



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 (≥ 15 mg 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

In combination with endocrine therapy for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, HER2-negative, node-positive early breast cancer at high risk of disease recurrence based on clinicopathological features and a Ki-67 score of at least 20%.

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. Patients must not have metastatic disease, inflammatory breast cancer, or prior treatment with a CDK4/6 inhibitor.
3. Treatment with abemaciclib should continue until confirmed disease progression or unacceptable toxicity or completion of 2 years of adjuvant therapy. Endocrine therapy can continue as monotherapy after the 2 years of abemaciclib.

Claim Notes:

- Retreatment with a CDK4/6 inhibitor may be reasonable in the metastatic setting if disease recurrence occurs greater than or equal to 6 months after completion of adjuvant abemaciclib.
- Approval period: 1 year
- Renewal 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 2023



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

In combination with prednisone 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.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- 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 \geq 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

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

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 have had an inadequate response to other systemic drugs (e.g., steroid or biologic), or for whom these treatments are not advisable.

Initiation Criteria

- Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:
 - Maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and
 - Maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)
- The physician must provide the Eczema Area and Severity Index (EASI) score and Investigator (Physician) Global Assessment score 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 2023



Health and Community Services

ACALABRUTINIB (CALQUENCE) 100MG CAPSULE and TABLET

1. As monotherapy for adult patients with relapsed or refractory chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) who have received at least one prior therapy.
2. As monotherapy for adult patients with previously untreated chronic lymphocytic leukemia (CLL) / small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is considered inappropriate due to high-risk cytogenetic markers (i.e., del17p, TP53 mutation, 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 Notes:

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

ACLIDINIUM BROMIDE (TUDORZA GENUAIR 400MCG INHALER)

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients:

- Experiencing persistent symptoms, as defined by a Medical Research Council (MRC) score of at least 3² or a COPD Assessment test (CAT) score ≥ 10 ³ and a post-bronchodilator FEV₁ < 80% predicted.

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids

OR

- at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.

1. COPD diagnosis as defined by spirometry is a post-bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered. In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., MRC dyspnea scale score of at least Grade 3)
2. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
3. The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Triple therapy:

COPD:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD.
- Combination therapy with LAAC/LABA/ICS will be considered for the treatment of COPD as defined by spirometry in patients who have inadequate control while being treated with a LAAC/LABA combination for at least 2 months.
- Inadequate control is defined as persistent symptoms or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 severe exacerbation of COPD requiring hospitalization.

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

Clinical Notes:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



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, **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 citrate free** 40mg/0.8ml PREFILLED SYRINGE, 40mg/0.8ml PREFILLED PEN, **IDACIO** PREFILLED AUTOINJECTOR 40mg/0.8ml, **HYRIMOZ**, 20mg/0.4ml PREFILLED SYRINGE, **HYRIMOZ** 40mg/0.8ml PREFILLED SYRINGE, **HYRIMOZ** 40mg/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 (≥ 15 mg 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:
 - Adalimumab: 40mg every two weeks 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.

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
- Approvals will be for a maximum of 40mg every two 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, 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 a maximum of 40mg every two weeks.
- Initial Approval: 12 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>

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.
- Approvals will be for a maximum of 40mg every two weeks.
- Initial approval period: 16 weeks
- 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>

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 a maximum of 160mg followed by 80 mg two weeks later, then 40mg every two weeks.
- Initial Approval: 12 weeks.
- Renewal Approval: 1 year. Confirmation of continued response is required.
- It is recommended that clinical response to adalimumab be assessed four weeks after the first induction dose, 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>

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.
- Approvals will be for a maximum of 80mg followed by 40mg in one week, then 40mg every two weeks thereafter.
- Initial Approval: 16 weeks.
- Renewal Approval: 1 year.
- Ongoing coverage for adalimumab 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>

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 ≥ 40 mg 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.
- 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.
- 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.
- Adalimumab should only be continued in patients who have responded during the first 8 weeks of therapy.
- Initial Approval: 8 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>

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 of oral antibiotics
- Prescribed by a practitioner with expertise in the management of patients with HS.

Initial renewal criteria:

- Requests for renewal should provide objective evidence of a treatment response, defined as at least a 50% reduction in inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline at week 12.

Note: treatment with adalimumab should be discontinued if there is no improvement after 12 weeks of treatment.

Subsequent renewal criteria:

- 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 adalimumab).

