaparib added once BRCA mutation is confirmed provided there has been no disease progression on treatment.
   - Requests will not be considered for patients previously treated with a PARP inhibitor or who experience disease progression on abiraterone in any setting.
   - Approval period: 1 year.

Ovarian Cancer

1. As monotherapy maintenance treatment of patients with newly-diagnosed, advanced, BRCA-mutated (germline or somatic), epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Complete or partial radiologic response after at least 4 cycles of first-line platinum-based chemotherapy
   - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
   - High-grade serous or endometrioid tumors classified as Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.
- Requests for treatment beyond 2 years will not be considered if there is no evidence of disease.

Clinical Notes:

1. Patients should have a good performance status and no active or uncontrolled metastases to the central nervous system.
2. Treatment should continue until unacceptable toxicity, disease progression, or to a maximum of 2 years of therapy if no evidence of disease, whichever comes first.[1]
3. Imaging is required for patients who are delayed in starting olaparib therapy, i.e. greater than 12 weeks after completion of platinum-based chemotherapy, or who have had a break in therapy for more than 14 days, to rule out progression prior to starting or re-starting olaparib.

[1]Patients with a partial response or stable disease at 2 years may continue to receive olaparib at the discretion of the treating physician.

Claim Notes:

- Requests for olaparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy
- Requests for olaparib in combination with bevacizumab will not be considered. Patients already on bevacizumab maintenance at the time of olaparib funding may be switched to olaparib, as long as there is no evidence of progression on imaging and is within 12 weeks of completion of chemotherapy.
- Approval period: 1 year
- Renewal period: 1 year

2. As monotherapy maintenance treatment for patients with platinum-sensitive, recurrent, BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Completed at least 2 previous lines of platinum-based chemotherapy
   - Received at least 4 cycles of the most recent platinum-based chemotherapy and in complete or partial radiologic response
   - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
   - High-grade serous or endometrioid histology

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
2. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.

3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests for olaparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2024

Health and Community Services

OMALIZUMAB (OMLYCLO 75mg/0.5mL prefilled syringe, 75mg/0.5mL autoinjector, 150mg/1.0mL prefilled syringe, 150mg/1.0mL auto-injector)

Chronic Idiopathic Urticaria (CIU):

For the treatment of patients ≥ 12 years of age with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H1 antihistamines.

Initial Requests:

- Documentation of the most recent urticaria activity score over 7 days (UAS7) must be provided on the submitted request (copy of the questionnaire must be attached).

Renewal Criteria:

- Requests for renewal will be considered if the patient has achieved:
  - complete symptom control for less than 12 consecutive weeks; or
  - partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline urticaria activity score over 7 days (UAS7)
  - renewal will require 2 x UAS & questionnaires – one assessment every 12 weeks i.e two in a 24 week approval period (in the middle of the approval period and at the end). *Only questionnaires completed by the patient or caregiver will be accepted. Questionnaires completed by the patient support program are not accepted.*

Clinical Notes:

- Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment
- Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period.
- In patients who discontinue treatment due to temporary symptom control, re-initiation can be considered if CIU symptoms reappear.
- Optimal management is defined as H1 antihistamines at up to 4 times the standard daily dose.
- Approvals will be for a maximum dose of 300mg every four weeks.
- Initial approval: 6 months
- Renewal Approval: Long-term

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Allergic Asthma:

For the treatment of patients 6 years of age and older with moderate to severe uncontrolled asthma who meet all of the following criteria:

- Patient is uncontrolled despite treatment high-dose inhaled corticosteroid (ICS) and a long-acting beta-agonist (LABA).

AND

- In the past 12 months, inadequately controlled asthma has resulted in at least one of the following:
    - Hospitalization for asthma OR
    - Two or more urgent care visits to a physician/nurse practitioner or emergency department for asthma exacerbations. OR
    - Use of two or more courses of high-dose oral corticosteroids (e.g. prednisone) or increase in the dose of chronic prednisone treatment to manage asthma exacerbations.

AND

- Patient has demonstrated a positive skin test or in vitro reactivity to a perennial aeroallergen (e.g. positive allergy testing by skin prick test or IgE RAST);

Note: Removal or reduction of allergic and environmental triggers of asthma to the fullest extent possible should be attempted.

AND

- Has a baseline Immunoglobulin E (IgE) level between 30IU/mL and 700IU/mL inclusive prior to start of omalizumab;

Note: Serum total IgE levels increase following administration of omalizumab due to formation of omalizumab: IgE complexes. Elevated serum total IgE levels may persist for up to 1 year following discontinuation of omalizumab. Serum total IgE levels obtained less than 1 year following discontinuation may not reflect steady state free IgE levels and should not be used to reassess the dosing regimen in asthma patients.

AND

- Has an actual body weight between 20kg to 150kg inclusive (Refer to Omlyclo product monograph for dosing in individuals 6 years of age and older by IgE level and weight);

Discontinuation Criteria:

- Baseline asthma control questionnaire score has not improved since the initiation of treatment, OR
- Number of clinically significant asthma exacerbations has increased since the initiation of treatment.

Clinical Notes:

- Prescribed by or in consultation with a specialist in respirology or allergy/clinical immunology.
- High-dose inhaled corticosteroids are defined as greater than or equal to 500 mcg of fluticasone propionate or equivalent daily dose.
- For patients 6 to 11 years old, medium dose ICS is defined as between 200 mcg and 400 mcg of fluticasone propionate or equivalent daily dose and high-dose ICS is defined as greater than 400 mcg of fluticasone propionate or equivalent daily dose.
- A baseline and a re-assessment of asthma symptom control using an asthma control questionnaire score must be provided.
- A baseline and a re-assessment of the number of clinically significant asthma exacerbations must be provided.
- Coverage will not be considered in combination with another biologic drug used for the treatment of asthma.
- Omalizumab will not be funded as a first line treatment for uncontrolled asthma and patients must try other conventional therapies for asthma that include a corticosteroid inhaler before being prescribed a biologic treatment.
- Proper inhaler technique (with a spacer if required/appropriate) and adherence to prescribed treatment should be confirmed.
- Patients may also be on other concomitant therapies.
- Approvals will be for a maximum of 375mg every 2 weeks.
- Initial approval duration: 6 months
- Renewal approval duration: Long-term

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2025

Health and Community Services

ONASEMNOGENE ABEPARVOVEC (ZOLGENSMA 2x10^{13}vector genomes/ml)

For the treatment of pediatric patients with 5q spinal muscular atrophy (SMA) with biallelic mutations in the survival motor neuron 1 (SMN1) gene, and all of the following conditions are met.

- Genetic documentation of 5q spinal muscular atrophy with biallelic mutations in the SMN1 gene, and
- symptomatic or pre-symptomatic with one to three copies of the SMN2 gene; and
- 180 days of age or younger; and
- not currently requiring permanent feeding or ventilatory support (either invasive or non-invasive). [1]

[1] Permanent ventilator support is defined as the need for a tracheostomy or requirement of 16 hours or more of respiratory assistance per day (via non-invasive ventilatory support) for 14 or more consecutive days in the absence of an acute reversible illness, excluding perioperative ventilation.

Prescribing conditions:

- Patient must be under the care of a specialist with experience in the diagnosis and management of SMA.
- Reimbursement is limited to one lifetime administration of onasemngene abeparovovec.
- **Note: Patients will not be eligible for coverage of nusinersen and/or risdiplam following administration of onasemnogene abeparvove**
- **Billing Instructions**: please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated October 2025

Health and Community Services

ONDANSETRON (ZOFRAN and generics) 4 MG, 8 MG TABLET, 4 MG ODT, 8 MG ODT, 4 MG/ML ORAL SOLUTION

The following Anti-emetics are covered by the Program as open benefits, with limitations, for chemo induced nausea and vomiting only:
Ondansetron 4mg and 8mg tab: up to 3 tablets in a 24 hour period
Granisetron 1mg tab: up to 2 tablets in a 24 hour period

The quantity limits above may only be filled as an open benefit for the first fill of any chemo antiemetic drug. A special authorization is required for a higher quantity dispensed than noted above for a first fill or for any subsequent fills of any chemo anti-emetic drug.

Coverage is considered for the treatment of emesis in patients who:

- are receiving moderate to highly emetogenic anticancer therapy OR
- are receiving mildly emetogenic anticancer therapy and have experienced episodes of nausea and vomiting related to such treatment, not responding to therapeutic doses of benefit antiemetics (metoclopramide, dexamethasone and prochlorperazine), or where these agents are not tolerated or contraindicated OR
- Post radiation therapy

Duration of therapy:

- Coverage will be provided to a maximum of 48 hours post anticancer therapy for all patients (i.e. to a maximum of 9 tablets of ondansetron for a 1 day IV anticancer regimen).
- Coverage will be provided for one dose per day of oral anticancer therapy.
- Coverage will be limited to one dose post-radiation therapy.

In order to accurately assess requests for coverage, we require the following information:
For Anticancer therapy:

- anticancer agents (including dose)
- number of days per cycle for each agent
- cycle frequency
- expected treatment duration (total number of cycles)
- previous antiemetic trials and the outcome

For Radiotherapy:

- targeted area
- number of days per cycle
- cycle frequency
- expected treatment duration (total number of cycles)
- previous antiemetic trials and the outcome

Other drug and non-drug causes or pre-existing nausea and vomiting should be identified and eliminated.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

OSELTAMIVIR (TAMIFLU 30mg, 45mg, 75mg capsules and generics)

For treatment and prevention of influenza in beneficiaries residing in long-term care facilities*:

- *For treatment of long-term care facility residents with clinically suspected or lab confirmed influenza A or B. A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B*
  circulating within the facility or surrounding community.
- *For prophylaxis of long-term care* residents where the facility has an influenza A or B outbreak. Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility.*
  - *Coverage will be approved for 14 days from the most recent case.*

** Long-term care facility refers to a licensed nursing home or personal care home.*

Please visit the following link if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Tamiflu-for-Long-Term-Care-Residents.pdf

Updated June 2025

Health and Community Services

OSIMERTINIB (TAGRISSO) 40MG AND 80MG TABLETS

Adjuvant Non-Small Cell Lung Cancer

For the adjuvant treatment of patients with completely resected stage IB to IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumors have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

Renewal Criteria:

- Written confirmation that the patient has not experienced disease recurrence.

Clinical Notes:

1. Patients must have a good performance status.
2. Patients should initiate treatment within 26 weeks of complete surgical resection if treated with adjuvant chemotherapy, or within 10 weeks if chemotherapy was not given.
3. Treatment should continue until disease recurrence, unacceptable toxicity, or until a maximum treatment duration of 3 years, regardless of dose reduction and dose interruption.

Claim Notes:

- Requests for treatment beyond 3 years will not be considered.
- Approval period: 1 year.

Advanced Non-Small Cell Lung Cancer

1. As monotherapy, or in combination with pemetrexed and platinum-based chemotherapy, for the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations.

2. As monotherapy for the treatment of patients with locally advanced (not amenable to curative therapy) or metastatic EGFR T790M mutation-positive NSCLC when used as:
   - first-line therapy for de novo T790M mutation, or
   - second-line therapy for T790M mutation following disease progression during treatment with an EGFR tyrosine kinase inhibitor.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

Clinical Notes:

1. Patients receiving osimertinib in combination with chemotherapy must have an ECOG performance status of 0 or 1.
2. Treatment with osimertinib should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who progress during or within 6 months of completing adjuvant therapy with osimertinib.
- Approval period: 1 year.

Locally Advanced, Unresectable (Stage III) Non-Small Cell Lung Cancer, Post Chemoradiation Therapy

For the treatment of patients with locally advanced, unresectable (stage III) NSCLC whose tumours have EGFR exon 19 deletions or exon 21 (L858R) substitution mutations and whose disease has not progressed during or following definitive platinum-based chemoradiation therapy.

Renewal Criteria:

Written confirmation that the patient has not experienced clinically meaningful disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Patients should initiate treatment within 10 weeks of completing chemoradiation therapy.
3. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease recurrence during or within 6 months of completing adjuvant treatment with osimertinib.
- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2026

Health and Community Services

Oxcarbazepine (Trileptal 150mg, 300mg, 600mg tablets, liquid & generics)

For use in patients who have a diagnosis of epilepsy AND have had an inadequate response or are intolerant to at least 3 other formulary agents (prior or current use) including carbamazepine.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

OZANIMOD (ZEPOSIA INITIATION PACK containing 4 X 0.23mg capsules and 3 X 0.46 mg capsules), 0.92 mg CAPSULE.

Ulcerative colitis (UC)

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 12 weeks. Treatment has to be initiated in all patients with an initiation pack that lasts for 7 days.
    - Days 1-4 0.23 mg once daily
    - Days 5-7 0.46 mg once daily
    - Days 8 and thereafter 0.92 mg once daily
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated February 2024

Health and Community Services

PALBOCICLIB (IBRANCE) 75MG, 100MG AND 125MG TABLETS

1. In combination with an aromatase inhibitor (e.g., letrozole) for the treatment of patients with HER2 negative advanced or metastatic breast cancer who meet all of the following criteria:
   - have not received prior endocrine therapy for advanced or metastatic disease, but may have received up to one prior line of chemotherapy, and
   - are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy, and
   - do not have active or uncontrolled metastases to the central nervous system.

   Renewal Criteria:
   - Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

   Clinical Notes:
   1. Resistance is defined as disease progression occurring during or within 12 months following (neo)adjuvant NSAI therapy.
   2. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist
   3. Patients must have a good performance status.
   4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

   Claim Notes:
   - Requests will not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy.
   - Initial approval period: 1 year
   - Renewal approval period: 1 year

2. In combination with fulvestrant for the treatment of hormone receptor-positive, HER2-negative advanced or metastatic breast cancer who:
   - have not received prior endocrine therapy or have experienced disease progression on endocrine therapy, and
   - have received up to one prior chemotherapy for advanced or metastatic disease, and
   - do not have active or uncontrolled metastases to the central nervous system.

   Renewal Criteria:
   - Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

   Clinical notes:

1. Pre- and peri-menopausal patients must be treated with a luteinizing hormone-releasing hormone agonist.
2. Patients must have a good performance status.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease recurrence during or within six months of stopping adjuvant CDK4/6 inhibitor therapy, or for patients who progress on a CDK4/6 inhibitor, fulvestrant or everolimus in the metastatic setting.
- Initial approval period: 1 year
- Renewal approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2025

Health and Community Services

PALIPERIDONE PALMITATE (INVEGA SUSTENNA 50mg/0.5ml, 75 mg/0.75ml, 100 mg/mL, 150 mg/1.5 mL, INVEGA TRINZA 175mg/0.875ml, 63mg/1.315, 350 mg/1.75ml, 525 mg/2.625ml)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2018

Health and Community Services

Pantoprazole magnesium (Tecta 40mg)

Pantoprazole magnesium doses ≤ 40mg daily (20mg and 40mg tablets tablets) are listed as regular benefits.

Doses above 40mg daily require special authorization.

Requests for pantoprazole 40mg BID will only be considered if there has been inadequate response to an 8 week trial of pantoprazole 40mg OD dosing for the indications listed below:

Indication and Diagnostic Information	Maximum Approval Period	
Symptomatic GERD or other reflux-associated indication (i.e. non-cardiac chest pain).	Considered for short-term (8 weeks) approval	
Erosive/ulcerative esophagitis or Barrett's esophagus	Considered for long term approval	
Peptic Ulcer Disease (PUD): Confirmed Gastric/duodenal ulcers	Considered for up to 12 weeks	
Zollinger-Ellison Syndrome	Considered for long term approval	
Gastro-duodenal protection (ulcer prophylaxis) for high risk patients (e.g. high risk NSAID users).	Considered for one year with reassessment.	
H pylori eradication	Regimen	Drugs and dose
	Bismuth quadruple (PBMT)	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Tetracycline 500 mg QID Bismuth subsalicylate[b]
	Non bismuth quadruple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PAC triple therapy (same as HP PAC)	PPI standard dose BID[a] Amoxicillin 1000 mg bid Clarithromycin 500 mg bid
	PMC triple therapy	PPI standard dose BID[a] Metronidazole 500 mg tid to qid

		Clarithromycin 500 mg bid
	PAM triple therapy	PPI standard dose BID[a] Amoxicillin 1000 mg bid Metronidazole 500 mg tid to qid
	A second treatment will be considered providing that at least a four-week period has elapsed since the end of the previous treatment and that retreatment within a three month period uses a different antibiotic regimen. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori. *A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.	

a. Standard dose PPI: lansoprazole 30 mg, omeprazole 20 mg, pantoprazole 40 mg, and rabeprazole 20mg.
b. Bismuth subsalicylate (Pepto Bismol) 262 mg 2 tablets four times daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Newfoundland Labrador

Health and Community Services

PALOVAROTENE (SOHONOS 1mg, 1.5mg, 2.5mg, 5mg, 10mg capsule)

To the treatment of adults and children (aged 8 years and above for females and 10 years and above for males) with:

- Have a confirmed clinical diagnosis of fibrodysplasia (myositis) ossificans progressive (FOP); AND
- Have completed genetic testing confirming presence of the R206H ACVR1 mutation; AND
- Do not have complete ankylosis of the whole body; AND
- Are under the care of a specialist with experience in the diagnosis and management of FOP.

A description of the patient's baseline assessments and individualized treatment goals for palovarotene treatment must be submitted with the initial coverage request. Baseline assessments should address the following:

- Ability to eat and feed
- Ability to perform activities of daily living
- Pain
- Mobility
- Joint range of motion
- Pulmonary function

Initial Approval Duration: 12 months

<u>Renewal Requests</u>

Patients who demonstrate continued benefit with palovarotene will be considered for renewal. Requesters must include a description of the patient's current response to palovarotene therapy and clearly outline how this response meets the clinical treatment goals established at initiation.

The response update should address the following:

- Ability to eat and feed
- Ability to perform activities of daily living
- Pain
- Mobility
- Joint range of motion
- Pulmonary function

- Current extent of ankylosis
    - Note: Coverage will be discontinued in patients where complete ankylosis of the whole body has occurred.
- Summary of individual benefit/risk assessment for the patient and the rationale for continuing treatment with palovarotene.

Patients must continue to be under the care of a specialist with experience in the diagnosis and management of FOP.

Renewal duration: Up to 12 months

Clinical Note:

- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.
- **Please contact NLPDP to request the specific FOP-CEC special authorization form.**

Updated September 2025

Health and Community Services

PATISIRAN (ONPATTRO 2MG/ML INTRAVENOUS SOLUTION)

For the treatment of polyneuropathy in adult patients with hereditary transthyretin-mediated (hATTR) amyloidosis in patients who meet all of the following criteria:

- Confirmed genetic diagnosis of hATTR.
- Symptomatic with early-stage neuropathy, defined as
  - polyneuropathy disability [PND] stage I to ” IIIB, or
  - familial amyloidotic polyneuropathy [FAP] stage I or II
- Does not have New York Heart Association class III or IV heart failure
- Has not previously undergone a liver transplant.