Claim Notes:

- Must be prescribed by a dermatologist or physician with experience in the treatment of HS.
- 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.
- Initial approval period: 12 weeks.
- Renewal 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 April 2024



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 2 MG/0.05 ML VIAL)*

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 both of the following criteria:

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

***Effective December 12, 2019, intravitreal bevacizumab will be the preferred therapy for:**

- treatment naïve patients,
- NLPDP beneficiaries who did not have a paid claim for Lucentis/Eylea under NLPDP between December 13, 2018 and December 12, 2019, and
- beneficiaries currently receiving Avastin.

Patients who have failed to respond to three injections of Avastin, have contraindications to the use of Avastin or are unable to tolerate Avastin will require a written request from their ophthalmologist detailing their contraindication(s) as noted below to access Lucentis or Eylea.

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

Grandfathering

Beneficiaries of the NLPDP that have had a paid claim for Lucentis or Eylea during the period **December 13, 2018 to December 12, 2019** will be grandfathered to continue on their current therapy, unless they have already switched to Avastin. In cases where a switch to Avastin has already occurred, beneficiaries should continue unless contraindicated.

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 October 2023



Health and Community Services

ALECTINIB (ALECENSARO 150MG CAPSULES)

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.
- Initial approval period: 1 year.
- Renewal approval period: 1 year.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions on different days with a single professional fee paid per 30 day supply.

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



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 authorization 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 authorization form:

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

Updated August 2021



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.ni.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



Health and Community Services

AMBRISANTAN (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) 60 MG TABLET

Non-metastatic Castration-resistant Prostate Cancer

In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer 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.
- 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 apalutamide will not be considered for patients who experience disease progression on enzalutamide.
- 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.ni.ca/health/prescription/standard_specauth_form.pdf

Updated March 2022



Health and Community Services

A POMORPHINE (KYNMOBI 10mg, 15mg, 20mg, 25mg, 30mg soluble film)

For the acute, intermittent treatment of “off” episodes in patients with Parkinson’s disease (PD), if the following criteria are met:

Clinical Note:

- Used as adjunctive therapy in patients who are experiencing “off” episodes despite receiving optimized PD therapy (levodopa and derivatives and adjunctive therapy such as dopaminergic agonists or MAO-B inhibitors or amantadine derivatives).
- Treatment should be discontinued unless an improvement of least 3.25 points is achieved in the Movement Disorders Society Unified Parkinson’s Disease Rating Scale Part III (MDS-UPDRS III) score measured within 30–60 minutes after a titrated dose is achieved. This assessment should occur not more than one year after apomorphine sublingual has been titrated to a stable and tolerated dose.
- The maximum amount required should not exceed five films per day or 90 mg in total (whichever is reached first).

Claim Notes:

- The patient must be under the care of a physician experienced in the diagnosis and treatment of Parkinson’s disease (PD).
- 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 2022



Health and Community Services

Aprepitant (Emend 80mg and 125mg tablets)

In combination with a 5-HT₃ 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 $\geq 70\text{mg}/\text{m}^2$) in patients who have experienced emesis despite treatment with a combination of a 5-HT₃ antagonist and dexamethasone in a previous cycle of highly emetogenic chemotherapy.

Please Note: The 5HT₃ antagonist should only be used on the first day of chemotherapy (eg cisplatin $\geq 70\text{mg}/\text{m}^2$) 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

ASCIMINIB (SCEMBLIX 20mg, 40mg tablets)

For the treatment of adult patients with chronic phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) who meet all of the following criteria:

- Treatment failure on or intolerance to two or more prior tyrosine kinase inhibitor (TKI) therapies; and
- Have no evidence of T315i or V299L mutations.

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. Requests will not be considered for patients with CML in accelerated phase or blast phase.

Claim Notes:

- 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 August 2023



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



Health and Community Services

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

For the prevention of migraine headaches in patients with a confirmed diagnosis of episodic 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.

Claim Notes:

- Coverage will not be considered in combination with other CGRP inhibitors for the prevention of migraine in adult patients with episodic migraine.
- The patient should be under the care of a physician with 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 special authorization form:
<https://www.gov.nl.ca/hcs/files/Standard-Special-Authorization-Form.pdf>

Updated April 2024

AXITINIB (INLYTA) 1 MG and 5 MG TABLET

For the treatment of patients with advanced or metastatic renal cell carcinoma when used as:

- first line therapy in combination with pembrolizumab
- second line therapy following disease progression on a vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI), or
- third line therapy following disease progression on first line nivolumab and ipilimumab combination therapy and a 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 May 2021



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 tobramycin¹.

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

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 m².

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 m² 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 m²
- 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

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/ μ L AND has experienced two or more clinically significant asthma exacerbations in the past 12 months
 - blood eosinophil count of ≥ 150 cells/ μ L 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:

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

Updated February 2021



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 reinstated.

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



Health and Community Services

BIMEKIZUMAB (BIMZELX 160mg/ml pre-filled syringe, 160mg/ml autoinjector)

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, 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 (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 is defined as:

- 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:

- 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.
- Must be prescribed by a dermatologist or physician experienced in the treatment of moderate to severe plaque psoriasis.
- Patients who experience gastrointestinal intolerance to PO methotrexate must have a trial of parenteral methotrexate before being accepted as refractor.
- Patients will not be permitted to switch back to a previously trialed biologic agent if they had an unsatisfactory response to treatment.
- Combined use of more than one biologic drug will not be reimbursed.
- Approvals will be for 320 mg given every 4 weeks for 16 weeks then 320 mg every 8 weeks thereafter.
- 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/Chronic-Plaque-Psoriasis-Medications.pdf>

Updated November 2023



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

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



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)

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 December 2018



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 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.
- 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: 16 weeks.
- 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 October 2023



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



Health and Community Services

BUDESONIDE/FORMOTEROL (SYMBICORT 100ug, 200ug)

Reversible Obstructive Airway Disease:

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of COPD, as defined by spirometry¹:

- When the LABA/ICS is part of **triple therapy** in patients with COPD.

Triple therapy: Combination therapy with LAAC/LABA/ICS will be considered for the treatment of COPD, as defined by spirometry in patients who have inadequate control² while being treated with a LAAC/LABA combination for at least 2 months.

OR

- In patients with **asthma/COPD (ACO) overlap** based on patient history and lung function studies indicating an ACO diagnosis
 - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

1. COPD diagnosis is defined by spirometry as a post bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered.

In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 severe exacerbation of COPD requiring hospitalization.

Clinical Notes

Triple therapy COPD:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD.
- LAAC coverage will be provided for the previously used LAAC/LABA combination product unless otherwise indicated on the special authorization request.

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



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 listing criteria 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.ni.ca/health/prescription/standard_specauth_form.pdf

Updated November 2022



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

Updated July 2022



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

Updated July 2022



Health and Community Services

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

Metastatic Renal Cell Carcinoma

For the treatment of patients with advanced or metastatic renal cell carcinoma who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy when used as:

- second-line therapy following disease progression on sunitinib, pazopanib, or pembrolizumab in combination with axitinib; or
- third-line therapy following disease progression on immunotherapy and VEGF TKI (i.e., sunitinib or pazopanib), used in any sequence.

Renewal Criteria:

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

Clinical Note:

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

Claim Notes:

- Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy.
- Initial approval period: 1 year.
- Renewal 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 atezolizumab in combination with bevacizumab.

- 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 September 2021



Health and Community Services

CANAGLIFLOZIN (INVOKANA 100mg, 300mg TABLET)

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

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.pdf>

Updated October 2023



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

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)

Initiation Criteria:

For the treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2) disease/ tripeptidyl peptidase I (TPP I) deficiency, in patients who meet the following criteria at the time of treatment initiation:

- Diagnosis of CLN2 disease is confirmed by TPPI enzyme activity and CLN2 genotype analysis; **AND**
- CLN2 Rating Scale demonstrates the following requirements:
 - A minimum score 2:1 in each of the motor and the language domains; **AND**
 - An aggregate motor-language score of 2: 3 on the CLN2 Clinical Rating Scale

AND

- Patient is under the care of a special list with expertise in the diagnosis and management of CLN2 disease.

Approval duration of initials: **24 weeks**

Discontinuation Criteria for Brineura:

Patients must be reassessed every 24 weeks for changes in motor and language score of the CLN2 Clinical Rating Scale.

Treatment with Brineura will be discontinued if:

- There is reduction of 2: 2 points in the aggregate motor-language score of the CLN2 Clinical Rating Scale that is maintained over any 2 consecutive 24-week assessments; **OR**
- The aggregate motor-language score of the CLN2 Clinical Rating Scale reaches 0 (zero) at 2 consecutive 24-week assessments.

Recommended 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 March 2020



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 (≥ 15 mg 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: 1 year with renewal requiring reassessment.

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

Chlorhexidine Gluconate 0.12% Mouthwash (Gum Pareox)

For the treatment of oral mucositis in patients receiving chemotherapy or radiotherapy related to cancer treatment.