Discontinuation Criteria

Treatment should be discontinued for patients who are:

- Patient is permanently bedridden and dependent on assistance for basic activities of daily living, or
- The patient is receiving end-of-life care.

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and management of hATTR.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers
- Initial approval period: 9 months
- Renewal approval period: 6 months.
- **Confirmation of continued response is required at each renewal.**

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2023

Health and Community Services

PAZOPANIB (VOTRIENT) 200 MG TABLET and generics

For the treatment of patients with advanced or metastatic renal cell carcinoma when used as:

- first-line therapy, or
- second-line therapy following disease progression on nivolumab and ipilimumab combination therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2022

Health and Community Services

PEGFILGRASTIM (LAPELGA 6 mg/0.6 ml SYRINGE, 6 mg/0.6 mL AUTO-INJECTOR, ZIEXTENZO 6 mg/0.6 ml SYRINGE, FULPHILA 6 mg/0.6 ml SYRINGE, NYVEPRIA 6 mg/0.6 ml SYRINGE)

Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy for:

Primary prophylaxis:

- When given as an integral part of an aggressive chemotherapy regimen with curative intent in order to maintain dose intensity in compressed interval or dose dense treatment, as specified in a chemotherapy protocol. ○ Chemotherapy protocol must be supplied with request
- For use in patients' ≥65 years who are receiving CHOP.

Secondary prophylaxis:

Coverage is considered for patients receiving moderate to severely myelosuppressive chemotherapy with curative intent who:

- have experienced an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; **OR**
- For use in patients who have experienced a dose reduction or treatment delay longer than one week due to neutropenia.

Clinical Note:

- Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia
- The recommended dose is single subcutaneous injection of 6mg, administered once per cycle of chemotherapy.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2024

Health and Community Services

Peginterferon alfa -2a (PEGASYS 180 MCG/0.5 ML SYRNGE/ProClick Auto Injector, PEGASYS 180MCG/ML VIAL,)

Hepatitis B:

For the treatment of **HBeAg negative** Chronic Hepatitis B in patients with compensated liver disease, liver inflammation and evidence of viral replication (both cirrhotic and non-cirrhotic) with demonstrated **intolerance or failure to lamivudine** therapy.

- Written request of a hepatologist or other specialist in this area.
- Maximum duration of coverage, **48 weeks**.

Hepatitis C:

For the treatment of individuals with (Peginterferon/RBV–treatment naïve) chronic hepatitis C (upon request from internal medicine specialist/ hepatologist/other appropriate specialist).

- Initial coverage of 24 weeks will be approved for all patients. Coverage for an additional 24 weeks will be approved for patients with HVC genotypes other than 2 or 3.
- A positive HCV RNA assay after 24 weeks of therapy is an indication to stop therapy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2014

Health and Community Services

PERAMPANEL (FYCOMPA 2mg, 4mg, 6mg, 8mg, 12mg tablets and generics)

As an adjunctive therapy in the management of partial-onset or primary generalized tonic-clonic seizures, in patients with epilepsy who are not satisfactorily controlled with conventional therapy, if the following clinical criteria and condition are met:

Clinical criteria:

- Patients are currently receiving two or more antiepileptic drugs
- Less costly AEDs are ineffective or not appropriate

Condition:
Patients are under the care of a physician experienced in the treatment of epilepsy

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2024

Health and Community Services

Pilocarpine (Salagen 5mg tablet)

- For the treatment of the symptoms of xerostomia due to salivary gland hypofunction caused by radiotherapy for cancer of the head and neck, in addition to treatment with topical lubricants, etc.

- For the treatment of Sjogren's syndrome where symptomatic treatment of topical lubricants, etc., fail to provide satisfactory control of symptoms.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador
Health and Community Services

PIRFENIDONE (ESBRIET 267 MG CAPSULE, 267 MG TABLET, 801 MG TABLET and generics)

Adult patients with a diagnosis of mild to moderate idiopathic pulmonary fibrosis (IPF):

- Diagnosis confirmed by a respirologist and a high-resolution CT scan within the previous 24 months.
- All other causes of restrictive lung disease (e.g. collagen vascular disorder or hypersensitivity pneumonitis) should be excluded.
- Mild to moderate IPF is defined as forced vital capacity (FVC) greater than or equal to 50% of predicted.
- Patient is under the care of a physician with experience in IPF.

Initial approval period: 7 months (allow 4 weeks for repeat pulmonary function tests).

Initial renewal criteria (at 6 months):
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% from initiation of therapy until renewal (initial 6 month treatment period). If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 6 months

Second and subsequent renewals (at 12 months and thereafter):
Patients must NOT demonstrate progression of disease defined as an absolute decline in percent predicted FVC of ≥10% within any 12 month period. If a patient has experienced progression as defined above, then the results should be validated with a confirmatory pulmonary function test conducted 4 weeks later.

Approval period: 12 months

Exclusion Criteria:
Combination use of Esbriet (pirfenidone) and Ofev (nintedanib) will not be funded.

Notes:
Patients who have experienced intolerance or failure to Esbriet (pirfenidone) or Ofev (nintedanib) will be considered for the alternate agent provided that the patient continues to meet the above coverage criteria.

Please visit the link below if you require the special authorization form:
https://www.gov.nl.ca/hcs/files/Atrial-Fibrillation-Medication-Request.pdf

Updated October 2023

Health and Community Services

Pomalidomide (Pomalyst and generics) 1mg, 2mg, 3mg and 4mg

For the treatment of patients with relapsed or refractory multiple myeloma when used:

- in combination with dexamethasone, with or without cyclophosphamide, for patients who have failed treatment on lenalidomide and bortezomib; or
- in combination with isatuximab and dexamethasone for patients who have failed treatment on lenalidomide and a proteasome inhibitor.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2023

Health and Community Services

PONATINIB (ICLUSIG) 15mg TABLET

For the treatment of patients with chronic, accelerated or blast phase chronic myelogenous leukemia (CML) or Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) who have:

- resistance or intolerance to two or more tyrosine kinase inhibitors (TKIs), or
- confirmed T315i mutation positive disease.

Renewal Criteria:

- Written confirmation of hematologic and cytogenetic response, and no evidence of disease progression.

Clinical Notes:

1. Patients must have an ECOG performance status of 0-2.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2026

Health and Community Services

POSACONAZOLE (POSACONAZOLE generic brands 100 MG TABLET)

For the prevention of invasive fungal infection (IFI) in allogeneic stem cell transplant recipients with a contraindication or intolerance to voriconazole.

- From time of engraftment until day +90

OR

- With graft versus host disease (GVHD) taking prednisone 1 mg/kg/day or more, until dose is less than 20 mg/day.

Clinical Notes:

- Must be prescribed by a hematologist, infectious disease specialist or medical microbiologist.
- Initial request will be approved for a maximum of 4 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Health and Community Services

PROPIVERINE HCL (MICTORYL PEDIATRIC 5 MG TABLET)

For the treatment of overactive bladder with symptoms of urgency incontinence and/or urinary frequency and urgency in pediatric patients under 18 years of age.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated September 2018

Health and Community Services

PROPRANOLOL (HEMANGIOL 3.75 MG/ML SOLUTION)

For the treatment of patients with proliferating infantile hemangioma that is:

- life- or function-threatening, OR
- ulcerated with pain and/or not responding to simple wound care measures, OR
- at risk of permanent scarring or disfigurement

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2019

Newfoundland Labrador

Health and Community Services

Raloxifene (Evista & generics)

- For the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or contraindicated.

- For the treatment of postmenopausal osteoporosis without documented fractures when patient at high 10-year fracture risk (based on age, sex and T-score, see Appendix 1 below for fracture risk table) and bisphosphonates are not tolerated or contraindicated.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

Age (yrs)	WOMEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	<- 3.9
55	> - 1.9	- 1.9 to - 3.4	< - 3.4
60	> - 1.4	- 1.4 to - 3.0	< - 3.0
65	> - 1.0	- 1.0 to – 2.6	< - 2.6
70	> - 0.8	- 0.8 to – 2.2	< - 2.2
75	> - 0.7	- 0.7 to – 2.1	< - 2.1
80	> - 0.6	- 0.6 to – 2.0	< - 2.0
85	> - 0.7	- 0.7 to – 2.2	< - 2.2

Age (yrs)	MEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	>-3.4	≤-3.4	---
55	>-3.1	≤-3.1	---
60	>-3.0	≤-3.0	---
65	>-2.7	≤-2.7	---
70	>-2.1	-2.1 to -3.9	<-3.9
75	>-1.5	-1.5 to -3.2	<-3.2
80	>-1.2	-1.2 to -3.0	<-3.0
85	>-1.3	-1.3 to -3.3	<-3.3

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

RANIBIZUMAB (RANOPTO 10 mg/mL (0.23ml/vial)

For patients with Neovascular (wet) age-related macular degeneration (AMD), Diabetic Macular edema (DME) or Macular edema secondary to retinal vein occlusion who meet the following criteria:

- have failed to respond to three consecutive injections of Avastin, OR
- have contraindications to the use of Avastin, OR
- are unable to tolerate Avastin; AND
- provide written confirmation from an ophthalmologist detailing the contraindication (s) as noted below.

Neovascular (wet) age-related macular degeneration (AMD):

- A diagnosis of neovascular (wet) age-related macular degeneration (AMD);
    - Ocular Coherence Tomography (OCT) is recognized by the NLPDP as a relevant diagnostic test for wet AMD;
- Evidence of recent (< 3months) disease progression (e.g. blood vessel growth, as indicated by either fluorescein angiography, OCT or recent visual acuity changes);
- A corrected Visual acuity between 6/12 and 6/96;
    - Patients falling outside of the proposed VA criterion can be considered by the NLPDP on a case-by-case basis.
- A lesion whose size is less than or equal to 12 disc areas in its greatest linear dimension;
- When there is no permanent structural damage to the central fovea.

Criteria for Exclusion:

- Patients who have “permanent retinal damage”, as defined by the Royal College of Ophthalmology guidelines, including any future amendments.

Diabetic Macular edema:

For the treatment of visual impairment due to diabetic macular edema meeting all of the following criteria:

- clinically significant diabetic macular edema for whom laser photocoagulation is also indicated, **and**
- a hemoglobin A1c of less than 11%.

Macular edema secondary to retinal vein occlusion:

For the treatment of visual impairment due to macular edema secondary to retinal vein occlusion in patients meeting one of the following criteria:

- clinically significant macular edema secondary to non-ischemic branch retinal vein occlusion (BRVO) or central retinal vein occlusion (CRVO).

Contraindications to use of (Avastin) bevacizumab:

- Allergy or hypersensitivity to bevacizumab
- Documented acute intra-ocular inflammation or endophthalmitis following intravitreal bevacizumab
- History of recent (within 6 months) thromboembolic event (stroke, myocardial infarction, etc)
- Thromboembolic event during treatment with bevacizumab
- Patient deemed very high risk for thromboembolic event
    - Multiple previous events with or without permanent deficits
- Documented treatment failure with intravitreal bevacizumab
    - No response (no reduction in central foveal thickness or no improvement in visual acuity) following 3 monthly bevacizumab treatments
    - Disease progression (increase in central foveal thickness, decrease in visual acuity or new hemorrhage) despite monthly bevacizumab treatments

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Ophthalmic-VEG-F-inhibitor-Form-1.pdf

Updated December 2025

Newfoundland Labrador

Health and Community Services

RAVULIZUMAB (ULTOMIRIS 300 mg/30 mL vial, 300 mg/3 mL vial, 1,100 mg/11 mL vial)

Generalized myasthenia gravis (gMG):

For the treatment of adult patients with generalized Myasthenia Gravis (gMG) who meet all the following criteria:

- Positive serologic test for anti-acetylcholine receptor (anti-AChR) antibodies.
- Myasthenia Gravis Activities of Daily Living (MG-ADL) score at baseline of ≥ 6.
- Myasthenia Gravis Foundation of America (MGFA) class II to IV disease.
- The patient is refractory to or intolerant of an adequate trial of rituximab for gMG (note that if rituximab is not appropriate for the patient, an adequate trial of another preventative treatment including but not limited to other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate or other immunosuppressants must have been used).
- vaccination against meningococcal infections.

Ravulizumab should not be initiated:

- during a gMG exacerbation or crisis
- within 12 months of thymectomy

Renewal

- Initial renewal may be considered in patients who have documented improvement (decrease) in the MG-ADL score of 2 points or greater.
- Subsequent renewals will require the physician reassessment confirming proof of no worsening of MG-ADL score.

Clinical Notes:

- Must be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- The MG-ADL score must be measured and provided by the physician at baseline and with each renewal request.
- Ravulizumab should not be used concomitantly with rituximab, efgartigimod alfa and/or complement inhibitors such as eculizumab.
- Initial Approval: 6 months
- Renewal: 12 months
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.

Neuromyelitis optica spectrum disorder (NMOSD):

For the treatment of adult patients with neuromyelitis optical spectrum disorder (NMOSD) who meet all of the following criteria:

- The patient is anti–aquaporin 4 (AQP4) seropositive.
- The patient has had at least one NMOSD attack or relapse in the previous 12 months.
- The patient has experienced an inadequate response or intolerance following a trial of rituximab, or has a contraindication to rituximab.
- The patient has an Expanded Disability Status Scale (EDSS) score of 7 points or less.

Renewal

- The patient must maintain an EDSS scores of 8 points or less (maintain annually)

Clinical Notes:

- Must be prescribed by or in consultation with a neurologist with expertise in the treatment of NMOSD.
- Ravulizumab should not be initiated during a NMOSD relapse episode.
- Coverage will not be considered when used in combination with rituximab, satralizumab, eculizumab, or inebilizumab.
- The physician should measure and provide EDSS scores every 12 months after the initial authorization to determine if the continuation of ravulizumab reimbursement should occur.
- Initial approval: 12 months
- Renewal: 12 months
- Billing Instructions: For claims that exceed the maximum allowable claim amount of $99,999.99 per claim, please contact (709) 729-1780 for billing guidance.

Paroxysmal nocturnal hemoglobinuria (PNH)

For the treatment of paroxysmal nocturnal hemoglobinuria (PNH), in adult patients who meet both of the following confirmatory results:

- Flow cytometry/FLAER exam with granulocytes clone or monocyte clone size of ≥ 10% AND
- LDH > 1.5 ULN

AND at least one of the following:

- A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy,
- Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months,
- Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70 g/L or by more than one measure of less than or equal to 100 g/L with concurrent symptoms of anemia,
- Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III)

and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded,
- Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73 m2, where causes other than PNH have been excluded.
- Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

Renewal will be considered for patients who:
- Demonstrate clinical improvement or disease stabilization of PNH compared to baseline clinical results and symptoms.
- Requests for renewal should be accompanied by confirmation of clone size (by flow cytometry). Granulocyte and monocyte clone size should be included to compare against the baseline results.
- Approval dosing (loading and maintenance): Weight-based dosing per the monograph with maintenance doses administered up to every four weeks for patients under 20kg and every eight weeks for those above or equal to 20kg.
- Initial Approval: 6 months
- Maintenance Renewal: 6 months

Exclusion criteria for both initial and renewal requests:
- Small clone size - granulocyte and monocyte clone sizes below 10%; **OR**
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity;
- Patients afflicted with PNH and another life-threatening or severe disease where the long term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome);
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.
- Patients who have experienced treatment failed with eculizumab administered for the treatment of PNH.
- Patients who have experienced treatment failure with ravulizumab administered for the treatment is PNH.
- Coverage will not be approved when any complement inhibitors are to be used in combination.

Clinical Notes:
- Must be prescribed by a hematologist with expertise in the treatment of PNH.
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).
- Approval Period: Initial approval: 6 months after commencing therapy and every six (6) months thereafter.
- Initial coverage may be approved for a period of up to six (6) months as follows: One loading dose of ravulizumab followed a maintenance dose at week 2, then one maintenance dose every eight (8) weeks.
- Doses are based on the patient's body weight. The loading dose is as follows: 2400 mg for patients weighing 40 kg to less than 60 kg, 2700 mg for patients weighing 60 kg to less than 100 kg, or 3000 mg for patients weighing 100 kg or

more. Maintenance dosing is as follows: 3000 mg for patients weighing 40 kg to less than 60 kg, 3300 mg for patients weighing 60 kg to less than 100 kg, or 3600 mg for patients weighing 100 kg or more.
- Continued coverage may be approved for one dose of ravulizumab administered every eight (8) weeks, for a period of six (6) months.
- The prescriber should submit relevant bloodwork to support the diagnosis including CBC, transfusion records, bone marrow report, flow cytometry/FLAER exam, LDH levels, and as possible, recent consult notes.
- Prescribers should comply the most current National Advisory Committee on Immunization (NACI) recommendations for meningococcal vaccination in patients with complement deficiencies to reduce the risk of serious infections. Appropriate vaccination for meningococcal disease should be accompanied at least 2 weeks prior to receiving the first dose of ravulizumab and if there is not possible, refer to the product monograph for the first dose mitigation instructions.
- Funding will not be considered if the patient and treating physician fails to comply adequately with treatment or measures, including monitoring requirements necessary to evaluate effectiveness of the therapy with ravulizumab.
- Coverage will not be approved when any complement inhibitors are to be used in combination. Patients will not be permitted to switch back to a previously trialed complement inhibitor.
- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99,999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Atypical hemolytic uremic syndrome (aHUS)

Initiation Criteria:

Adult and pediatric patients 1 month of age and older must meet all 3 of the following criteria for initial treatment:

1. Confirmed diagnosis of aHUS at initial presentation, defined by presence of thrombotic microangiopathy (TMA):
    - A baseline disintegrin and metalloproteinase with a thrombospondin type 1 motif, member 13 (ADAM-13) activity greater than or equal to 10% on blood samples taken prior to plasma exchange (PE) or plasma infusion (PI); AND
    - A Shiga toxin–producing *Escherichia coli* (STEC) test negative in patients with a history of bloody diarrhea in the preceding 2 weeks.
    - Presence of an unexplained non-disseminated intravascular coagulation thrombotic microangiopathy (TMA) (i.e. not a secondary TMA).

AND

2. Patients must have evidence of ongoing active TMA and progressing, defined by laboratory test abnormalities despite plasmapheresis, if appropriate. Patients must demonstrate:
    - Thrombocytopenia (platelet count < 150×10^9/L) that is unexplained by another cause including secondary TMA and hemolysis as indicated by the documentation of 2 of the following: schistocytes on the blood film;

low or absent haptoglobin; or lactate dehydrogenase (LDH) above normal. OR
- Tissue biopsy confirms TMA in patients who do not have evidence of platelet consumption and hemolysis.