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 January 2017



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 tract 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 tract 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



Health and Community Services

CLADRIBINE (MAVENCLAD 10MG TABLET)

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

- Confirmed diagnosis based on McDonald criteria
- Has 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)

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 with experience in the treatment of multiple sclerosis.
- Approvals will be for 1.75mg/kg to a maximum of 200mg per treatment year.
- Approval period: 2 years.

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 2021



Health and Community Services

Clozapine (Clozaril, Gen 25mg, 50mg, 100mg, 200mg, Apo 25mg, 100mg)

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, akathisia 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 February 2015

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)

For second-line treatment for patients with ALK-positive advanced non-small cell lung cancer (NSCLC), with an ECOG performance status of 0-2.

OR

For first-line treatment for patients with an ALK-positive NSCLC, with an ECOG performance status of 0-2.

OR

For first-line treatment for patients with ROS1-positive non-small cell lung cancer (NSCLC) as monotherapy, with an ECOG performance status of 0-2.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression AND who have not developed unacceptable toxicities that require discontinuation of crizotinib.

Claim Notes:

- Approval period: 6 months
- Recommended Dose: 250mg twice 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 2020



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 cystinosis (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 cystinosis, 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

DAPAGLIFLOZIN / METFORMIN HCL (XIGDUO 5 MG-850 MG, 5 MG-1000 MG TABLET and generics)

For the treatment of type 2 diabetes mellitus in patients with inadequate glycemic control on metformin and a sulfonylurea and who are not using insulin AND who are already stabilized on therapy with metformin, a sulfonylurea and dapagliflozin, to replace the individual components of dapagliflozin and metformin in these patients.

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

Updated October 2023



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



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

DAROLUTAMIDE (NUBEQA) 300 MG TABLET

In combination with androgen-deprivation therapy (ADT) for the treatment of patients with non-metastatic 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 3 PSA rises at least one week apart, with the last PSA > 2 ng/mL.
2. Castrate levels of testosterone must be maintained.
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.
- Initial approval period: 1 year
- Renewal approval period : 1 year



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



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 (PROLIA 60 MG/ML 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:

1. 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.
2. 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 ($\geq 20\%$) as defined by the CAROC or FRAX tool.

Updated on July 2022



Health and Community Services

DENOSUMAB (XGEVA 120 MG/1.7 ML 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 April 2014



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 \leq 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



Health and Community Services

DOLUTEGRAVIR (TIVICAY 50 MG TABLET)

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



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

DULOXETINE (CYMBALTA 30mg & 60mg & generics)

For the treatment of chronic pain in patients who:

- have had an inadequate response or intolerance to at least one first-line agent.

Clinical Note:

- First-line agents include gabapentin and pregabalin for chronic neuropathic pain and non-steroidal anti-inflammatory drugs for chronic non-neuropathic pain.

Dose to be limited to a maximum of 60mg 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 May 2021



Health and Community Services

DUPIUMAB (DUPIXENT 150 mg/mL prefilled syringe, 175 mg/mL prefilled syringe, 300 mg single-dose prefilled pen)

For the treatment of moderate to severe atopic dermatitis in patients 12 years of age and older who meet all of the following criteria:

Initiation criteria

- Refractory to or have contraindication to an adequate trial with topical prescription therapies, and
- Refractory, intolerant to or have contraindications phototherapy (where available), methotrexate, and cyclosporine, and
- Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Score of 7.1.

Renewal criteria

- Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation.
- Proof of maintenance of EASI-75 response from baseline every six months for subsequent authorizations.

Clinical Note:

- Dupilumab is not to be used in combination with phototherapy or immunosuppressant drugs, such as methotrexate or cyclosporine.

Claim Notes:

- Must be prescribed by a dermatologist.
- Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter.
- Initial approval period: 6 months.
- Renewal approval period: 6 months.

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

<https://www.gov.nl.ca/hcs/files/Special-Authorization-Form-Dupixent.pdf>

Updated October 2023



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

Efavirenz/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**:

- **Efavirenz/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

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 \leq 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/IVACAFTON/IVACAFTOR (TRIKAFTA)
100mg/50mg/75mg/150mg TABLET, 50mg/25mg/37.5 mg/75 mg TABLET)**

For the treatment of patients aged 6 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

Initial coverage:

The patient must meet the following

- Confirmed diagnosis of CF with at least one F508del mutation in the CFTR gene.
- Patients should be optimized with best supportive care for their CF at the time of initiation.