AND

3. Patients must have documented evidence of at least 1 of the following clinical features of active organ damage or impairment:
    - Kidney impairment, as demonstrated by one of the following:
        1. A decline in estimated glomerular filtration rate (eGFR) of > 20% in a patient with pre-existing renal impairment; and/or
        2. Serum creatinine (SCr) > upper limit of normal (ULN) for age or GFR < 60mL/min and renal function deteriorating despite prior plasma exchange or plasma infusion (PE/PI) in patients who have no history of preexisting renal impairment (i.e., who have no baseline eGFR measurement); OR
        3. SCr > the age-appropriate ULN in pediatric patients (as determined by or in consultation with a pediatric nephrologist)

    OR
    - The onset of neurological impairment related to TMA.
    - Other TMA-related manifestations, such as cardiac ischemia, bowel ischemia, pancreatitis, and retinal vein occlusion.

Initiation Criteria for kidney transplant patients:

Transplant patients with a documented history of aHUS (i.e., history of TMA [not a secondary TMA only] with ADAMTS 13 > 10%) would be eligible for ravulizumab if they:
- Develop TMA immediately (within hours to 1 month) following a kidney transplant; **OR**
- Previously lost a native or transplanted kidney due to the development of TMA **OR**
- Have a history of proven aHUS and require prophylaxis with ravulizumab at the time of a kidney transplant

Exclusion Criteria (for initial and renewal requests):

Patients with a history of ravulizumab treatment failure (i.e., treated with ravulizumab for a previous aHUS occurrence/recurrence) will not be eligible for coverage.

Treatment failure defined as any of the following occurring while receiving ravulizumab:
- Dialysis-dependent at 6 months, and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
- On dialysis for ≥ 4 of the previous 6 months while receiving ravulizumab and failed to demonstrate resolution or stabilization of neurological or extrarenal complications if these were originally present; OR
- Worsening of kidney function with a reduction in eGFR or increase in SCr ≥ 25% from baseline.

Initial Renewal (after 6 months):

After initial 6 months of ravulizumab treatment, coverage may be renewed if **ALL** of the following criteria are met:

- The patient has demonstrated response to treatment, as defined as but not limited to:
    - hematological normalization (e.g., platelet count, LDH), AND
    - stabilization of end-organ damage (such as acute kidney injury and brain ischemia), AND
    - transplant graft survival in susceptible individuals, AND
    - dialysis avoidance in patients who are pre- end-stage kidney disease (ESKD).

AND

- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above.

Subsequent Renewal Criteria (at initial 12 months and then every 12 months thereafter):

For patients requiring ongoing ravulizumab treatment, coverage may be renewed if **ALL** of the following are met:

- The patient continues to demonstrate response to treatment, as defined in the Initial Renewal Criteria above; and
- The patient has not experienced treatment failure, as defined in the Exclusion Criteria above; and
- The patient has limited organ reserve, or a high-risk genetic mutation (e.g., Factor H deficiency) associated with aHUS recurrence.
    - Limited organ reserve is defined as significant cardiomyopathy, neurological, gastrointestinal, or pulmonary impairment related to TMA; or Stage 4 or 5 chronic kidney disease (eGFR < 30mL/min).

Re-initiation criteria:

A patient previous diagnosed with aHUS and who respond to treatment with ravulizumab and has not failed ravulizumabis eligible to restart ravulizumab if the patient redevelops a TMA related to aHUS and meets the following clinical criteria:

- Significant hemolysis as evidenced by presence of schistocytes on the blood film, or low or absent haptoglobin, or LDH above normal;

AND at least ONE of the following:

- Platelet consumption as measured by either ≥ 25% decline from patient baseline or thrombocytopenia (platelet count < 150,000 × 109/L); **OR**
- TMA-related organ impairment (e.g., unexplained rise in serum creatinine with onset of urine dipstick positive for hemoglobin) including on recent biopsy.

Clinical Notes:

- Must be prescribed by or in consultation with a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.

- Initial approval: 6 months initially, then 6 months at 12 months then yearly thereafter
- Renewal: 12 months (after initial 12 months).
- Initial coverage may be approved for up to 600 mg every 4 weeks for patients weighing 5 kg to less than 20 kg, or up to 3,600 mg every 8 weeks for patients weighing 20 kg or greater for a period of 6 months.
- Following this assessment, continued coverage may be approved for up to 600 mg every 4 weeks for patients weighing 5 kg to less than 20 kg, or up to 3,600 mg every 8 weeks for patients weighing 20 kg or greater for a period of 6 months and every 12 months thereafter.
- Prescribers should comply the most current National Advisory Committee on Immunization (NACI) recommendations for meningococcal vaccination in patients with complement deficiencies to reduce the risk of serious infections. Appropriate vaccination for meningococcal disease should be accompanied at least 2 weeks prior to receiving the first dose of ravulizumab and if there is not possible, refer to the product monograph for the first dose mitigation instructions.
- Coverage will not be approved when any complement inhibitors are to be used in combination. Patients will not be permitted to switch back to a previously trialed complement inhibitor.
- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99,999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2026

Health and Community Services

REGORAFENIB (STIVARGA) 40 MG TABLET

Osteosarcoma
For the treatment of patients with metastatic osteosarcoma who have received at least one prior line of therapy.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
- Patients must have a good performance status
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 6 months

Advanced Hepatocellular Carcinoma
For the second-line treatment of patients with unresectable hepatocellular carcinoma who meet all of the following criteria:
- Child-Pugh class status of A
- ECOG performance status of 0 or 1
- Disease progression on sorafenib or lenvatinib

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.
- Requests for regorafenib will not be considered for patients who experience disease progression on cabozantinib or immunotherapy (atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab).
- Approval period: 6 months.

Gastrointestinal Stromal Tumor
For the treatment of patients with metastatic or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:
- Patients must have a good performance status
- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2026

Health and Community Services

RIBOCICLIB (KISQALI) 200MG TABLET

1. In combination with an aromatase inhibitor (e.g., letrozole) for the treatment of hormone receptor positive, HER2 negative advanced or metastatic breast cancer in patients who:
   - have not received prior endocrine treatment for advanced or metastatic disease, and
   - are not resistant to prior (neo)adjuvant non-steroidal aromatase inhibitor (NSAI) therapy), and
   - do not have active or uncontrolled metastases to the central nervous system

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. For patients who received (neo)adjuvant NSAI therapy, a minimum disease-free interval of twelve months after stopping therapy is required.
3. Eligible patients include men and women independent of their menopausal status; pre and peri-menopausal women should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests will be considered for patients who have received up to one prior chemotherapy for advanced or metastatic disease.
- Patients with disease progression on ribociclib are not eligible for reimbursement of further CDK4/6 inhibitor therapy or everolimus.
- Approval period: 12 months

2. In combination with Fulvestrant for the treatment of hormone receptor-positive, HER2-negative advanced or metastatic breast cancer, who:
   - have not received prior endocrine therapy or following disease progression on endocrine therapy (excluding prior fulvestrant), and
   - have received up to one prior chemotherapy for advanced or metastatic disease, and
   - do not have active or uncontrolled metastases to the central nervous system

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical notes:

1. Patients must have a good performance status.
2. Eligible patients include men and women independent of their menopausal status; pre and peri-menopausal women must be rendered postmenopausal, either chemically or surgically, and should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist or bilateral salpingo-oophorectomy
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a CDK4/6 inhibitor, fulvestrant or everolimus..
- Approval period: 12 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2023

Health and Community Services

RIFABUTIN (MYCOBUTIN)

For the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced HIV infection.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

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Updated June 2012

Health and Community Services

RIFAXIMIN (ZAXINE 550 MG TABLET)

For reducing the risk of overt hepatic encephalopathy (HE) recurrence (i.e., 2 or more episodes), if the following clinical criteria are met:

Clinical Criteria:

- Patients are unable to achieve adequate control of HE recurrence with maximal tolerated dose of lactulose alone.
- Must be used in combination with maximal tolerated doses of lactulose.
- For patients not maintained on lactulose, information is required regarding the nature of the patient's intolerance to lactulose.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2016

Health and Community Services

RILPIVIRINE (EDURANT 25 MG TABLET)

For the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-naive patients, when used in combination with other antiretroviral agents.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2012

Health and Community Services

Riluzole (Rilutek 50mg & generics)

For the treatment of amyotrophic lateral sclerosis (ALS) or Lou Gehrig's Disease, when initiated by a neurologist with expertise in the management of ALS, when the patient has:

- Probable or definite diagnosis of ALS as defined by the World Federation of Neurology criteria.
- ALS symptoms for less than five years.
- FVC > 60% predicted upon initiation of therapy
- No tracheostomy for invasive ventilation.

Coverage will be reviewed every six months.
Coverage cannot be renewed once the patient has a tracheostomy for the purpose of invasive ventilation or mechanical ventilation.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2015

Health and Community Services

RIOCIGUAT (ADEMPAS 0.5 mg, 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets and generics)

For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH, World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (>18 years of age) with WHO Functional Class (FC) II or III pulmonary hypertension (PH).

Should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2024

Health and Community Services

RIPRETINIB (QINLOCK) 50 mg Tablets
As monotherapy for the treatment of adult patients with advanced gastrointestinal stromal tumors (GIST) who have progression on, or intolerance to, imatinib, sunitinib, and regorafenib.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Patients must not have active CNS metastases.
3. Patients must not have clinically significant cardiac conditions or other comorbidities.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 6 months

Please visit the link below if you require our special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2024

Health and Community Services

RISANKIZUMAB (SKYRIZI 75 mg/0.83mL Prefilled syringe, 150mg/ml Prefilled syringe, 150mg/ml Prefilled pen, 360mg/2.4 mL Prefilled Cartridge with On-body injector, 180mg/1.2 mL Prefilled Cartridge with On-body injector, 600mg/10.0 mL Vial)

Ulcerative Colitis (UC)

For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); **OR**
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, **AND**
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Coverage will not be considered when combined with biological or other JAK inhibitor treatments for UC. Combined use of more than one biologic DMARD will not be reimbursed.
- The recommended dose is 1200 mg administered by intravenous infusion at Week 0, Week 4, and Week 8, followed by 180 mg or 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter. Use the lowest effective dosage needed to maintain therapeutic response.

- Initial Approval: 16 weeks
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Chronic Plaque Psoriasis:

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:
For continued coverage, patients must meet the following criteria:
- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical notes:
- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:
- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 150 mg at weeks 0 and 4, then every 12 weeks thereafter.
- Initial approval: 6 months.
- Renewal approval: 1 year.

- Ongoing coverage for maintenance therapy should only be provided for responders, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Crohn's Disease

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approvals will be for 600 mg administered by intravenous infusion at Week 0, Week 4, and Week 8, followed by 360 mg administered by subcutaneous injection at Week 12, and every 8 weeks thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to be assessed at 12 weeks then yearly using criteria such as a 100-point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less, or a decrease in score of 4 or more.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated July 2026

Health and Community Services

RISDIPLAM (EVRYSDI 0.75 mg/mL powder for solution)

For the treatment of 5q spinal muscular atrophy (SMA), if the following criteria are met:

- Genetic documentation of 5q SMA homozygous gene deletion or compound heterozygote.
- Patient does not currently require permanent invasive ventilation.
- Patient who is symptomatic with two or three copies of the SMN2 gene and is:
  - 2 months to 7 months of age, or
  - 8 months to 25 years of age and non-ambulatory.

Discontinuation Criteria:

Treatment should be discontinued upon meeting any of the following circumstances:

- There is no demonstrated achievement in, or maintenance of, motor milestone function as assessed using an age-appropriate measurement after treatment initiation in patients aged between 2 months and 2 years at the time of treatment initiation;
- There is no demonstrated maintenance of motor function (as assessed using an age-appropriate measurement) after treatment initiation in patients aged between 2 years and 25 years at the time of treatment initiation; or
- permanent invasive ventilation is required.

It should be noted that the decision to discontinue reimbursement should be based on 2 assessments separated by no longer than a 12-week interval, with the first evaluation taken close to (i.e. within 3 months) of the date of renewal of funding. The second assessment is only required for patients who demonstrated a decline in motor milestones/motor function at the time of the first evaluation.

Clinical Notes:

- An age-appropriate scale is defined as the Hammersmith Infant Neurological Examination (HINE) Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders (CHOP INTEND), or Hammersmith Functional Motor Scale-Expanded (HFMSE).
- A baseline assessment using an age-appropriate scale must be completed prior to initiation of treatment.
- Yearly assessments must be completed using an age-appropriate scale no more than 12 weeks prior to the renewal date.
- Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause

Claim Notes:

- The patient must be under the care of a specialist experienced in the treatment of SMA.
- Combination therapy with nusinersen will not be reimbursed.
- Requests for risdiplam will not be considered for patients who have received adeno-associated virus (AAV) vector-based gene therapy.
- Patients currently receiving SMA drug therapy may be eligible to switch to an alternate SMA drug therapy; however, patients will not be permitted to switch back to a previously trialed SMA drug.
- Approvals will be for a maximum of 0.2 mg/kg/day for patients 2 months to less than 2 years of age, 0.25 mg/kg/day for patients greater than or equal to 2 years of age weighing less than 20 kg, or 5 mg/day for patients greater than or equal to 2 years of age and weighing greater than or equal to 20 kg.
- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2023

Health and Community Services

Risperidone (Risperdal Consta 12.5mg/vial, 25/mg/vial, 37.5mg/vial and 50mg/vial)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- who are non-adherent to an oral antipsychotic.

OR

- who are currently receiving a long-acting injectable antipsychotic and require a switch to another injectable.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

RITUXIMAB (RUXIENCE 10 MG/ML VIAL, RIXIMYO 10 MG/ML VIAL, TRUXIMA 100 MG/10 ML VIAL, 500mg/50ml VIAL)

For the treatment of patients with rheumatoid arthritis[1], vasculitis[2], or other autoimmune disease[3].

Clinical Notes:

- Severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent.
- Severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide.
- Previously failed treatments must be provided if applicable.

Claim Note:

- Must be prescribed by a specialist.
- Initial approval period: 6 months. Confirmation of response is required.
- Renewal approval period: Long term.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated July 2026

Health and Community Services

RIVASTIGMINE (EXELON 2mg/ml oral solution)

For the treatment of patients with mild to moderate dementia who are unable to swallow oral solid dosage formulations.

Please visit the link below if you require the special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated March 2024

Health and Community Services

ROMOSOZUMAB (EVENITY 105 MG/1.17 ML SYRINGE)

For the treatment of osteoporosis in postmenopausal women who meet all of the following:

- Patients with a history of osteoporotic fracture and who are at high risk for future fracture, defined as a 10-year fracture risk ≥ 20% as defined by the FRAX tool.
- The patient must be treatment naive to osteoporosis medications, except for calcium and/or vitamin D.

Clinical Notes

- Coverage will not be considered concurrently with other osteoporosis medications, except for calcium and/or vitamin D.
- Maximum duration of reimbursement is 12 months.
- Approved dose: 210 mg administered once every month.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated November 2023

Health and Community Services

ROTIGOTINE (NEUPRO TRANSDERMAL PATCH 24 HOURS 1mg/24 hour, 2mg/24 hour, 3mg/24 hour, 4mg/24 hour, 6mg/24 hour, 8mg/24 hour)

For adjunctive treatment of patients with advanced stage Parkinson's disease who are currently receiving a levodopa-decarboxylase inhibitor combination.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2017

Health and Community Services

ROZANOLIXIZUMAB (RYSTIGGO 140MG/ML SINGLE-DOSE VIAL)

For the treatment of adult patients with generalized myasthenia gravis (gMG) have all of the following:

- The patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies OR anti-muscle-specific kinase (MuSK) antibodies.
- The patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of three or higher at baseline (with at least 3 points coming from non-ocular symptoms).
- The patient has Myasthenia Gravis Foundation of America (MGFA) class II to IV disease.
- The patient is refractory to or intolerant of an adequate trial of rituximab for gMG (note that if rituximab is not appropriate for the patient, an adequate trial of another preventative treatment including but not limited to other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate or other immunosuppressants must have been used).

Rozanolixizumab should not be initiated in either of the following cases:

- during a gMG exacerbation or crisis
- for those who have had a thymectomy within 3 months.

Renewal:

- For continued coverage beyond the initial 6 weeks, the patient must have documented improvement in the MG-ADL score of two points or greater from baseline.
- Following this assessment, continued coverage may be approved for up to 840 mg once weekly for six weeks (per treatment cycle) (with a minimum of 4 weeks between treatment cycles) for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed every 12 months and has maintained a response to therapy as indicated by no worsening of the MG-ADL.

Clinical Notes:

- Must be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- Coverage cannot be considered for rozanolixizumab when this medication is intended for use in combination with other biologics (including rituximab) or complement inhibitors for the treatment of gMG and/or complement inhibitors such as eculizumab.
- The MG-ADL score must be measured and provided by the physician at baseline.
- Patients will not be permitted to switch back to a previously trialed biologic agent/complement inhibitor if they were deemed unresponsive to therapy.

- Patients will be permitted to switch from one biologic agent/complement inhibitor to another following an adequate trial of the first biologic agent/complement inhibitor if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Initial Approval: coverage may be approved for up to 840 mg as a subcutaneous (SC) infusion once weekly for six weeks (one treatment cycle).
- Renewal: After the initial 6 weeks, reassessment will be every 12 months.
- Subsequent renewals will require the physician reassessment confirming proof of no worsening of MG-ADL score.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated May 2026

Newfoundland Labrador

Health and Community Services

RUFINAMIDE (BANZEL 100mg, 200mg, 400mg TABLET and generics)

For the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children 4 years and older and adults who meet all of the following criteria:

- Are under the care of a physician experienced in treating Lennox-Gastaut syndrome associated seizures, and
- Are currently receiving two or more antiepileptic drugs, and
- In whom less costly antiepileptic drugs are ineffective or not appropriate.

BANZEL is not indicated for the treatment of any other type of seizure disorder.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Health and Community Services

RUXOLITINIB PHOSPHATE (JAKAVI 5mg, 10mg, 15mg, 20mg tablet)

Acute Graft Versus Host Disease (aGvHD)

For the treatment of patients aged 12 years and older with corticosteroid-refractory or corticosteroid-dependent acute graft-versus-host disease (aGvHD) and a confirmed diagnosis of grade II to IV aGvHD according to the National Institute of Health (NIH) criteria.

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by an overall response (i.e., complete response, very good partial response, partial response, or stable disease with significant reduction in corticosteroid dose), according to NIH criteria at day 28 of treatment.
- Requests for renewal will not be considered upon the occurrence of any of the following:
  - Progression of aGvHD, defined as worsening of symptoms or occurrence of new symptoms
  - Unacceptable toxicity
  - Addition of systemic therapies (except calcineurin inhibitors) for aGvHD after day 28
  - Recurrence or relapse of underlying hematological malignancy

<u>Clinical Notes:</u>

- Clinical details supporting the diagnosis of grade II to IV aGvHD must be provided at baseline (e.g., organ involvement and staging).
- Corticosteroid refractory is defined according to the EBMT-NIH-CIBMTR Task Force position statement criteria, as one or more of the following:
  - Progressing based on organ assessment after at least 3 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid with or without a calcineurin inhibitor.
  - Failure to achieve, at a minimum, partial response based on organ assessment after 7 days compared to organ stage at the time of initiation of a high-dose systemic corticosteroid with or without a calcineurin inhibitor.
  - Patients who fail corticosteroid taper, defined as either an increase in the corticosteroid dose to methylprednisolone greater than or equal to 2 mg/kg per day (or equivalent prednisone dose of greater than or equal to 2.5 mg/kg per day) or failure to taper the methylprednisolone dose to less than 0.5 mg/kg/day (or equivalent prednisone dose less than 0.6 mg/kg/day) for a minimum 7 days.
- Corticosteroid dependence is defined as the inability to taper prednisone under 2 mg/kg/day after an initially successful treatment of at least 7 days or as the recurrence of aGvHD activity during steroid taper.
- Treatment with ruxolitinib must not be added to concurrent systemic therapies for the treatment of aGvHD other than corticosteroids with or without a calcineurin inhibitor

Claim Notes:

- Must be prescribed by a physician with experience in the treatment of aGvHD.
- Approvals will be for a maximum dose of 10 mg twice daily.
- Initial approval period: 4 weeks.
- Renewal approval period: 12 weeks.

Chronic graft-versus-host disease (cGvHD)

For the treatment of patients aged 12 years and older with chronic graft-versus-host disease (cGvHD) who meet all of the following criteria:

- Confirmed diagnosis of moderate to severe cGvHD according to National Institutes of Health (NIH) consensus criteria
- Refractory to corticosteroids or other systemic therapies

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by an overall response (i.e., complete response, partial response, or stable disease with significant reduction in corticosteroid dose), according to NIH criteria, after 24 weeks of therapy.
- Requests for renewal will not be considered upon the occurrence of any of the following:
    - Progression of cGvHD, defined as worsening of symptoms or occurrence of new symptoms.
    - Recurrence or relapse of underlying hematological malignancy.

Clinical Notes:

- Clinical details supporting the diagnosis of cGvHD must be provided including the affected organs or systems.
- Corticosteroid refractory is defined, according to NIH consensus criteria irrespective of the concomitant use of a calcineurin inhibitor, by any of the following:
    - Lack of response, or disease progression, after administration of a minimum dose of 1 mg/kg/day of prednisone for at least 1 week (or equivalent).
    - Disease persistence without improvement despite continued treatment with prednisone at greater than 0.5 mg/kg/day or 1 mg/kg/every other day for at least 4 weeks (or equivalent).
    - Increased prednisone dose to greater than 0.25 mg/kg/day after two unsuccessful attempts to taper the dose (or equivalent).
- Treatment with ruxolitinib must not be added to concurrent systemic therapies for the treatment of cGvHD other than corticosteroids with or without a calcineurin inhibitor.

Claim Notes:

- Must be prescribed by a physician with experience in the treatment of cGvHD.
- Approvals will be for a maximum dose of 10 mg twice daily.
- Initial approval period: 6 months.
- Renewal approval period: 1 year.

Myelofibrosis

For the treatment of splenomegaly and/or disease-related symptoms in adult patients with primary myelofibrosis, post-polycythemia vera myelofibrosis, or post-essential thrombocythemia myelofibrosis who meet all of the following criteria:

- Intermediate to high risk disease, or low risk disease with symptomatic splenomegaly, as assessed using DIPSS Plus
- Previously untreated or refractory to other treatment

Renewal Criteria:

- Confirmation that the patient has responded to treatment as evidenced by a reduction in spleen size or symptom improvement.

Clinical Notes:

1. Patients must have an ECOG performance status of less than or equal to 3
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression following treatment with fedratinib or momelotinib.
- Recommended dose: 5 to 25mg twice daily
- Approval period: 6 months

Polycythemia vera

For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU).

Renewal:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
3. Resistance is considered if, after at least 3 months of HU therapy at the maximum tolerated dose, patients experience at least one of the following:
    - Need for phlebotomy to maintain hematocrit (HCT) < 45%
    - Uncontrolled myeloproliferation (i.e. platelet count > 400 x 109 /L and white blood cell count > 10 x 109 /L)
    - Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation
4. Intolerance to HU is considered if patients experience at least one of the following:
    - Absolute neutrophil count < 1.0 x 109 /L, platelet count < 100 x 109 /L or hemoglobin < 100 g/L at the lowest dose of HU required to achieve a response. A response to HU is defined as HCT < 45% without phlebotomy, and/or all of the following: platelet count < 400 x 109 /L, white blood cell count < 10 x 109 /L, and non-palpable spleen.

- Presence of leg ulcers or other unacceptable HU-related non-hematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever
- Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity

Claim Notes:
- Recommended dose: 5 to 10mg twice daily
- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2026

Newfoundland Labrador

Health and Community Services

SACUBITRIL/VALSARTAN (ENTRESTO) 24MG-26MG, 49MG-51MG, 97MG-103MG

For the treatment of heart failure (HF) with reduced ejection fraction in patients with New York Heart Association (NYHA) Class II or III HF to reduce the incidence of cardiovascular (CV) death and HF hospitalization, if all of the following clinical criteria are met:

- Reduced left ventricular ejection fraction (LVEF) < 40% AND
- Patient has NYHA class II to III symptoms despite at least four weeks of treatment with an optimal stable dose of an angiotensin-converting enzyme inhibitor (ACEI) or an angiotensin II receptor antagonist (ARB) AND
- In combination with a beta blocker and other recommended therapies, including an aldosterone antagonist (if tolerable).

Clinical Notes:

- Patients should be under the case of a specialist experienced in the treatment of heart failure for patient selection, titration follow-up and monitoring.
- For patients who have not received four weeks of therapy with a beta blocker or aldosterone antagonist due to an intolerance or contraindication, details must be provided.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2025

Health and Community Services

SALMETEROL (SEREVENT 50MCG DISKUS)

For the treatment of chronic obstructive pulmonary disease (COPD) in patients who have failed or are intolerant to a long-acting muscarinic antagonist (LAMA).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

SAPROPTERIN (REDDY- SAPROPTERIN 100MG SACHET, REDDY-SAPROPTERIN 500MG SACHET)

For the treatment of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive Phenylketonuria (PKU) in patients who meet ALL the following initiation criteria:

- A diagnosis of Phenylketonuria (PKU) confirmed through genetic testing.
- Compliance with a low protein diet and formulas.
- Baseline blood phenylalanine (Phe) levels > 360 µmol/L despite compliance with a low protein diet (require at least 2 baseline levels during a 3 to 6 month time frame)[1].
- Baseline protein intake assessment by a dietitian.
- Ability to comply with medication regimen.
- Managed by a physician specialized in metabolic/biochemical diseases.

[1]Pregnant Patients may qualify upon meeting the following modified criteria:

- A diagnosis of Phenylketonuria (PKU) confirmed through genetic testing.
- Baseline blood phenylalanine (Phe) levels > 360 µmol/L despite compliance with all recommendations for dietary intervention and monitoring. Pregnant patients only require demonstration of one baseline Phe level > 360 µmol/L despite compliance with low protein diet.
- Managed by a physician specialized in metabolic/biochemical diseases.

Note:

- A baseline Phe tolerance level must be documented and Phe tolerance levels must be documented at months 1 to 2 and 4 to 6 during the initial 6 months of therapy.
- Pregnant patients maintaining a decrease in Phe concentration to less than 360 µmol/L will be eligible for funding for the duration of the pregnancy. However, renewal of funding will require meeting the criteria for non-pregnant patients.

Dosage: Up to a maximum of 20 mg/kg per day

Duration of Approval: 6 month trial period

Exclusion Criteria:

Funding will not be considered for patients meeting any of the following exclusion criteria:

- Patients who are not on the low protein diet or who are not compliant with their low protein diet.

- Patients with a baseline Phe level <360 µmol/L prior to the start of the Drug Product for pregnant and non-pregnant patients.

Renewal Criteria:

Following the initial 6 month trial period, coverage will continued in patients who meet ALL the following criteria:

- Compliance with low protein diet, formulas, and treatment with the Kuvan

AND

- Achievement of one or more of the following:
    - Normal sustained blood phenylalanine (Phe) levels [> 120 µmol/L and < 360 µmol/L] (at least 2 levels measured at least 1 month apart);

OR

    - Sustained blood Phe reduction of at least 30% (at least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is less than 1200 µmol/L;

OR

    - Sustained blood Phe reduction of at least 50% (at least 2 levels measured at least 1 month apart) compared to baseline if the Phe baseline level is greater than 1200 µmol/L;

AND

- Demonstrated increase of dietary protein tolerance based on targets set between the clinician and patient;
- Managed by a physician specialized in metabolic/biochemical diseases.

Dosage: Up to a maximum of 20 mg/kg per day
Approval duration of initial coverage request: 6 months
Approval duration of first renewal: 1 year.

- Renewals will require ongoing treatment responses and dietary and compliance with Kuvan as described above.
- Requests for renewal must provide a recent follow-up from a prescriber specialized in metabolic/biochemical diseases.

Exclusion Criteria:
Funding will not be considered for patients meeting any of the following exclusion criteria:

- Patients who are not on the low protein diet or who are not compliant with their low protein diet.
- Patients with a baseline Phe level <360 µmol/L prior to the start of the Drug Product for pregnant and non-pregnant patients.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated February 2024

Health and Community Services

SARILUMAB (KEVZARA 150 mg/1.14 mL
pre-filled pen, 200 mg/1.14 mL, pre-filled pen)

Rheumatoid Arthritis (RA)

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

or

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for a maximum of 200 mg every other week.
- Initial approval period: 16 weeks.
- Renewal approval period: 1 year. Confirmation of continued response is required.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Updated January 2024

Health and Community Services

SATRALIZUMAB (ENSPRYNG 120 mg/mL pre-filled syringe)

For the treatment of patients aged 12 years and older with neuromyelitis optica spectrum disorder (NMOSD), who meet all of the following criteria:

Initiation

1. Aquaporin 4 antibody (AQP4) positive; AND
2. Expanded Disability Status Scale (EDSS) score of 6.5 points or less; AND
3. Has experienced at least ONE relapse of NMOSD in the previous 12 months despite an adequate trial of rituximab for NMOSD (Note that if the patient is not appropriate for rituximab, an adequate trial of another preventative treatment such as azathioprine or mycophenolate must have been used).

Renewal

- Requests for renewal will be considered for patients who maintain an EDSS score of less than 8 points.

Clinical Notes:

- The prescribing is a neurologist with expertise in the diagnosis and treatment of NMOSD.
- Satralizumab should not be initiated during a NMOSD relapse episode.
- Coverage will not be provided in combination with other biologics for NMOSD.
- Approvals will be for a maximum of 120 mg at week 0, 2 and 4, then 120 mg every four weeks thereafter.
- Approval Period: 1 year

Discontinuation:

- Treatment should be discontinued in patients if the EDSS score is 8 points or greater.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2023

Health and Community Services

SAXAGLIPTIN / METFORMIN (KOMBOGLYZE 2.5mg-500mg, 2.5mg-850mg, 2.5mg-1000mg)

For the treatment of type 2 diabetes mellitus in patients with inadequate glycemic control on metformin and who are not using insulin. Patients must be already stabilized on therapy with metformin and saxagliptin. Coverage will be provided to replace the individual components of saxagliptin and metformin in these patients.

Clinical Note:

- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after KOMBOGLYZE is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

SAXAGLIPTIN (ONGLYZA 2.5mg, 5mg)

For the treatment of type 2 diabetes mellitus when added to metformin for patients with inadequate glycemic control on metformin, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after ONGLYZA is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Newfoundland Labrador

Health and Community Services

SECUKINUMAB (COSENTYX 75mg/0.5ml prefilled syringe, 150mg/ml prefilled syringe, 150mg/ml pre-filled SensoReady pen, 300 mg/2 mL pre-filled syringe 300 mg/2 mL pre-filled UnoReady® pen)

Chronic Plaque Psoriasis:

For the treatment of patients aged 6 and older with chronic moderate to severe plaque psoriasis who meet **all** of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:
For continued coverage, patients must meet the following criteria:

- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical Notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.
- For patients aged 6 to 16, a Children's Dermatology Life Quality Index (CDLQI) greater than 7 will be considered.
- For pediatric patients an adequate trial of a weight-based appropriate dose of methotrexate will be considered.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for a maximum of 300 mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- For pediatric patients weighing less than 50kg, approvals will be for a maximum of 75mg given at weeks 0, 1, 2, 3, and 4, then monthly.
- Initial approval period: 6 months
- Renewal approval period: 1 year.
    - Ongoing coverage for maintenance therapy should only be provided for responder, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Psoriatic Arthritis:

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints.
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial approval: the recommended dose is 150 mg by subcutaneous injection with initial dosing at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing.
- If a patient is an anti-TNFalpha inadequate responder and continues to have active psoriatic arthritis, consider using the 300 mg dose.
- For psoriatic arthritis patients with coexistent moderate to severe plaque psoriasis, use the dosing and administration recommendations for plaque psoriasis (i.e. 300 mg at weeks 0, 1, 2, and 3, followed by monthly maintenance dosing starting at week 4).
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
    - Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response criteria).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Hidradenitis Suppurativa (HS)

For the treatment of patients with moderate to severe hidradenitis suppurativa (HS) who meet all of the following criteria:

- the patient currently has a total abscess and nodule count (AN) of 3 or greater
- lesions are in at least 2 distinct anatomical areas, one of which must be Hurley stage II or III
- the patient has an inadequate response to a 90 day trial of antibiotics.

Initial renewal:
- Requests for renewal should provide evidence of beneficial clinical effect, defined at least a 50% reduction in abscess and inflammatory nodule count (AN count) with no increase in abscess or draining fistula count relative to baseline at week 12.

Subsequent renewals:
- Requests for renewal should provide objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count and draining fistula count should be compared to the count prior to initiating treatment with secukinumab).

Clinical Notes:
- Must be prescribed by a dermatologist or physician with expertise in the management of patients with HS.
- Coverage will not be provided in combination with other biologic DMARDS.
- An inadequate response is be defined as an inability to maintain a minimum 50% reduction in the sum of AN count with no increase in abscess count or draining fistula count relative to baseline.
- Conventional therapy typically refers to systemic antibiotic therapy. An adequate trial was defined as 12 weeks of treatment with systemic antibiotic therapy
- Approvals will be for 300mg given at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on clinical response, a maintenance dose of 300 mg every 2 weeks can be considered.
- The physician must provide a baseline assessment of AN count, abscess count, and draining fistula count at the time of initial request for reimbursement.
- Initial Approval: 6 months
- Renewal approval: 1 year

SECUKINUMAB (COSENTYX 150mg/ml pre-filled syringe, pre-filled SensoReady pen)

<u>Ankylosing spondylitis:</u>

For the treatment of patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms* and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

<u>OR</u>

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose

for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:

- Decrease of at least 2 points on the BASDAI scale compared with the pre-treatment score,

OR

- An adequate clinical response as indicated by significant functional improvement (e.g., measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.
- combined use of more than one biologic DMARD will not be reimbursed)

Claim Notes:

- Must be prescribed by a rheumatologist or internist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Approvals will be for 150 mg at Weeks 0, 1, 2, 3, and 4 followed by monthly maintenance dosing. If a patient continues to have active ankylosing spondylitis, consider a monthly maintenance dosage of 300 mg. Each 300 mg dose is given as two subcutaneous injections of 150 mg.
- Initial Approval: 6 months.
- Renewal Approval: 1 year

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Updated June 2026

Health and Community Services

SELEXIPAG (UPTRAVI 200mg, 400mg, 600mg, 800mg, 1000mg, 1200mg, 1400mg, 1600ug)

For the long-term treatment of idiopathic pulmonary arterial hypertension (PAH), heritable PAH, PAH associated with connective tissue disorders, and PAH associated with congenital heart disease, in adult patients with World Health Organization (WHO) functional class (FC) II to III to delay disease progression, if the following clinical criterion and conditions are met:

- Inadequate control with Phosphodiesterase (PDE)-5 inhibitor (i.e. tadalafil or sildenafil) AND an endothelin receptor antagonist (ERA) (i.e. bosentan or ambrisentan).
- Prescribed by a clinician with experience in the diagnosis and treatment of PAH

NOTE: Combination therapy with prostacyclin or prostacyclin analogs therapies will NOT be covered

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Health and Community Services

SELINEXOR (XPOVIO) 20 MG TABLET

In combination with bortezomib and dexamethasone (SVd) for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:

1. Treatment should be discontinued upon disease progression or unacceptable toxicity.
2. Prior treatment with a proteasome inhibitor is permitted provided:
    - The previous response was at least a partial response
    - The patient did not discontinue for grade 3 or higher toxicity
    - Proteasome inhibitor treatment-free interval has been at least 6 months.

Claim Notes:

- Approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

SELPERCATINIB (RETEVMO) 40 MG AND 80 MG CAPSULE and TABLET

Differentiated Thyroid Carcinoma
As monotherapy for the treatment of rearranged during transfection (RET) fusion positive differentiated thyroid carcinoma (DTC) in adult patients with advanced or metastatic disease, not amenable to surgery or radioactive iodine therapy, following prior treatment with lenvatinib.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 1 year

Medullary Thyroid Cancer
As monotherapy for the treatment of patients 12 years of age and older with unresectable advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who have progressed on, are intolerant to, or have a contraindication to first-line therapy.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Approval period: 1 year

Non-Small Cell Lung Cancer
As monotherapy for the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as first line therapy, or after prior systemic therapy.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. If central nervous system metastases are present, patients must be asymptomatic or have stable disease.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

SELUMETINIB (KOSELUGO 10mg, 25mg capsules)

For the treatment of pediatric patients aged 2 to 18 years with neurofibromatosis type 1 (NF1) with symptomatic plexiform neurofibromas (PNs), where:

- The PN is unable to be completely surgically removed without risk of substantial morbidity due to encasement of, or close proximity to, vital structures, or invasiveness or high vascularity of the PN; **OR**,
- Surgical PN removal did not result in improvement of symptoms.