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 FEV₁ 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: 1 year
- 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 July 2023



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 GALNS¹ 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 keratan sulfate (KS) determination: specific KS determination is preferred over total glycosaminoglycans (GAGs)
- Cardiac echocardiogram

¹Note: 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 \geq 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 and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.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 October 2023



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 a sulfonylurea and who are not using insulin AND who are already stabilized on therapy with metformin, a sulfonylurea and empagliflozin, to replace the individual components of empagliflozin and metformin in these patients

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

Updated October 2023



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



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 \leq 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 efavirenz 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)

Men Who Have Sex With Men (MSM) and Transgender Women (TGW):

For pre-exposure prophylaxis (PrEP), in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in adults at high risk who report condomless anal sex within the last six months and any of the following:

- Infectious syphilis or rectal bacterial sexually transmitted infection (STI), particularly if diagnosed in the preceding 12 months;
- Recurrent use of nonoccupational postexposure prophylaxis (nPEP) (more than once);
- Ongoing sexual relationship with an HIV-positive partner who is not receiving stable ART and/or does not have an HIV viral load <200 copies/ mL. (i.e. not on ART or >200 copies/mL); or
- High-incidence risk index (HIRI)-MSM risk score ≥ 11 .
Please refer to the [BC-CfE PrEP guidelines](#) or the [Canadian PrEP Guidelines](#) which include details about how to calculate the HIRI-MSM risk score.

Heterosexual exposure:

For pre-exposure prophylaxis (PrEP), in combination with safer sex practices, to reduce the risk of sexually acquired HIV-1 infection in heterosexual men and women at high risk of acquiring HIV infection who meet both of the following:

- Condomless vaginal or anal sex; and
- Ongoing sexual relationship with an HIV-positive partner who is not receiving stable ART and/or does not have an HIV viral load <200 copies/ mL. (i.e. not on ART or >200 copies/mL).

People who inject drugs (PWID):

For pre-exposure prophylaxis (PrEP) for PWID who are at high risk of acquiring HIV infection and meet both of the following:

- Report sharing of injection equipment; and
- Have an HIV-positive injecting partner who is not receiving stable ART and/or does not have an HIV viral load < 200 copies/mL.

Clinical notes:

- PrEP should be part of a combination prevention strategy that includes behavioural interventions such as condoms and risk reduction counseling.
- PrEP is not recommended in the context of a stable closed relationship with a single partner with no or negligible risk of having transmissible HIV.

Claim Notes:

- It is suggested that patients be monitored with repeat EGFR and adherence after first 30 days.
- Although special authorization approvals will be for a 1 year period, prescriptions should only be issued every 3 months after confirmation of a negative HIV test.
- Approval period: 1 year

Please NOTE:

For initial consultation, please contact Dr. Debbie Kelly at 709-864-7805 or by email at dvkelly@mun.ca.

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 October 2023



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



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 **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 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.

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 2023



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

ENZALUTAMIDE (Xtandi) 40MG CAPSULES

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.

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.

Non-metastatic Castration-resistant Prostate Cancer

In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic 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.

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



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

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



Health and Community Services

EPTINEZUMAB (VYEPTI 100MG/ML 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:

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

Updated October 2023



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 $> 176\mu\text{mol/L}$ (2mg/dL) OR GFR $< 1\text{ml/sec}/1.73\text{m}^2$ (60 mL/min/1.73m²) for three or more months AND who have an anemia work-up showing hemoglobin $< 100\text{g/L}$ (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 $\leq 90\text{g/L}$ 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



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)

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 (≥ 15 mg 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:
 - 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.

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 week.
- 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>

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.
- Approvals will be for a maximum of 0.8mg/kg, up to 50mg per week.

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.
- Approvals will be for a maximum of 50mg per week.
- 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 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 50mg twice weekly for 12 weeks then 50mg weekly for maintenance. 12 week initial approval

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 October 2023



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

**EVOLOCUMAB (REPATHA 140 MG/ML PREFILLED AUTOINJECTOR, 120mg/ml
AUTOMATED MINI-DOSER WITH PREFILLED CARTRIDGE)**

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:

- Maximum dose approved: 140mg every 2 weeks or 420mg monthly.
- 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

FARICIMAB (VABYSMO 6 mg/0.05 mL VIAL)

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 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%,

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 November 2023



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.
- 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 2023



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

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 the treatment of patients with Clostridium Difficile Infection (CDI), where the patient has:

- a second or subsequent recurrence following treatment with oral vancomycin; or
- treatment failure with oral vancomycin for the current CDI episode; or
- an intolerance or contraindication to oral vancomycin.

Re-treatment criteria:

- Re-treatment with fidaxomicin will only be considered for an early relapse occurring within 8 weeks of the start of the most recent fidaxomicin course.

Clinical Notes:

1. Treatment failure is defined as 14 days of vancomycin therapy without acceptable clinical improvement.
2. Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented.

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 January 2019



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 ≤ 70 kg use 1ml vial (300ug).
- Patients > 70 kg 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 $\leq 0.1 \times 10^9$ 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 m² 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 m² 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



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 courses¹ of at least one at least one disease modifying therapy publicly listed on the NLPDP Formulary ; **OR** documented intolerance² 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.)

Requirements for Initial Requests:

- 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.

Renewal requests will be considered:

- 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 fingolimod 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/m² 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

Fluoxetine 20mg/5ml liquid

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 2010



Health and Community Services

FLUTICASONE/SALMETEROL (ADVAIR DISKUS 100ug, 250ug, 500ug, ADVAIR MDI 125ug, 250ug and generics)

Reversible Obstructive Airway Disease:

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of COPD, as defined by spirometry¹:

- When the LABA/ICS is part of **triple therapy** in patients with COPD.

Triple therapy: Combination therapy with LAAC/LABA/ICS will be considered for the treatment of COPD, as defined by spirometry in patients who have inadequate control² while being treated with a LAAC/LABA combination for at least 2 months.

OR

- In patients with **asthma/COPD (ACO) overlap** based on patient history and lung function studies indicating an ACO diagnosis
 - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

1. COPD diagnosis is defined by spirometry as a post bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered.

In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 severe exacerbation of COPD requiring hospitalization.

Clinical Notes

Triple therapy COPD:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD.
- LAAC coverage will be provided for the previously used LAAC/LABA combination product unless otherwise indicated on the special authorization request.

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

**FLUTICASONE FUROATE/UMECLIDINIUM/VILANTEROL (TRELEGY ELLIPTA
100mcg/62.5mcg/25mcg)**

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry, in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting anticholinergic (LABA/LAAC).

Clinical Notes:

- COPD diagnosis as defined by spirometry as a post-bronchodilator FEV1/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted.

In rare occasions when spirometry cannot be obtained, reasons must be clearly explained and other evidence of COPD severity provided (i.e. MRC Dyspnea Scale Score grade).

- Inadequate control while being treated with a LABA/LAAC is defined as persistent symptoms for at least two months, or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization.
- Patients should not be started on a LABA, LAAC and an inhaled corticosteroid (triple inhaled therapy) as initial therapy.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

FORMOTEROL (FORADIL 12ug CAPSULE FOR INHALATION, OXEZE 6ug, 12ug TURBUHALER)

Reversible Obstructive Airway Disease:

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control.

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients:

- Experiencing persistent symptoms, as defined by a Medical Research Council (MRC) score of at least 3² **or** a COPD Assessment test (CAT) score ≥ 10 ³ **and** a post- bronchodilator FEV₁ < 80% predicted.

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids

OR

- at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.

1. COPD diagnosis as defined by spirometry is a post-bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered. In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., MRC dyspnea scale score of at least Grade 3)
2. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
3. The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical notes

- Coverage for both a LAAC and LABA as two separate inhalers will not be considered.

Please visit the link below if you require the special authorization form:
<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



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

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/prescription-standard-specauth-form.pdf>

Updated April 2022



Health and Community Services

FULVESTRANT (FASLODEX 250MG/5ML SYRINGE and generics)

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 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

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.

Updated January 2022



Health and Community Services

GABAPENTIN (NEURONTIN 100mg, 300mg, 400mg, 600mg capsules and generics)

- For adjunctive management of epilepsy not satisfactorily controlled by conventional therapy.
- For the treatment of post-herpetic neuralgia, diabetic peripheral neuropathy, and post-traumatic neuropathic pain.
- For treatment of fibromyalgia.

Clinical Note:

Treatment should be reassessed in six months.

- For the treatment of alcohol use 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 May 2021



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/prescription-standard-specauth-form.pdf>

Updated March 2023

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



Health and Community Services

GLATIRAMER ACETATE (GLATECT 20 MG/ML SYRINGE, COPAXONE 20 MG/ML SYRINGE¹)

For the treatment of Multiple Sclerosis (MS) in patients who meet the following criteria:

- Written request from a neurologist.
- Subjects over 18 years.
- Confident diagnosis of relapsing-remitting, relapsing-progressive, or secondary progressive 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).