Initial Request:

- The initial coverage request must include current baseline information on the patient's PN location(s) and size(s), PN-related pain, PN-related functional impairment, and description of overall NF1 disease activity.
- Initial approval duration: 18 months

Renewal Request:
Renewal of coverage will be considered in patients who:

- Are demonstrating an improvement in or stabilization of clinical status as compared to baseline; **AND**,
- Continue to be under the care of a neurooncologist or other specialist in oncology or neurology with expertise in the diagnosis and management of NF1.

Renewal requests should include updated information on **ALL** of the following parameters, as determined through clinical assessment and/or imaging:

- Reduction in PN-related pain
- Improved function in PN-affected anatomical areas
- Reduction in PN size
- Achievements in NF1 disease stabilization

Renewal duration: 12 months

Discontinuation Criteria:

- Patients will not be eligible for renewal of if they have experienced disease worsening or progression (e.g., worsening of motor function or pain) as compared to baseline.

Clinical Notes:

- Patients should be under the care of a neurooncologist or other specialist in oncology or neurology with expertise in the diagnosis and management of NF1.

- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated Augst 2025

Health and Community Services

SEMAGLUTIDE (OZEMPIC 2mg/1.5ml prefilled, 4mg/3ml prefilled pen and generics)

For the treatment of type 2 diabetes mellitus in combination with metformin, when diet and exercise plus therapy with metformin do not achieve adequate glycemic control.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.
- Injectable semaglutide will not be considered in combination with oral semaglutide.

Please note:

- Coverage will be considered for 0.25 mg once weekly, after 4 weeks, the dose should be increased to 0.5 mg once weekly. If additional glycemic control is needed after 4 weeks, the dose may be increased to 1 mg once weekly to further improve glycemic control.
- Maximum dose: 1 mg once weekly

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated July 2026

Health and Community Services

SEMAGLUTIDE (RYBELSUS 3mg, 7mg, 14mg TABLET)

For the treatment of type 2 diabetes mellitus in combination with metformin, when diet and exercise plus therapy with metformin do not achieve adequate glycemic control.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.
- Oral semaglutide will not be considered in combination with injectable semaglutide.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated May 2026

Health and Community Services

SEPELIPASE ALPHA (KANUMA 2mg/ml Vial)

For the treatment of lysosomal acid lipase (LAL) deficiency in patients meeting ALL the following criteria:

- Has documented biochemical evidence of deficient LAL activity; **AND**
- Has two documented pathogenic mutations in the LIPA gene; **AND**
- The onset of clinical manifestations of LAL deficiency occurred before six months of age;

Renewal may be continued for patients who do not experience any of the following adverse events from sebelipase alfa:

- hypersensitivity reactions (including anaphylaxis, hypotension, or fever), which cannot be managed with standard treatment, and/or have a significant impact on the patient's quality of life, or are life-threatening.

OR

Patient is six months of age or older; **AND**

Presents with one or more of the following:

- Persistently elevated transaminases (Alanine aminotransferase (ALT) > 1.5 x ULN[1] or Aspartate transaminase (AST) > 1.5 x ULN[1]) as measured by two assessments three to six months apart
- Persistent dyslipidemia (Low-density lipoprotein cholesterol (LDL-C) and/or Triglycerides (TG) values in the top 5th percentile based on sex and age) as measured by two assessments three to six months apart
- Any documented hepatomegaly or hepatosplenomegaly
- Liver fibrosis confirmed by biopsy
- Failure to thrive
- Growth impairment[2]
- Evidence of intestinal affection and/or malabsorption;

AND

Does not present with any of the following:

- Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new clinical presentation of portal hypertension (e.g., esophageal varices); OR • Severe hepatic dysfunction (Child-Pugh Class C);

OR

- End-stage liver disease.

NOTE:
The requesting prescriber must provide baseline values for the chosen clinical manifestation at the time of initial request for coverage.

Discontinuation Criteria:
Coverage will be discontinued in patients who have experienced adverse events from sebelipase alfa (particularly hypersensitivity reactions, including anaphylaxis, hypotension, or fever), which cannot be managed with standard treatment, and/or which have a significant impact on the patient's quality of life, or are life-threatening.

For patients with onset of clinical manifestations of LAL deficiency at six months of age and older, reimbursement will be **discontinued** if:

- Patient has progressed to end-stage liver failure or multi-organ failure; OR
- Patient has at least three out of the five following response components compared with baseline values after 12 months of therapy: ○ Less than 10% improvement in ALT or AST ○ Worsening of liver fibrosis confirmed by biopsy
    - Persisting growth impairment[2] despite sebelipase alfa therapy and nutritional interventions
    - At least a 15% increase in spleen volume and/or greater than 15% increase in liver volume on ultrasound
    - Increased portal vein pressures, or de novo evidence of portal hypertension on ultrasound and Doppler, or new presentation of portal hypertension (e.g. esophageal varices)

[1] Based on age- and sex-specific normal values for ALT and AST

[2] Growth impairment is defined as decreased body weight across at least two of the major centiles on a World Health Organization (WHO) weight-for-age chart, or body weight below 10th centile and no weight gain within two weeks and/or decreased height across at least two of the major centiles on a WHO height-for-age chart (URLs: https://www.who.int/toolkits/child-growth-standards/standards/weight-for-age, https://www.who.int/toolkits/child-growth-standards/standards/length-height-for-age)

Claim Notes:

- The patient must be under the care of a specialist with experience in the diagnosis and management of LAL deficiency.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2025

Health and Community Services

SETMELANOTIDE (IMCIVREE 10mg/mL vial)

For weight management in adult and pediatric patients aged 6 years and older with clinically or genetically confirmed Bardet-Biedl syndrome (BBS) and obesity.

Initial approval criteria:

The physician must provide proof of beneficial clinical effect, including:

- at least a 5% reduction in BMI or total body weight in patients who are at least 12 years of age, OR
- a reduction in BMI Z score that is considered clinically beneficial by the treating physician as appropriate for patients who are 6 to 11 years of age.

Subsequent Renewal:

The physician must provide proof that the initial response achieved after the first 26 weeks of therapy with setmelanotide has been maintained, including:

- maintenance of BMI or total body weight, OR
- maintenance of BMI Z score

Clinical Notes:

- Obesity is defined as BMI ≥ 30 for patients aged ≥ 16 years, or weight > 97th percentile for age and sex in patients aged < 16 years.
- Clinical diagnosis of BBS is to be based on the Beales criteria.
- The patient must be under the care of an endocrinologist, pediatric endocrinologist, and/or specialist in weight management or obesity.
- Initial approval: 26 weeks
- Subsequent renewals: 1 year
    - the physician must provide proof that the initial response achieved after the first 26 weeks of therapy with setmelanotide has been maintained.
- Approvals will be for a maximum of 2.0 mg daily for patients aged 6 to 17 years old and up to 3.0 mg daily for patients aged 18 years and older.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2025

Newfoundland Labrador

Health and Community Services

SEVELAMER CARBONATE (RENVELA 800mg, 0.8 GRAM POWDER PACKET, 2.4 GRAM POWDER PACKET, ACCEL-SEVELAMER 800 MG TABLET)

For the management of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end-stage renal disease (eGFR < 15 mL/min) who have:

- Inadequate control of phosphate levels on a calcium based phosphate binder, OR
- Hypercalcemia (corrected for albumin), OR
- calciphylaxis (calcific arteriolopathy)

Claim Notes:

- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided).
- Request from a nephrologist or an internist within a dialysis unit.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Phosphate-Binders.pdf

Updated October 2023

Newfoundland Labrador

Health and Community Services

Sildenafil (Revatio 20mg & generics)

Idiopathic Pulmonary Arterial Hypertension (IPAH) functional class III:

- For the treatment of patients with World Health Organizaton (WHO) functional class III idiopathic pulmonary arterial hypertension (IPAH) who do not demonstrate vasoreactivity on testing or who do demonstrate vasoreactivity on testing but fail a trial of calcium channel blockers (CCB) or are intolerant to CCB.

Pulmonary Arterial Hypertension (PAH) secondary to connective tissue disease (functional class III):

- For the treatment of patients with World Health Organization (WHO) functional class III pulmonary hypertension associated with connective tissue disease who do not respond to conventional therapy.

Diagnosis of PAH should be confirmed by right heart catheterization.

Written request of a PAH specialist only.

Dose of Sildenafil will be limited to 20mg three times daily.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

SILODOSIN (RAPAFLO 4mg, 8mg Capsule and generics)

For the treatment of benign prostatic hyperplasia in male patients aged 50 years or older who are unable to take Tamsulosin CR tablets due to the inability to swallow whole dosage formulations.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2023

Health and Community Services

SIPONIMOD (MAYZENT 0.25 MG TABLET, 2 MG TABLET)

For the treatment of patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features characteristic of multiple sclerosis inflammatory activity, to delay the progression of physical disability, only if the following conditions are met.

Initiation criteria:
Patients who meet all of the following criteria:

- a history of relapsing-remitting multiple sclerosis (RRMS) and current active SPMS; and
- an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5; and
- documented EDSS progression during the two years prior to initiating treatment (≥ 1 point if EDSS < 6.0; ≥ 0.5 point if EDSS ≥ 6.0 at screening).

Renewal criteria:

- Patients should be assessed for a response to siponimod every 6 months.
- Renewal is considered for patients who do not exhibit evidence of disease progression since the previous assessment.
    - Disease progression is defined as an increase in the EDSS score of ≥ 1 point if the EDSS score was 3.0 to 5.0 at initiation, or an increase of ≥ 0.5 points if the EDSS score 5.5 to 6.5 at initiation.

Discontinuation Criteria
Treatment should be discontinued in patients who exhibit either of the following:

- Progression to an EDSS score of equal to or greater than 7.0 at any time during treatment with Siponimod, or
- Confirmed worsening of at least 20% on the timed 25-foot walk (T25W) since initiating siponimod treatment.

Prescribing conditions:

- The patient is under the care of a specialist with experience in the diagnosis and management of MS.
- Coverage will not be approved in combination with other disease-modifying treatments (DMTs) used to treat MS.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated April 2022

Health and Community Services

SITAGLIPTIN (JANUVIA 25mg, 50mg, 100mg tablet and generics)

For the treatment of type 2 diabetes mellitus when added to metformin for patients with inadequate glycemic control on metformin, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin due to contraindications or intolerances, details must be provided.
- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after JANUVIA is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

SITAGLIPTIN / METFORMIN (JANUMET 50-500mg, 50-850mg & 50-1000mg tablets and generics, JANUMET XR 50mg/500mg, 50mg/1000mg, 100mg/1000mg and generics)

For the treatment of type 2 diabetes mellitus in patients with inadequate glycemic control on metformin and who are not using insulin. Patients must be already stabilized on therapy with metformin and sitagliptin. Coverage will be provided to replace the individual components of sitagliptin and metformin in these patients.

Clinical Note:

- Approvals will be for 12 months and renewals may be requested by the patient or healthcare provider. Coverage will not be continued for patients who start insulin after JANUMET/JANUMET XR is approved.
- For the treatment of type 2 diabetes alone, reimbursement will be limited to one agent only, from the following classes - DPP-4 inhibitor, SGLT2 inhibitor, and GLP-1 receptor agonist.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents-1.pdf

Updated September 2024

Health and Community Services

SODIUM BICARBONATE 500mg tablets

For the treatment of metabolic acidosis in patients with chronic kidney disease who have a serum bicarbonate (CO_2) < 22mmol/L.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2017

Health and Community Services

SODIUM CHLORIDE 7% (HYPER-SAL 7%, NEBUSAL 7%)

NHP# 80029414, NHP# 80029758

For use in patients with cystic fibrosis (CF) to help reduce pulmonary exacerbations and improve lung function.

Notes:
The combination of HyperSal **or** Nebusal **and** Pulmozyme will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2015

Health and Community Services

SODIUM PHENLUBUTYRATE (PHEBURANE 483 MG/G GRANULES)

For the chronic management of urea cycle disorders (UCD).

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2018

Newfoundland Labrador

Health and Community Services

SOFOSBUVIR (SOVALDI 400 MG TABLET)

For treatment-naïve or treatment-experienced adult patients with hepatitis C virus (HCV) who meet the following criteria:

- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative HCV RNA value within the last 12 months **OR**
- TWO Quantitative HCV RNA values ≥ 12 months ago
  - tests must have been completed within 6 months apart)

	Approval Period and Regimen
Genotype 2 • Without cirrhosis • With compensated cirrhosis	12 weeks in combination with ribavirin (RBV)
Genotype 3 • Without cirrhosis • With compensated cirrhosis	24 weeks in combination with RBV

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent
- Retreatment for failure or re-infection in patients who have received an adequate prior course of an HCV direct-acting antiviral drug regimen may be considered on an exceptional case-by-case basis

Clinical Notes:

1. Treatment-experienced is defined as patients who have been previously treated with a peginterferon/ribavirin regimen and have not experienced an adequate response.
2. Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).
3. Decompensated cirrhosis is defined as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Special Authorization requests must include the genotype report from the latest post-treatment course.
- Special Authorization requests must include the most recent HCV RNA test performed in the last 12 months **OR** TWO positive HCV RNA results ≥ 12 months ago (tests must have been completed within 6 months apart).

- Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Hepatitis-C-Treatment-Request-.pdf

Updated April 2025

Health and Community Services

SOFOSBUVIR/VELPATASVIR (EPCLUSA 400 MG-100 MG TABLET)

For treatment-naïve or treatment-experienced adult patients with hepatitis C virus (HCV) who meet the following criteria:

- Quantitative HCV RNA value within the last 12 months **OR**
- TWO Quantitative HCV RNA values ≥ 12 months ago
    - tests must have been completed within 6 months apart)

	Approval Period and Regimen
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • Patients with compensated cirrhosis • Patients without cirrhosis	12 weeks
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes • Patients with decompensated cirrhosis	12 weeks in combination with ribavirin

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent.

Clinical Notes:

1) Treatment-experienced is defined as a patient who has been previously treated with a peginterferon/ribavirin regimen, including regimens containing HCV protease inhibitors and who have not experienced an adequate response.
2) Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A) and decompensated cirrhosis as a CTP score of 7 or above (Class B or C).

Claim Notes:

- Special Authorization requests must include the most recent HCV RNA test performed in the last 12 months **OR** TWO positive HCV RNA results ≥ 12 months ago (tests must have been completed within 6 months apart).
- Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Hepatitis-C-Treatment.pdf

Updated March 2026

Health and Community Services

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (VOSEVI) 400MG/100MG/100MG TABLET)

For treatment-experienced[1] adult patients with hepatitis C virus (HCV) who meet the following criteria:

- Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes and have previously been treated with an antiviral drug regimen containing a 5A (NS5A) inhibitor;

OR

- Laboratory confirmed hepatitis C genotype 1, 2, 3, 4 and have previously been treated with an antiviral drug regimen containing sofosbuvir without a NS5A inhibitor;

AND

- Laboratory confirmed quantitative HCV RNA value within the last 12 months; **OR**
- TWO laboratory confirmed quantitative HCV RNA values ≥ 12 months ago
    - tests must have been completed within 6 months apart)

Duration of therapy:

- Treatment-experienced, without cirrhosis or with compensated cirrhosis: 12 weeks.

Exclusion criteria:

- Patients currently being treated with another HCV antiviral agent

Clinical Notes:

1) Treatment experienced is defined as a patient who has been previously treated with an NS5A inhibitor for genotype 1, 2, 3, 4, 5 or 6 or sofosbuvir without an NS5A inhibitor for genotype 1, 2, 3 or 4 and who has not experienced an adequate response.
2) Compensated cirrhosis is defined as a Child-Turcotte-Pugh (CTP) score of 5 to 6 (Class A).

Claim Notes:

- NS5A inhibitors include: ledipasvir (as part of Harvoni), velpatasvir (as part of Epclusa)
- Special Authorization requests for laboratory confirmed hepatitis C genotype 1, 2, 3, 4, previously treated with an antiviral drug regimen containing sofosbuvir without a NS5A inhibitor, must include the genotype report from the latest post-treatment course.
- Special Authorization requests must include the most recent HCV RNA test performed in the last 12 months **OR** TWO positive HCV RNA results ≥ 12 months ago (tests must have been completed within 6 months apart).
- Please note: A single professional fee will be paid per 30 day supply.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Hepatitis-C-Treatment-Request-.pdf

Updated April 2025

Newfoundland Labrador

Health and Community Services

SOMATROPIN (NGENLA 24 mg/1.2 mL (20 mg/mL) PEN INJECTOR, 60 mg/1.2 mL (50 mg/mL) PEN INJECTOR)

For the long-term treatment of pediatric patients with growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency [GHD]) who meet all of the following criteria:

Initiation:

- Pubertal children who are at least 3 years of age, and
- who are diagnosed with either isolated GHD, OR growth hormone insufficiency as part of multiple pituitary hormone deficiency.

Discontinuation:

- Treatment should be discontinued upon the occurrence of any of the following:
    1. Height velocity is less than 2 cm per year and bone age is more than 16 years in boys and 14 years in girls, or
    2. Closure of the epiphyseal growth plates

Prescribing:

- Patient must be under the care of a pediatric endocrinologist
- Limited to patients covered under the Growth Hormone Program

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated December 2023

Health and Community Services

SORAFENIB (NEXAVAR) 200 MG TABLET

Advanced Hepatocellular Carcinoma
For the treatment of unresectable hepatocellular carcinoma, as first-line or second-line therapy after progression on immunotherapy (atezolizumab in combination with bevacizumab or durvalumab in combination with tremelimumab), for patients who meet all of the following criteria:

- Child-Pugh class status of A
- ECOG performance status of 0-2
- Progressed on trans-arterial chemoembolization (TACE) or not suitable for the TACE procedure

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Claim Notes:

- Requests for sorafenib will not be considered for patients who have progressed on lenvatinib.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Metastatic Renal Cell Carcinoma
For the treatment of patients with advanced or metastatic renal cell carcinoma when used as a second-line therapy following disease progression on cytokine therapy.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have an ECOG performance status of ≤ 2.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Newfoundland Labrador
Health and Community Services

SOTATERCEPT (WINREVAIR 45 mg/vial, 60 mg/vial, 45 mg/vial (1 vial kit), 45 mg/vial (2 vials kit), 60 mg/vial (1 vial kit), 60 mg/vial (2 vials kit))

For use as add-on therapy in adult patients with WHO Group 1 pulmonary arterial hypertension (PAH) who have Functional Class (FC) II or III symptoms and meet all of the following criteria:

- The diagnosis of Group 1 PAH has been confirmed by right-heart catheterization, AND
- The patient is currently receiving optimal background therapy at stable doses for PAH for at least 3 months, AND

Note: Optimal background therapy is defined treatment with at least two other PAH medications from different classes, including: an endothelin receptor antagonist (ERA), a phosphodiesterase type 5 inhibitor (PDE5i), and/or prostacyclin analogues or prostacyclin receptor agonists. The patient is not considered low risk.

- Low risk is defined by COMPERA 2.0 or Simplified French Risk Score as as meeting all of the following:
    - FC I or II and
    - 6-minute walk distance (MWD) > 440 m and
    - NT-proBNP < 300 ng/L or BNP < 100 ng/L

Renewal:
For renewal after the initial authorization period, clinicians must demonstrate a beneficial clinical effect, defined as:

- Stability or improvement in the patient's risk status when requesting continuation of reimbursement.

Discontinuation Criteria:
Therapy should be discontinued in patients who have undergone lung transplantation.

Clinical Notes:

- Must be prescribed by a cardiologist or respirologist with experience in the diagnosis and treatment of PAH.
- Approval will be for a maximum dose of 0.7mg/kg administered every 3 weeks
- Initial and renewal approval duration: 12 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2026

Health and Community Services

STIRIPENTOL (DIACOMIT 250mg, 500mg CAPSULE, 250og, 500mg POWDER PACKET)

DIN 02398958, 02398966, 02398974 and 02398982

For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone.

The patient must be under the care of a neurologist or a pediatrician.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2015

Health and Community Services

SUCROFERRIC OXYHYDROXIDE (VELPHORO 500 MG CHEWABLE TABLET)

For the management of hyperphosphatemia (serum phosphate greater than 1.8 mmol/L) in patients with end-stage renal disease who are on dialysis who have:

- Inadequate control of phosphate levels on a calcium based phosphate binder, **OR**
- Hypercalcemia (corrected for albumin), **OR**
- calciphylaxis (calcific arteriolopathy)

Claim Notes:

- Initial Approval: 6 months.
- Renewal Approval: 1 year. Confirmation of improvement of phosphate levels is required (lab values must be provided).
- Request from a nephrologist or an internist within a dialysis unit

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Phosphate-binders.pdf

Updated September 2020

Health and Community Services

Sumatriptan nasal spray (Imitrex 5mg, 20mg nasal spray)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018

Health and Community Services

Sumatriptan sc injection (Imitrex 12mg/ml injection):

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefits (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

May 2018

Health and Community Services

SUNITINIB (SUTENT) 12.5 MG, 25 MG, 50 MG CAPSULE and generics)

Gastrointestinal Stromal Tumor (GIST)

For the treatment of patients with unresectable or metastatic gastrointestinal stromal tumour who experience disease progression on, or intolerance to, imatinib.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Note:

- Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Metastatic Renal Cell Carcinoma

For the treatment of patients with advanced or metastatic renal cell carcinoma when used as:

- first-line therapy, or
- second-line therapy following disease progression on nivolumab and ipilimumab combination therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Pancreatic Neuroendocrine Tumors (pNET)

For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumours.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2021

Health and Community Services

Tacrolimus (Protopic 0.03%, 0.1% ointment)

Protopic 0.1%:

For the intermittent use for moderate to severe atopic dermatitis in adults who have:

- failed or are intolerant to a site appropriate strength of corticosteroid therapy (i.e., low potency on face versus intermediate to high potency for trunk and extremities).

Protopic 0.03%:

For children greater than 2 years of age with refractory* atopic dermatitis for a 12 month period.

*failure to improve after adequate hydration of the skin and traditional topical corticosteroid therapy.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Newfoundland Labrador

Health and Community Services

TAFAMIDIS (VYNDAQEL 20mg and VYNDAMAX 61mg CAPSULE)

For the treatment of cardiomyopathy in adult patients with documented wild-type or hereditary transthyretin-mediated amyloidosis (TTR) who meet the following criteria:

- New York Heart Association (NYHA) Class I to III
- At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic
- Has not previously undergone heart or liver transplant
- Does not have an implanted cardiac mechanical assist device (CMAD)

Discontinuation Criteria:

The patient has:

- progressed to NYHA Class IV, or
- received a heart or liver transplant, or
- received an implanted CMAD.

Clinical Notes:

1.0 Wild-type ATTR-CM consists of all of the following:

- absence of a variant TTR genotype
- evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness >12 mm
- presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac) OR Tc-99m-pyrophosphate nuclear scintigraphy (PYP scan) indicating TTR-related cardiac amyloidosis
- and TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometry.

2.0 Hereditary ATTR-CM consists of all of the following:

- presence of a variant TTR genotype associated with cardiomyopathy and presenting with a cardiomyopathy phenotype
- evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness >12 mm
- presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac) OR PYP scan indicating TTR-related cardiac amyloidosis.

Claim Notes:

- The patient must be under the care of a specialist with experience in the diagnosis and management of ATTR-CM.
- Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR-CM will not be reimbursed.

- Initial approval period: 9 months.
- Renewal approval period: 1 year.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated January 2023

Health and Community Services

TAZAROTENE (ARAZLO 0.045% LOTION)

For the topical treatment of acne vulgaris in patients 10 years of age and older when conventional therapies with benefit topical agents have failed.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated December 2023

Newfoundland Labrador
Health and Community Services

TEDUGLUTIDE (REVESTIVE 5MG/VIAL KIT)

Adult patients

For the ongoing treatment of adult patients 18 years of age and older with Short Bowel Syndrome (SBS) as a result of major intestinal resection (e.g. volvulus, vascular disease, cancer, Crohn's disease, injury) who meet following criteria:

- Resection resulting in dependency on parenteral support (PS) for at least 12 months
- Prior to initiating teduglutide, parenteral support required at least three times weekly to meet caloric, fluid or electrolyte needs due to ongoing malabsorption
- Parenteral support frequency and volume have been stable for at least one month

Renewal Criteria:

- Patient has maintained at least a 20% reduction in parenteral support volume from baseline at 12 months.

Clinical Note:

- Parenteral support is defined as parenteral nutrition which encompasses parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and/or intravenous fluids which addresses fluid and electrolyte needs of patients

Claim Notes:

- Must be prescribed by a gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
- Approval period: 1 year.

Pediatric patients

For the ongoing treatment of pediatric patients with Short Bowel Syndrome who are dependent on parenteral nutrition only if the following conditions are met:

- Children between 1 and 17 years old.
- Prior to initiating teduglutide, parenteral support requirements must be stable or there must have been no improvement in enteral feeding for at least the preceding three months.
- Parenteral support must provide more than 30% of caloric and/or fluid/electrolyte needs.

- The cumulative lifetime duration of parenteral support therapy must be at least 12 months.

Renewal Criteria:

- Patient has maintained at least a 20% reduction in parenteral support volume from baseline at 12 months.

Clinical Note:

- Parenteral support is defined as parenteral nutrition which encompasses parenteral delivery of lipids, protein and/or carbohydrates to address caloric needs, and/or intravenous fluids which addresses fluid and electrolyte needs of patients

Claim Notes:

- Must be prescribed by a pediatric gastroenterologist or an internal medicine specialist with a specialty in gastroenterology.
- Approval period: 6 months.
- Renewal period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2021

Newfoundland Labrador

Health and Community Services

TERIFLUNOMIDE (AUBAGIO 14MG TABLET and generics)

For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet the following criteria:

- Confirmed diagnosis based on McDonald criteria
- Has experienced one or more disabling relapses or new MRI activity in the past two years
- Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5)

Clinical Note:

- Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7.

Claim Notes:

- Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis.
- Combined use with other disease modifying therapies to treat MS will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated June 2023

Health and Community Services

TESTOSTERONE TOPICAL (ANDROGEL 2.5mg & 5mg sachets, TESTIM 1% gel and generics)

- For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

  Primary: Cryptorchidism, Klinefelter's, orichidectomy, and other established causes.

  Secondary: Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria. Limited to 5 g/day gel or 5 mg patch.

- For use in gender affirming hormone therapy when open benefit testosterone options are not appropriate.

  Claim Notes:

  Limited to 5 g/day gel.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2022

Health and Community Services

Testosterone Undecanoate (Andriol 40mg capsule and generics)

For the treatment of congenital and acquired primary or secondary hypogonadism in males with a specific diagnosis of:

> **Primary:** Cryptorchidism, Klinefelter's, orichidectomy, and other established causes.
>
> **Secondary:** Pituitary-hypothalamic injury due to tumors, trauma, radiation.

Testosterone deficiency should be clearly demonstrated by clinical features and confirmed by two separate biochemical tests before initiating any T therapy.

Older males with non-specific symptoms of fatigue, malaise or depression who have low testosterone (T) levels do not satisfy these criteria.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

TEZEPELUMAB (TEZSPIRE 210 mg/1.91 mL (110 mg/mL) Pre-filled syringe, 210 mg/1.91 mL (110 mg/mL) Pre-filled pen)

For the adjunctive treatment of severe asthma in adults and adolescents 12 years and older with severe asthma who meet the following criteria:

- Asthma inadequately controlled with high-dose inhaled corticosteroids (ICSs), defined as ≥ 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., Long-acting beta-agonists (LABAs)).
- Experienced 2 or more clinically significant asthma exacerbations in the past 12 months.

A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed before initiation.

Renewal criteria:
The effects of treatment should be assessed every 12 months using the same asthma control questionnaire used at baseline.

Discontinuation Criteria:
Treatment should be discontinued if any of the following occur:

- The 12-month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment.
- The asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently.
- The number of clinically significant asthma exacerbations has increased within the previous 12 months.
- In patients on maintenance treatment with oral corticosteroids (OCSs), there has been no decrease in the OCS dose in the first 12 months of treatment.
- In patients on maintenance treatment with OCSs, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained or improved subsequently.

Clinical Notes:

- Must be prescribed by an allergist or respirologist with experience managing severe asthma.
- Combined use of Tezepelumab with other biologics used to treat asthma will not be reimbursed.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Biologics-for-Asthma-1.pdf

Updated November 2024

Health and Community Services

Thyrotropin alpha (Thyrogen 0.9mg/ml)

For preparation prior to radioiodine ablation in patients who have undergone thryroidectomy for papillary or follicular thyroid cancer.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

TICAGRELOR (BRILINTA 90 MG TABLET and generics)

1. In combination with ASA for patients with ST elevation myocardial infarction (STEMI) or non-ST elevation acute coronary syndrome (NSTEACS) who receive percutaneous coronary intervention (PCI).

Claim Notes:
- Approval period: 1 year.

2. For the treatment of patients who have recurrent cardiovascular events (STEMI or NSTEACS), or definite stent thrombosis, while on clopidogrel and ASA therapy.

Clinical Note:
- Definite stent thrombosis, according to the Academic Research Consortium, is a total occlusion originating in or within 5 mm of the stent or is a visible thrombus within the stent or is within 5 mm of the stent in the presence of an acute ischemic clinical syndrome within 48 hours.

Claim Notes:
- Approval period: Long term.

TICAGRELOR (BRILINTA 60 MG TABLET and generic)

In combination with ASA for patients with a history of STEMI or NSTEACS in the previous 3 years who are at high risk for subsequent cardiovascular events.

Clinical Note:
- High risk for subsequent cardiovascular events is defined as age 65 years or older, diabetes, second prior spontaneous myocardial infarction, multivessel coronary artery disease, or chronic renal dysfunction (creatinine clearance <60mL/min).

Claim Notes:
- Approval period: Up to 3 years.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Antiplatelet-Therapy-Form.pdf

Updated October 2023

Health and Community Services

TILDRAKIZUMAB (ILUMYA 100MG/ML Subcutaneous pre-filled syringe, Subcutaneous (SC) injection / pre-filled pen)

Chronic Plaque Psoriasis

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Renewal:
For continued coverage, patients must meet the following criteria:

- Greater than or equal to 75% reduction in PSAI score, **OR**
- Greater than or equal to 50% reduction in PSAI and greater than or equal to 5 points in the DLQI.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.

- Approvals will be for a 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.
- Initial Approval: 6 months
- Renewal Approval: 1 year.
    - Ongoing coverage for maintenance therapy should only be provided for responders, as noted above.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Updated August 2026

Health and Community Services

INNOHEP SODIUM (INNOHEP 10000U, 20000U vial, 3500U, 8000U, 10,000U, 12000U, 16000U syringe)

For the prevention of VTE following:

- total hip replacement (THR) surgery or hip fracture surgery (maximum coverage up to 35 days)
- total knee replacement (TKR) surgery (maximum coverage up to 10 days)

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/LMWH-for-VTE-Prevention-Following-Surgery-.pdf

For treatment of acute Venous Thromboembolism (VTE)

- coverage is limited to 7 to 10 days while establishing a therapeutic INR
- extended treatment of recurrent VTE may be considered in patients with treatment failure on therapeutic doses of warfarin. Coverage will be limited to a 3 month period.

For prophylaxis, coverage is limited to patients with concomitant anticoagulation syndromes, or in patients who have failed to reach therapeutic INR while on oral anticoagulant therapy.

- Coverage will be limited to a 3 month period.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated October 2023

Newfoundland Labrador

Health and Community Services

TIOTROPIUM / OLODATEROL (INSPIOLTO RESPIMAT 2.5MCG-2.5MCG)

- For the treatment of moderate to severe COPD (CAT score ≥ 10 or mMRC ≥ 2) **OR**
- For patients who have experienced an exacerbation of COPD in the previous 12 months while on a LAMA or LABA inhaler.

Clinical Notes

- Coverage of a LABA and LAMA as two separate inhalers will not be considered.
- mMRC Grade 2 is described as: walking on level ground slower than people of same age because of breathlessness or having to stop for breath when walking at your own pace on the level.
- The COPD assessment test (CAT) is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at https://www.catestonline.org/patient-site-test-page-english.html

Limitations to coverage:

- ICS inhalers will not be reimbursed concurrently with a LAMA/LABA inhaler. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control.

LAMA/LABA inhaler as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be

done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.

- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

TOBRAMYCIN (TOBI 300 MG/5ML SOLUTION for INHALATION)
TOBRAMYCIN (TOBI PODHALER 28 MG POWDER for INHALATION)

- For the management of patients with moderate to severe* chronic Pseudomonas aeruginosa infections, in Cystic Fibrosis (CF) patients aged 6 years and older, when used as cyclic treatment (28-day cycles),

AND

- The patient has had a hypersensitivity reaction (e.g. edema, respiratory distress, serum sickness, anaphylaxis) to a non-medicinal ingredient contained in the interchangeable generic tobramycin product.

*Moderate to severe CF is defined as FEV1 of 25-75%.

Please note:

- Generic brands are available as an open benefit
- Restricted to patients eligible under the Select Needs Program.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2016

Health and Community Services

TOCILIZUMAB (TYENNE 80mg/4ml Vial, 200mg/10ml Vial, 400mg/20ml Vial, 162mg/0.9ml pre-filled syringe, 162mg/0.9ml Auto injector, AVTOZMA 80 mg/4 mL Vial, 200 mg/10mL Vial, 400 mg/20mL Vial, 162mg/0.9ml pre-filled syringe, 162mg/0.9ml auto-injector)

Rheumatoid Arthritis (RA):

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 24 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: Long term
- Maximum Dosage Approved:
    - *For patients weighing less than 100 kg, initial coverage may be approved for one 162 mg dose of tocilizumab administered every other week. Dose may be increased up to weekly based on clinical response.*

- *For patients weighing 100 kg or more, initial coverage may be approved for one 162 mg dose of tocilizumab administered every week, with no dose escalation permitted.*
- *Tocilizumab intravenous infusion: Initial approvals will be for 4mg/kg/dose every four weeks, with a maximum maintenance dose escalation up to 8mg/kg, to a maximum of 800mg per infusion for patients >100kg.*

Systemic Juvenile Idiopathic Arthritis (sJIA)

For the treatment of active systemic juvenile idiopathic arthritis (sJIA), in patients 2 years of age or older, who have responded inadequately to non-steroidal anti-inflammatory drugs (NSAIDs) and systemic corticosteroids (with or without methotrexate) due to intolerance or lack of efficacy.

Clinical Notes:
- Coverage will be approved for a dose of 12 mg/kg for patients weighing less than 30kg or 8 mg/kg for patients weighing greater than or equal to 30kg to a maximum of 800mg, administered every two weeks.
- Continued coverage will be dependent on a positive patient response as determined by a pediatric rheumatologist.

Claim Notes:
- Must be prescribed by, or in consultation with, a pediatric rheumatologist.
- Initial approval: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Polyarticular Juvenile Idiopathic Arthritis (pJIA)

For the treatment of children (age 2-17) with polyarticular juvenile rheumatoid arthritis who have:
- not responded to an adequate trial with one or more disease modifying antirheumatic drug (DMARD) for at least 3 months, OR has experience intolerance to DMARDs

Claim Note:
- Must be prescribed by a rheumatologist who is familiar with the use of DMARDs and/or biologic DMARDs in children.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Giant Cell Arteritis (GCA)

For the treatment of adult patients with new onset or relapsed giant cell arteritis (GCA) in combination with glucocorticoids.

Claim Note:

- Must be prescribed by, or in consultation with, a rheumatologist or other physician experienced in the treatment of GCA.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Subcutaneous injection: Approvals will be for 162 mg every week.
- Initial Approval: Long term

Updated October 2026

Health and Community Services

TOFACITINIB (XELJANZ 5mg, 10mg TABLET and generics, XELJANZ XR 11mg TABLET)

Rheumatoid Arthritis (RA):

TOFACITINIB (XELJANZ 5 MG TABLET, XELJANZ XR 11mg TABLET)

For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks;

OR

- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:

- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- If the patient is intolerant to triple DMARD therapy, then dual therapy with DMARDs (methotrexate, hydroxychloroquine, leflunomide, sulfasalazine) must be considered.
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use with a biologic immunomodulator drug or another JAK inhibitor will not be reimbursed.

- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved:
    - TOFACITINIB: Maximum daily dosage not to exceed 10 mg (i.e., 5 mg twice daily) or XR 11mg once daily.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Ulcerative colitis (UC)

TOFACITINIB (XELJANZ 5 MG TABLET, XELJANZ 10 MG TABLET)

For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with a biologic immunomodulator drug - or another JAK inhibitor will not be reimbursed.
- Approvals will be for a maximum dose of 10 mg twice daily (Xeljanz).

- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated October 2023

Health and Community Services

TOPIRAMATE (TOPAMAX) 15mg and 25mg sprinkle capsules

For patients who cannot take the tablet form of topiramate and require sprinkle capsules for proper administration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2020

Health and Community Services

TRAMETINIB (MEKINIST) 0.5mg, 2mg tablets

Adjuvant Melanoma
In combination with dabrafenib (Tafinlar) for the adjuvant treatment of patients with cutaneous melanoma who meet all of the following criteria:

- Stage IIIA (limited to lymph node metastases of greater than 1 mm) to stage IIID disease (8th edition of American Joint Committee on Cancer [AJCC] staging system)
- BRAF V600-mutation positive
- Completely resected disease including in-transit metastases

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should continue until disease recurrence, unacceptable toxicity, or up to a maximum of 12 months.