Claim Notes:

- New requests for coverage of Copaxone will not be considered.
- Glatect brand of glatiramer is the preferred glatiramer therapy who are treatment naïve.
- **coverage will only be considered for the Copaxone 20MG/ML¹ brand in patients stabilized prior to August 21, 2018)**

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 2018



Health and Community Services

GLECAPREVIR/PIBRENTASVIR (MAVIRET 100 MG-40 MG TABLET)

For treatment-naïve and treatment-experienced* adult patients with chronic hepatitis C infection:

	Approval Period
Genotype 1, 2, 3, 4, 5, or 6 • Treatment-naïve	8 weeks
Genotype 1, 2, 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: - Daclatasvir (DCV)/SOF; or - 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:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection).
- Laboratory confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6
- Patient has a quantitative HCV RNA value within the last six (6) months

****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.***

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 October 2023



Health and Community Services

GLUCAGON (BAQSIMI 3 mg nasal powder device)

For the treatment of severe hypoglycemia reactions in patients with diabetes mellitus who are receiving insulin therapy and are at high risk for severe hypoglycemia when impaired consciousness precludes oral carbohydrates.

Initiation and renewal criteria

- Patient is receiving insulin, and
- Patient is at high risk for severe hypoglycemia

Note:

- Approval will be provided to replace used or expired units as needed.
- The recommended dose of Baqsimi (glucagon) is 3 mg given intranasally in both adult and pediatric 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 2022



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 (≥ 15 mg 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

GUSELKUMAB (TREMIFYA® 100mg/ml Pre-filled Syringe, 100 mg/mL AUTO-INJECTOR)

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 on December 2023



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/Duobrii.pdf>

Updated October 2023



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)

1. For patients with previously untreated chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) for whom fludarabine-based treatment is considered inappropriate, such as patients with high risk disease (example: chromosome 17p deletion).
2. For patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or retreatment with a fludarabine-based regimen.
3. For the treatment of patients with relapsed / refractory mantle cell lymphoma (MCL)

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:

Sequential use of ibrutinib and Zydelig (idelalisib) will not be reimbursed. Exceptions may be considered in the case of intolerance or contraindication without disease progression, or when required as a bridge to allogeneic stem cell transplant.

Initial approval: 1 year

Renewal approval: 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 2018



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

**INDACATEROL/GLYCOPYRRONIUM/MOMETASONE (ENERZAIR BREEZHALER
150 mcg-50 mcg-160 rncg)**

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/prescription-standard-specauth-form.pdf>

Updated May 2022



Health and Community Services

INDACATEROL/GLYCOPYRRONIUM (ULTIBRO BREEZHALER 110-50 MCG)

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients who have inadequate control² while being treated with either long-acting beta₂ agonist (LABA) or long-acting anticholinergic (LAAC).

1. COPD diagnosis, as defined by spirometry, is a post bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered.

In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms after at least 1 month of LAAC or LABA; and an MRC score of at least 3 or a COPD Assessment test (CAT) score \geq 10).
 - MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
 - The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical Notes

- Coverage for LABA and LAAC as two separate inhalers will not be considered.
- LAAC/LABA inhalers are not intended to be used in combination with an inhaled corticosteroid (ICS) unless criteria for triple therapy is fulfilled.

Please visit the link below if you require our special authorization form:
<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

INDACATEROL ACETATE/MOMETASONE (ATECTURA BREEZHALER 150-80 mcg, 150 mcg-160 mcg, 150 mcg-320 mcg)

For the treatment of asthma in patients who are aged 12 years and older with reversible obstructive airways disease who are:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control.

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 2022



Health and Community Services

INFLIXIMAB (INFLECTRA 100MG Vial, RENFLEXIS 100MG/Vial, AVSOLA 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 (≥ 15 mg 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 Inflectra, Renflexis or Avsola to another infliximab product or vice versa, if previously trialed and deemed unresponsive to therapy.
- Initial Approval: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.

- 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.

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 physician with expertise in treating ankylosing spondylitis.
- Combined use of more than one biologic DMARD will not be reimbursed.
- Initial Approval: 6 months.
- Renewal Approval: 1 year.
- 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 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 5mg/kg induction (0, 2, 6 weeks) then every 8 weeks.

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: 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).
- 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>

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.
- Initial Approval: 3 infusions of infliximab 5mg/kg at week 0, 2 & 6.
- 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.

The maximum approved dose is 5mg/kg every 8 weeks.