Claim Notes:

- Requests will be considered for patients with regional lymph nodes with micrometastases after sentinel lymph node biopsy.
- Requests will not be considered for patients who received adjuvant immunotherapy for greater than three months. Patients may switch to BRAF targeted therapy within the first three months of initiating immunotherapy to complete a total of 12 months of adjuvant treatment.
- Approval period: Up to 12 months.

Metastatic Melanoma
For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with dabrafenib.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have an ECOG performance status of 0 or 1.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Trametinib will not be reimbursed in patients who have progressed on BRAF targeted therapy.

- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2023

Health and Community Services

Treprostinil (Remodulin 1mg/ml, 2.5mg/ml, 5mg/ml & 10mg/ml)

For patients with primary pulmonary hypertension or pulmonary hypertension secondary to collagen vascular disease, with New York Heart Association class lll or lV disease who have:

- failed to respond to non-prostanoid therapies, **and**:
- who are not candidates for epoprostenol therapy because of:
    - prior recurrent complications with central line access (infec/thrombosis) **or**
    - inability to operate the complicated delivery system of epoprostenol, **or**
    - they reside in an area without ready access to medical care, which could complicate problems associated with an abrupt interruption of epoprostenol therapy.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

TRIENTINE (WAYMADE-TRIENTINE 250mg CAPSULE, MAR-TRIENTINE 250 MG CAPSULE)

For the treatment of patients diagnosed with Wilson's Disease (WD) who have experienced unacceptable intolerance(s) from treatment with d-penicillamine OR who have contraindication(s) to d-penicillamine.

Renewal criteria:

- Renewal will be provided for patients who continue to respond to treatment and who do not develop unacceptable intolerances.

Clinical Notes:

- Must be prescribed by a physician with experience in the treatment and management of Wilson's disease. For pediatric patients, consult notes from an expert in Wilson's disease may be provided to support the request from prescribers.
- Please include a description of the d-penicillamine intolerances and/or contraindications with your initial request.
- Approval Period: 1 year

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2024

Health and Community Services

TRIFLURIDINE-TIPIRACIL (LONSURF) 15 MG/6.14 MG, 20 MG/8.19 MG TABLET

Metastatic Colorectal Cancer

In combination with bevacizumab, for the treatment of adult patients with either unresectable or metastatic colorectal cancer who have been previously treated with or are not candidates for prior chemotherapy regimens.

- Prior treatment must include fluoropyrimidine-, oxaliplatin-, or irinotecan-based chemotherapies, anti-VEGF biologic agents, and/or an anti-EGFR agent if RAS wild-type.
- There should be disease progression or demonstrated intolerance to no more than 2 prior chemotherapy regimens (note: encorafenib and panitumumab do not count as chemotherapy regimens).

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no active central nervous system metastases.
2. Patients will be eligible for Lonsurf plus bevacizumab regardless of prior bevacizumab exposure.
3. If bevacizumab is discontinued due to intolerance or contraindication, Lonsurf can be continued at the discretion of the physician.
4. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Patients who received neoadjuvant or adjuvant chemotherapy and experienced recurrence during or within 6 months of completion count as 1 line of therapy.
- Approval period: 6 months

Metastatic Gastric Cancer

For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria:

- Previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate, with HER2/neu-targeted therapy.
- ECOG performance status of 0 or 1.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Trifluridine / tipiracil should be used in combination with best supportive care.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy provided they received at least 2 lines of alternate chemotherapy.
- Approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2025

Health and Community Services

TRIHEPTANOIN (DOJOLVI 100% w/w oral liquid)

For the treatment of adult and pediatric patients with an acute life-threatening long-chain fatty acid oxidation disorders (LC-FAOD) as a source of calories and fatty acids only if the following conditions are met:

- patients with a confirmed diagnosis of LC-FAOD and acute life-threatening events who require alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation or
- patients without a confirmed diagnosis of LC-FAOD presenting with acute life-threatening events consistent with LC-FAOD who require alternative therapy to conventional even-chain MCT supplementation.

Clinical Notes:

- Patients should be under the care of a specialist with expertise in the diagnosis and management of LC-FAOD.
- Approval period: 1 year. Confirmation of continued response is required for renewal.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated September 2023

Newfoundland Labrador

Health and Community Services

TROSPIUM CHLORIDE (TROSEC 20mg)

For the treatment of overactive bladder (not stress incontinence) after a reasonable trial, titrated, and of appropriate length* of oxybutynin IR, tolterodine OR solifenacin are not tolerated.

*an appropriate trial is considered to be of 12 weeks duration.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2018

Health and Community Services

TUCATINIB (TUKYSA) 50MG, 150MG TABLET

In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab, and a HER2-targeted antibody-drug conjugate (e.g. Kadcyla, Enhertu), where at least one was given in the advanced or metastatic setting.

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression, unacceptable toxicity or if both trastuzumab and capecitabine are discontinued.

Claim Notes:

- Approval period: 6 months

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2023

Health and Community Services

UMECLIDINIUM/VILANTEROL (ANORO ELLIPTA 62.5MCG-25MCG INHALER)

- For the treatment of moderate to severe COPD (CAT score ≥ 10 or mMRC ≥ 2) **OR**
- For patients who have experienced an exacerbation of COPD in the previous 12 months while on a LAMA or LABA inhaler.

Clinical Notes

- Coverage of a LABA and LAMA as two separate inhalers will not be considered.
- mMRC Grade 2 is described as: walking on level ground slower than people of same age because of breathlessness or having to stop for breath when walking at your own pace on the level.
- The COPD assessment test (CAT) is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at https://www.catestonline.org/patient-site-test-page-english.html

Limitations to coverage:

- ICS inhalers will not be reimbursed concurrently with a LAMA/LABA inhaler. Special Authorization may be considered for Triple Therapy in patients who require additional symptom control.

LAMA/LABA inhaler as part of Triple Therapy (LAMA/LABA/ICS) for patients with a diagnosis of COPD:

Fixed dose LAMA/LABA/ICS inhalers are the preferred options for patients requiring Triple Therapy. Triple Therapy fixed dose inhalers considered by NLPDP are Trelegy 100-62.5-25 mcg and Breztri 160-7.2-5 mcg.

LABA/ICS plus LAMA or LAMA/LABA plus ICS may be considered as Triple Therapy for COPD in patients who **cannot use Trelegy 100 or Breztri**. Details must be provided to support the use of separate inhalers. In this instance, special authorization will be required for both inhalers in the desired combination.

Triple Therapy with LAMA/LABA/ICS is considered for the treatment of COPD in patients who have experienced:

- Two or more exacerbations of COPD requiring treatment with antibiotics and/or systemic corticosteroids in the last 12 months **OR**
- At least one exacerbation of COPD in the last 12 months requiring hospitalization or an emergency department visit **OR**
- Moderate symptom burden (e.g. CAT score ≥ 10 or mMRC ≥ 2) despite treatment with LAMA/LABA or LABA/ICS for at least 2 months

Notes:

- Post bronchodilator spirometry is required to confirm the diagnosis of COPD if requesting Triple Therapy. Exceptions are considered if spirometry cannot be done or has been ordered but not yet completed (waitlisted). Details must be provided on the special authorization request.
- Note: Trelegy 200-62.5-25 mcg is not considered for coverage by NLPDP.
- Criteria for Enerzair (LAMA/LABA/ICS) for treatment of asthma without concurrent COPD, remains unchanged.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Inhalers-for-Asthma-and-COPD.pdf

Updated April 2025

Health and Community Services

UPADACITINIB (RINVOQ 15mg, 30mg, 45mg TABLET)

Rheumatoid Arthritis (RA):

For the treatment of moderate to severely active rheumatoid arthritis, alone or in combination with methotrexate or other disease-modifying anti-rheumatic drugs (DMARDs), in patients who are refractory, intolerant or have contraindication to:

- Methotrexate (oral or parenteral) at a dose of ≥ 20 mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks, followed by methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; OR
- Initial use of triple DMARD therapy with methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks.

Clinical Notes:
- For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered.
- Optimal treatment response may take up to 24 weeks, however if no improvement is seen after 12 weeks of triple DMARD use, therapy should be changed.
- For patients who have intolerances preventing the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried.
- Refractory is defined as lack of effect at the recommended dose and for duration of treatment specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:
- Must be prescribed by a rheumatologist or other specialized physician with experience treating rheumatoid arthritis.
- Combined use of more than one biologic DMARD or Janus kinase inhibitors will not be reimbursed.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved: Maximum daily dose is 15 mg.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Psoriatic Arthritis (PsA):

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, and
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist or other specialized physician with experience treating psoriatic arthritis.
- Combined use of more than one biologic DMARD or Janus kinase inhibitors will not be reimbursed.
- Maximum Dosage Approved: Maximum daily dose is 15 mg.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Requests for renewal can be reassessed for yearly coverage dependent on achieving improvement in symptoms of at least 20% (20% improvement in the American College of Rheumatology response criteria (ACR 20) or response using the Psoriatic Arthritis Response Criteria).

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Atopic Dermatitis (AD)

For the treatment of patients 12 years of age and older with refractory moderate to severe atopic dermatitis (AD) who meet all of the following criteria:

- Refractory or intolerant to an adequate trial with maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy (where available), and
- Refractory, intolerant, or contraindicated to an adequate trial of maximally tolerated prescription topical therapies for atopic dermatitis combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine), and
- The physician must provide the Eczema Area and Severity Index (EASI) score and validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD) at the time of initial request for reimbursement.

Renewal Criteria

- The maximum duration of initial authorization is 20 weeks.
- For renewal after initial authorization, the physician must provide proof of beneficial clinical effect when requesting continuation of reimbursement, defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) 20 weeks after treatment initiation.
- For subsequent renewal, the physician must provide proof of maintenance of EASI-75 response from baseline every 6 months for subsequent authorizations.

Clinical Notes:

- The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe atopic dermatitis.
- Combined use of more than with phototherapy, any immunomodulatory agents (including biologics) or other JAK inhibitor treatment for moderate to severe AD will not be considered.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Special-Authorization-Form-Dupixent.pdf

Crohn's Disease (CD)

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Coverage will not be considered when combined with biological or other JAK inhibitor treatments for CD.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.
- Approvals will be for 45mg once daily for 12 weeks, then 15mg to 30mg daily thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to be assessed at 12 weeks then yearly using criteria such as a 100-point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less, or a decrease in score of 4 or more.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Ulcerative Colitis (UC)

For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:

- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Coverage will not be considered when combined with biological or other JAK inhibitor treatments for UC. Combined use of more than one biologic DMARD will not be reimbursed.
- Approval will be for 45mg once daily for 8 weeks then 15mg once daily or 30 mg daily thereafter.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Ankylosing Spondylitis:

For the treatment of adult patients with moderate to severe active ankylosing spondylitis (e.g., Bath AS Disease Activity Index (BASDAI) score ≥4 on 10-point scale) who:

- Have axial symptoms and who have failed to respond to the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each or in whom NSAIDs are contraindicated,

OR

- Have peripheral symptoms and who have failed to respond, or have contraindications to, the sequential use of at least 2 NSAIDs at the optimum dose for a minimum period of 2 weeks each and have had an inadequate response to an optimal dose or maximal tolerated dose of a DMARD.

Requests for renewal must include information demonstrating the beneficial effects of the treatment, specifically:

- Decrease of at least 2 points on the BASDAI scale compared with the pre-treatment score,

OR

- An adequate clinical response as indicated by significant functional improvement (e.g., measured by outcomes such as HAQ or “ability to return to work”).

Clinical Notes:

- Patients with recurrent uveitis (2 or more episodes within 12 months) as a complication to axial disease do not require a trial of NSAIDs alone.

Claim Notes:

- Must be prescribed by a rheumatologist or physician with expertise in treating ankylosing spondylitis.
- Combined use with other biologic drugs or janus kinase inhibitors will not be reimbursed.
- Approvals will be for a maximum of 15 mg daily.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Updated November 2024

Health and Community Services

USTEKINUMAB (JAMTEKI 45mg/0.5mL prefilled syringe, 90mg/ml prefilled syringe, WEZLANA 45mg/0.5ml prefilled syringe, 90mg/1.0mL prefilled syringe, 45mg/0.5ml single-use Vial, 130mg/26mL single-use Vial, STEQEYMA 45mg/0.5mL prefilled syringe, 90mg/ml prefilled syringe, 130mg/26ml single use vial, YESINTEK 45 mg/0.5 mL single-use vial, 45 mg/0.5 mL prefilled syringe, 90 mg/1.0 mL prefilled syringe, 130 mg/26 mL single-use vial)

Chronic Plaque Psoriasis:

For the treatment of patients with moderate to severe plaque psoriasis who meets all of the following criteria:

- Psoriasis Area Severity Index (PASI) > 10 **AND** Dermatology Life Quality Index (DLQI) >10 **OR**
- Major involvement of visible areas (i.e. face, hands, feet), scalp, genitals, or nails.

AND

- Refractory or intolerant to or unable to access phototherapy
- Refractory or intolerant or have contraindications to methotrexate (oral or parenteral) at a dose of greater than or equal to 20 mg weekly (greater than or equal to 15 mg if patient is greater than or equal to 65 years of age) for a minimum of 12 weeks **OR** cyclosporine for a minimum of 6 weeks treatment.

Clinical notes:

- Refractory defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractory.

Claim Notes:

- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Combined use of more than one biologic drug will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for 45mg or 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter.
- Approval period: Long term

Please visit the link below if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/Chronic-Plaque-Psoriasis-Medications.pdf

Psoriatic Arthritis*:*

For patients with active psoriatic arthritis who meet **all** of the following criteria:

- Have at least three active and tender joints, AND
- Have not responded to an adequate trial of two DMARDs or have an intolerance or contraindication to DMARDs.

Claim Notes:

- Must be prescribed by a rheumatologist.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Approvals will be for 45 or 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter.
- Approval period: Long term

Please visit the link below if you require the NLPDP special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-initiation.pdf
https://www.gov.nl.ca/hcs/files/prescription-ra-meds-continuation-request.pdf

Crohn's Disease*:*

For the treatment of patients with moderately to severely active Crohn's disease who have contraindications, or are refractory, to therapy with corticosteroids and other immunosuppressants.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) score.

Initial Dosing with I.V.:

Body weight at time of dosing	Dosing	Number of 130mg I.V. Vials
≤ 55kg	260mg	2
> 55kg to ≤ 85kg	390mg	3
> 85kg	520mg	4

- Subcutaneous maintenance dosing: first subcutaneous dose should be given at week 8 following the intravenous induction dose. Subsequent doses should be given every 8 weeks thereafter.
- Approval period: Long term

Please visit the link below if you require the NLPDP special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Ulcerative colitis

For the treatment of patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Clinical Notes:
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.
- Consideration will be given for patients who have not received a four-week trial of aminosalicylates if disease is severe (partial Mayo score > 6).

Claim Notes:
- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.

Initial Dosing with I.V.:

Body weight at time of dosing	Dosing	Number of 130mg I.V. Vials
≤ 55kg	260mg	2
> 55kg to ≤ 85kg	390mg	3
> 85kg	520mg	4

- Subcutaneous maintenance dosing: first subcutaneous dose should be given at week 8 following the intravenous induction dose. Subsequent doses should be given every 8 weeks thereafter.
- Approval period: Long term

Please visit the link below if you require the NLPDP special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated April 2026

Newfoundland Labrador

Health and Community Services

VALGANCICLOVIR (VALCYTE 50 MG/ML SOLUTION and generics)

For the prevention or treatment of cytomegalovirus (CMV) in patients for whom oral tablets are not an option.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2024

Health and Community Services

VANDETANIB (CAPRELSA) 100MG AND 300MG TABLETS

For the treatment of symptomatic and/or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advance or metastatic disease.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Initial approval period: 1 year
- Renewal approval period: 1 year

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated November 2021

Health and Community Services

VANZACAFTOR/TEZACAFTOR/DEUTIVACAFROR (ALYFTREK 4MG/20MG/50MG TABLET, ALYFTREK 10MG/50MG/125MG TABLET)

For the treatment of patients aged 6 years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Alyftrek.

Initial renewal criteria:

For patients new to CFTR modulator treatment:

For the initial renewal, the patient must meet at least ONE of the following criteria:

- Improvement of lung function by 5% of predicted or more (ppFEV1 compared to baseline (baseline lung function should be measured within a 3-month period prior to beginning treatment with Alyftrek); OR
- A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment; OR
- A decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6- month period prior to initiating treatment; OR
- Decreased number of CF-related hospitalizations at 6 months compared with the 6-month period prior to initiating Alyftrek treatment; OR
- No decline in BMI (BMI z score in children) at 6 months compared with the baseline BMI assessment; OR
- Improvement by 4 points or more in the CF Questionnaire-Revised (CFQ-R) Respiratory Domain scale compared to baseline.

For patients who switched from another CFTR modulator:

For the initial renewal, the patient must meet at least ONE of the following criteria:

- No decline in lung function at 6 months relative to baseline before the switch to Alyftrek; OR
- No increase in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the 6-month period prior to the switch; OR
- No increase in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6- month period prior to the switch; O
- No increase in the number of CF-related hospitalizations in the 6 months after the switch; OR
- No decline in BMI (BMI z score in children) at 6 months compared with the baseline BMI assessment prior to the switch; OR
- No reduction in the CFQ-R Respiratory Domain scale at 6 months compared to baseline scores prior to the switch.

Clinical Notes:

1. The following measurements must be completed prior to initiating treatment with Alyftrek:
   - Baseline spirometry measurements of FEV_1 and ppFEV1 within the last 90 days prior to initiating treatment;
   - Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months;
   - Number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months;
   - Number of CF-related hospitalizations in the previous 6 months;
   - Weight, height, and BMI; and
   - CFQ-R Respiratory Domain score.

2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- Restricted to patients under the Select Needs Program.
- The patient must be under the case of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Initial approval: 7 months.
- Renewal approval period: Longterm
- The recommended dosage for patients who weigh less than 40 kg is 3 of the 4/20/50 mg tablets once daily, and for patients who weigh at least 40 kg, it is 2 tablets of the 10/50/125 mg tablets once daily.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2026

Health and Community Services

VEDOLIZUMAB (ENTYVIO 300mg VIAL, 108 mg/0.68 mL prefilled syringe and prefilled pen)

Ulcerative Colitis

- For the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are:
- refractory or intolerant to conventional therapy (i.e. 5-ASA for a minimum of 4 weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or
- corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year.)

Renewal requests must include information demonstrating the beneficial effects of the treatment specifically:

- a decrease in the partial Mayo score ≥ 2 from baseline, and
- a decrease in the rectal bleeding subscore ≥1.

Clinical Notes:

- Consideration will be given for patients who have not received a four week trial of aminosalicylates if disease is severe (partial Mayo score > 6).
- Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above.
- Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Intravenous infusion: Initial Approval will be for a maximum of 300mg at week 0, 2 & 6, then 300mg every eight weeks.
- Subcutaneous injection: Initial Approval will be for a maximum of 108mg every 2 weeks following at least two intravenous infusions of vedolizumab.
- Initial Approval: 14 weeks
- Renewal approval: 1 year

Please visit the following link if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Crohn's Disease

- For the treatment of adult patients with moderately to severely active* Crohn's disease (CD) with contraindications to or not achieving remission with glucocorticosteroids **AND** immunosuppressive therapy.
    - Initial request must include current Crohn's Disease Activity Index (CDAI) or the Harvey Bradshaw Index Assessment (HBI) score.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Concurrent use of other biologic DMARDS not approved.
- Intravenous infusion: Initial Approval will be for a maximum of 300mg at week 0, 2 & 6 then 300mg every eight weeks.
- Subcutaneous injection: Initial Approval will be for a maximum of 108mg every 2 weeks following at least two intravenous infusions of vedolizumab.
- Initial Approval: 14 weeks
- Renewal approval: 1 year
- Renewal Approval: Continued coverage dependent on evidence of response using criteria such the 100 point reduction in Crohn's Disease Activity Index (CDAI) or the Harvey-Bradshaw Index Assessment (HBI) with a score of 5 or less or a decrease in score of 4 or more.

Please visit the following link if you require our special authorization form:
https://www.gov.nl.ca/hcs/files/forms-pdf-ibd.pdf

Updated October 2023

Health and Community Services

VEMURAFENIB (ZELBORAF) 240MG TABLETS

For the treatment of patients with BRAF V600 mutation-positive unresectable or metastatic melanoma when used alone or in combination with cobimetinib (Cotellic).

Renewal criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. If brain metastases are present, patients should be asymptomatic or have stable symptoms.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity

Claim Notes:

- Vemurafenib will not be reimbursed in patients who have progressed on BRAF targeted therapy.
- Requests will be considered for patients who received adjuvant BRAF targeted therapy if disease progression occurred at least 6 months following completion of therapy.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated March 2023

Health and Community Services

VENETOCLAX (VENCLEXTA) 10MG, 50MG, 100MG TABLETS and STARTER PACK

Chronic Lymphocytic Leukemia/Small Cell Lymphoma

1. In combination with acalabrutinib for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL).

   Clinical Notes:
   1. Patients must have a good performance status.
   2. Patients with central nervous system (CNS) involvement, Richter's syndrome, uncontrolled autoimmune hemolytic anemia or idiopathic thrombocytopenic purpura are not eligible.
   3. Combination treatment should be initiated following two cycles of acalabrutinib monotherapy and continued for 12 cycles, or until disease progression or unacceptable toxicity, whichever occurs first.

   Claim Notes:
   - Requests for re-treatment with venetoclax in combination with acalabrutinib will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
   - Approval period: 12 cycles.

2. In combination with obinutuzumab for the treatment of adult patients with previously untreated CLL / SLL.

   Clinical Notes:
   1. Patients must have a good performance status.
   2. Treatment should be given for a total of 12 months (six 28-day cycles in combination with obinutuzumab, followed by six months of monotherapy), or until disease progression or unacceptable toxicity, whichever occurs first.

   Claim Notes:
   - Requests for re-treatment with venetoclax in combination with obinutuzumab will be considered in the relapsed setting if no disease progression was experienced during treatment or within 12 months after completion of first-line venetoclax plus obinutuzumab.
   - Approval period: 1 year.

3. In combination with ibrutinib for the treatment of adult patients with previously untreated CLL/SLL.

   Clinical Notes:
   1. Patients must have a good performance status and no CNS involvement or Richter's transformation.

2. Combination treatment should be initiated following three months of ibrutinib monotherapy and continued for a total of 12 months, or until disease progression or unacceptable toxicity, whichever occurs first.
3. If ibrutinib is discontinued for intolerance, venetoclax monotherapy may be continued.

Claim Notes:

- Requests for re-treatment with venetoclax in combination with ibrutinib will be considered for patients who experience a relapse-free interval of at least one year following completion of initial treatment.
- Approval period: 1 year.

4. In combination with rituximab for the treatment of adult patients with CLL/SLL who have received at least one prior therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression or unacceptable toxicity.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment may be continued until disease progression or unacceptable toxicity, up to a maximum of two years.
3. Addition of Rituximab is allowed for patients currently receiving and responding to Venetoclax monotherapy, but who have not achieved an adequate response. The funded duration of Venetoclax therapy from the point of rituximab addition will be up to a maximum of 2 years.

Claim Notes:

- Requests will not be considered for patients previously treated with anti-CD20 therapy if relapse occurs less than six months following completion of therapy. However, for patients previously treated with venetoclax, the relapse-free interval must be 12 months or greater.
- Approval period: 1 year

5. As monotherapy for the treatment of patients with CLL/SLL who have received at least one prior therapy, and who have failed or are intolerant to a B-cell receptor inhibitor (BCRi).

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression or unacceptable toxicity.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients previously treated with venetoclax-based therapy if relapse occurs less than 12 months following completion of therapy.
- Approval period: 1 year

Mantle Cell Lymphoma
In combination with ibrutinib for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least one prior line of therapy for MCL.

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression or unacceptable toxicity.

Clinical Notes:
1. Patients must have a good performance status.
2. Treatment may be continued until disease progression or unacceptable toxicity, up to a maximum of two years.
3. If one component of venetoclax plus ibrutinib is discontinued permanently because of tolerability concerns, the other component may be continued as monotherapy; however an alternative BTK inhibitor in combination with venetoclax cannot be given if intolerant to ibrutinib.

Claim Notes:
- Patients previously treated with a BTK or BCL2 inhibitor, who did not experience disease progression during therapy and completed treatment at least 6 months earlier, may be eligible to receive venetoclax in combination with ibrutinib.
- Approval period: 1 year

Acute Myeloid Leukemia
In combination with azacitidine for the treatment of patients with newly diagnosed acute myeloid leukemia who are 75 years of age or older, or who have comorbidities that preclude use of intensive induction chemotherapy*.

Renewal Criteria:
- Written confirmation that the patient is responding to treatment and there is no evidence of disease progression.

Clinical Note:
1. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for patients previously treated with a hypomethylating agent or chemotherapy for myelodysplastic syndrome will not be considered.
- Requests for patients with high-risk myelodysplastic syndrome will not be considered.
- Approval period: 1 year.

*Patients with AML who are considered ineligible for standard intensive induction chemotherapy are defined as either of the following:

- Age 75 years or older and an ECOG performance status of 0 to 2
- Age 18 to 74 years and fulfill at least one of the following:
  - ECOG performance status of 2 to 3
  - History of congestive heart failure requiring treatment, ejection fraction ≤50%, or chronic stable angina
  - DLCO ≤65% or FEV1 ≤65%
  - Creatinine clearance ≥30 mL/min to 45 mL/min
  - Moderate hepatic impairment with total bilirubin >1.5 to ≤3.0 ULN

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http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2026

Health and Community Services

VERICIGUAT (VERQUVO 2.5mg, 5mg, 10mg tablets)

For the treatment of symptomatic chronic heart failure (HF) as an adjunct to standard-of-care therapy in adult patients (18 years of age and older) with reduced ejection fraction who are stabilized after a recent HF decompensation event if the following conditions are met:

- Patients with symptomatic chronic HF with reduced ejection fraction (i.e., Left Ventricular Ejection Fraction <45%) AND

- Patients must have a recent HF decompensation event requiring hospitalization and/ or IV diuretic therapy.

Clinical Notes:

- HF decompensation event or progressive HF is defined as worsening symptoms while on conventional therapy, resulting in treatment escalation and hospitalization or outpatient IV diuretic treatment. The laboratory and diagnostic tests to define worsening HF include elevated BNP or NT-proBNP, or reduction in ejection fraction.
- Therapy to be initiated in consultation with a cardiologist or clinician with expertise in the management of HF.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated August 2024

Health and Community Services

VIGABATRIN (SABRIL 500mg tablet, 500mg POWDER IN PACKET, Dr. Reddy's VIGABATRIN Product for Oral Solution USP, Tablets USP)

- For the adjunctive management of epilepsy in those patients who do not respond to alternative treatment combinations, or in who other drug combinations have not been tolerated.
- For the management of infantile spasms.

Claim Note:

- The maximum approved dose will be 4g/day
- Dr. Reddy's Vigabatrin can be claimed using the following PINs:
  Vigabatrin Product for Oral Solution USP PIN 09858315
  Vigabatrin Tablets USP PIN 09858318

Please visit the link below if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated November 2023

Health and Community Services

VISMODEGIB (Erivedge) 150mg

For patients with metastatic basal cell carcinoma (BCC) or with locally advanced BCC (including patients with basal cell nevus syndrome, i.e. Gorlin syndrome) who have measurable metastatic disease or locally advanced disease, which is considered inoperable or inappropriate for surgery and inappropriate for radiotherapy; AND

- Patient 18 years or age or older; AND
- Patient has ECOG ≤ 2

Approval period: 9 months

Dosing: 150 mg daily

Renewals will be considered for patients who do not have evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of vismodegib.

Please visit the link below if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated October 2014

Health and Community Services

VORICONAZOLE (VFEND 50mg, 200mg tablets and generics)

- For culture proven invasive candidiasis with documented resistance to fluconazole.

- For the management of invasive aspergillosis.

Clinical Notes:

- Must be prescribed by a hematologist, infectious disease specialist or medical microbiologist.
- Initial requests will be approved for a maximum of 3 months.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated April 2023

Health and Community Services

VUTRISIRAN (AMVUTTRA 25mg/0.5ml pre-filled syringe)

For the treatment of polyneuropathy in patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis) who meet all of the following criteria:

- Age 18 years of age or older; AND
- Have a confirmed genetic diagnosis of hereditary transthyretin-mediated amyloidosis; AND
- Symptomatic with Polyneuropathy disability (PND) stage I to ≤ IIIB, or familial amyloidotic polyneuropathy (FAP) stage I or II.

Exclusions:

- Pre-symptomatic patients
- Patients diagnosed with severe heart failure symptoms (defined as New York Heart Association class III or IV)
- Patients who are recipients of a liver transplant
- Patients who will be using vutrisiran in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR.

Discontinuation Criteria:
Treatment with vutrisiran will be discontinued for patients who are:

- Permanently bedridden and dependent on assistance for basic activities of daily living, OR
- Receiving end-of-life/palliative care where survival of less than one year is expected.

Renewal Criteria

- Renewal of coverage will be considered if patients do not meet the discontinuation criteria.
- Patients should be assessed after 9 months of treatment and then every six months thereafter.
- Duration of Approval of Initial approval: 10 months
- Duration of Approval of first renewal: 6 months
- Duration of Approval of 2nd and subsequent renewals: 1 year

Clinical Criteria:

- The patient must be under the care of a specialist with experience in the diagnosis and management of hATTR-PN.
- Coverage will not be considered in combination with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat hATTR.
- The initial request should contain the following:

    - Laboratory documentation for the genetic mutation for hATTR must be included with the initial request.
    - Sign and symptoms of polyneuropathy should be listed.
    - A list of all drugs that the patient is using including whether they are using any of the following: diflunisal, inotersen, tafamidis, patisiran.
    - Confirmation that the patient does not meet each of the listed exclusions must be provided on the request.
- **Billing Instructions**: For claims that exceed the maximum allowable claim amount of **$99,999.99 per claim**, please contact (709) 729-1780 for billing guidance.

Definitions:
Familial Amyloid Polyneuropathy (FAP) stage: Clinical staging system for the neuropathy symptoms of hATTR (formerly termed familial amyloid neuropathy).

- FAP Stage 1: Walking without assistance, mild neuropathy (sensory, autonomic, and motor) in lower limbs
- FAP Stage 2: Walking with assistance, moderate impairment in lower limbs, trunk, and upper limbs
- FAP Stage 3: wheelchair or bed-ridden, severe neuropathy

Polyneuropathy disability score (PND): A five-stage measure of neuropathy impairment ranging from 0 (no impairment) to 4 (confined to a wheelchair or bedridden).

- Stage 0: no impairment
- Stage I: sensory disturbances but preserved walking capability
- Stage II: impaired walking capability but ability to walk without a stick or crutches
- Stage IIIA: walking only with the help of one stick or crutch
- Stage IIIB: walking with the help of two sticks or crutches
- Stage IV: confined to a wheelchair or bedridden

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https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf

Updated June 2025

Health and Community Services

Wet Nebulization Coverage Criteria (Ipratropium, salbutamol, ipratropium/salbutamol, sodium cromoglycate, budesonide nebules and generics)

Wet nebulization solutions will be approved upon the written request of a physician for those patients who meet the following criteria:

- Adult patients with a vital capacity of 900 ml or less.
- Patients with a respiratory rate greater than 25 breaths per minute.
- Patients who have demonstrated they cannot follow instructions, cannot hold the spacer device or cannot hold the device long enough to actuate it, **OR**
- Other situations as deemed appropriate, on a case by case basis.

Please note: Coverage will not be provided for the concurrent use of nebules and inhalers, with the exception of salbutamol inhaler for rescue therapy. Concurrent use will result in discontinuation of nebulized solution coverage.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

Zanamivir (Relenza 5mg Diskhaler)

For beneficiaries residing in long-term care facilities* during an influenza outbreak situation and further to the recommendation of a Medical Officer of Health:

- For treatment of long-term care facility residents with clinically suspected or lab confirmed influenza A or B **AND** there is suspected or confirmed oseltamivir resistance **or** in patients where oseltamivir is contraindicated.

  A clinically suspected case is one in which the patient meets the criteria of influenza-like illness and there is confirmation of influenza A or B circulating within the facility or surrounding community

- For prophylaxis of long-term care residents where the facility has an influenza A or B outbreak **AND** there is suspected or confirmed oseltamivir resistance **or** in patients where oseltamivir is contraindicated.
  - Prophylaxis should be continued until the outbreak is over. An outbreak is declared over 7 days after the onset of the last case in the facility

* *Long-term care facility* refers to a licensed nursing home.

Please visit the following link if you require our standard special authorization form:

http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated July 2010

Health and Community Services

ZANUBRUTINIB (BRUKINSA) 80MG AND 160MG CAPSULE

Chronic Lymphocytic Leukemia

1. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, or unmutated IGHV).
2. As monotherapy for the treatment of adult patients with relapsed or refractory CLL / SLL who have received at least one prior systemic therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status and no evidence of prolymphocytic leukemia or Richter's transformation.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Requests will not be considered for patients who experience disease progression on a Bruton's tyrosine kinase (BTK) inhibitor or idelalisib.
- Approval period: 1 year.

Waldenström Macroglobulinemia

For the treatment of adult patients with relapsed or refractory Waldenström macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must meet at least one criterion for treatment as per International Workshop on WM (IWWM) consensus panel.
2. Patients must have a good performance status and no evidence of disease transformation.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Note:

- Approval period: 1 year.

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http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated August 2025

Health and Community Services

ZILUCOPLAN (ZILBRYSQ 16.6mg syringe, 23mg syringe, 32.4mg syringe)

For the treatment of adult patients with generalized myasthenia gravis (gMG) who meet all of the following criteria:

- The patient has a positive serologic test for anti-acetylcholine receptor (AChR) antibodies.
- The patient has a Myasthenia Gravis Activities of Daily Living (MG-ADL) score of 6 or higher at baseline.
- The patient has a Myasthenia Gravis Foundation of America (MGFA) class of II to IV disease
- The patient is refractory to or intolerant of an adequate trial of rituximab for gMG (note that if rituximab is not appropriate for the patient, an adequate trial of another preventative treatment including but not limited to other monoclonal antibodies, acetylcholinesterase inhibitors (AChEIs), azathioprine, mycophenolate or other immunosuppressants must have been used).

Exclusion criteria:

Zilucoplan should not be initiated:

- during a gMG exacerbation or crisis, OR
- within 3 months of thymectomy.

Renewal:

- For continued coverage beyond the initial 6 months, the patient must have documented improvement in the MG-ADL score of two points or greater from baseline.
- Following this assessment, continued coverage may be approved for up to 32.4 mg daily for a period of 12 months. Ongoing coverage may be considered if the patient is re-assessed every 12 months and has maintained a response to therapy as indicated by no worsening of the MG-ADL.

Clinical Notes:

- Must be prescribed by or in consultation with a neurologist with expertise in managing patients with gMG.
- The MG-ADL score must be measured and provided by the physician at baseline.
- Coverage cannot be provided for zilucoplan when this medication is intended for use in combination with other biologics (including rituximab) or complement inhibitors for the treatment of gMG.
- Patients will not be permitted to switch back to a previously trialed biologic agent/complement inhibitor if they were deemed unresponsive to therapy.

- Patients will be permitted to switch from one biologic agent/complement inhibitor to another following an adequate trial of the first biologic agent/complement inhibitor if unresponsive to therapy, or due to serious adverse effects or contraindications. An adequate trial is defined as at a minimum the completion of induction dosing (e.g. initial coverage period).
- Initial Approval: Initial coverage may be approved for up to 32.4 mg daily for a period of 6 months.
- Renewal: After the initial 6 months, reassessment will be every 12 months.
- Subsequent renewals will require the physician reassessment confirming proof of no worsening of MG-ADL score.

Please visit the link below if you require our standard special authorization form:
https://www.gov.nl.ca/hcs/files/prescription-standard-specauth-form.pdf

Updated May 2026

Health and Community Services

Ziprasidone (Zeldox 20mg, 40mg, 60mg & 80mg)

For the treatment of schizophrenia and related psychotic disorders (not dementia related) in patients:

- with a history of inadequate response or intolerance to at least one less expensive antipsychotic agent

OR

- who have a contraindication to less expensive options.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated December 2016

Health and Community Services

ZOLMITRIPTAN nasal spray (ZOMIG 2.5 MG/DOSE nasal spray)

For the treatment of patients with acute migraine attacks who have an intolerance or insufficient response to all triptans listed as regular benefit (e.g. almotriptan, rizatriptan, sumatriptan, zolmitriptan).

Coverage limited to 6 doses / 30 days[1]

- More than 6 doses / 30 days considered for patients with >3 migraines/month on average despite prophylactic therapy (up to a maximum of 12 doses / 30 days).

[1]Reimbursement will be available for a maximum quantity of 6 triptan doses per 30 days regardless of the agent(s) used within the 30 day period.

Please visit the following link if you require our standard special authorization form:
http://www.health.gov.nl.ca/health/prescription/standard_specauth_form.pdf

Updated May 2018