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 have 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.)

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 sub-score ≥ 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 Approval: 12 weeks.
- Renewal Approval: 1 year.
- **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 October 2023



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



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

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



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



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 FEV₁ 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

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 AND Body Surface Area (BSA) involvement of at least 10%,
OR involvement of the face, hands, feet or genital regions,
- 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 (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 PSAI score, **or**
- Greater than or equal to 50% reduction in PSAI 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.
- Initial approval limited to 12 weeks.
- Approved for maintenance therapy not exceeding 80mg every four weeks.
- 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.

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 2023



Health and Community Services

LACOSAMIDE (VIMPAT 50mg, 100mg, 150mg & 200mg tablets and generics)

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**
- Who have had an inadequate response or intolerance to at least three 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 2022



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.ni.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
	<p>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.</p> <p>Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori.</p> <p>*A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.</p>	

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

LEDIPASVIR/SOFOSBUVIR (HARVONI 90mg/400mg TABLET)

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet all of the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other prescribers with expertise in the treatment of hepatitis C infection)
- Lab-confirmed hepatitis C genotype 1
- Quantitative HCV RNA value within the last 6 months.

Approval Period and Regimen	
Genotype 1 <ul style="list-style-type: none">• Treatment-naïve without cirrhosis, who have pre-treatment HCV RNA level < 6 million IU/mL and mono-HCV infected only	8 weeks
Genotype 1 <ul style="list-style-type: none">• 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 <ul style="list-style-type: none">• Treatment-experienced with compensated cirrhosis	24 weeks
Genotype 1 <ul style="list-style-type: none">• 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
- 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 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 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions on different days.
- 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 October 2023

LENALIDOMIDE (REVLIMID 2.5 MG, 5 MG, 10 MG, 15 MG, 20 MG & 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.
2. For the treatment of patients with multiple myeloma when used in combination with bortezomib and dexamethasone as induction therapy prior to autologous stem cell transplant.
3. For the treatment of relapsed or refractory multiple myeloma (MM-AOPT), when used:
 - In combination with dexamethasone for patients who have not progressed on lenalidomide: OR
 - In combination with carfilzomib and dexamethasone for patients who have not progressed on bortezomib or lenalidomide; OR
 - In combination with daratumumab and dexamethasone for patients who have not progressed on lenalidomide.
4. For the maintenance treatment of patients with newly diagnosed multiple myeloma, following autologous stem cell transplant, who have stable disease or better, with no evidence of disease progression. (NDMM)
 - Initial Dose: 10mg daily AND dose adjustments (5-15mg) may be necessary based on individual patient characteristics/responses

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:

- Lenalidomide will not be reimbursed for patients who have had disease progression on prior lenalidomide therapy.
- Initial approval period: 1 year.
- Renewal approval period: 1 year

Myelodysplastic Syndrome (MDS)

For the treatment of Myelodysplastic Syndrome (MDS) in patients with:

- Demonstrated diagnosis of MDS on bone marrow aspiration
- Presence of 5-q deletion documented by appropriate generic testing
- International Prognostic Scoring System (IPSS) risk category low or intermediate-1*
- Presence of symptomatic anemia (defined as transfusion dependent)**

* Calculator available on www.uptodate.com

** Requests for patients who are not transfusion-dependent will be considered on a case-by-case basis. The physician should provide clinical evidence of symptomatic anemia affecting the patient's quality of life and the rationale for why transfusions are not being used.

Renewal criteria:

- For patients who were transfusion-dependent and have demonstrated 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:

- 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 2023



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.

- 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 atezolizumab in combination with bevacizumab, 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 November 2023



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 (PDP-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 2023



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



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 treatment¹ of CAP in patients
 - with co-morbidity² upon radiographic confirmation of pneumonia, *or*
 - who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment¹ of AECB in complicated patients³ 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**

- FEV₁ < 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 a sulfonylurea and who are not using insulin AND who are already stabilized on therapy with metformin, a sulfonylurea and linagliptin, to replace the individual components of linagliptin and metformin in these patients

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

Updated October 2023



Health and Community Services

LINAGLIPTIN (TRAJENTA 5 MG TABLET)

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

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.pdf>

Updated October 2023



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)

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 extended release methylphenidate (Concerta and/or generics*), dextroamphetamine, or mixed salts amphetamine with unsatisfactory results.

Claim Notes:

- The maximum dose reimbursed is 60mg daily.
- Reimbursement will not be considered for Vyvanse concurrently with methylphenidate (immediate release or sustained release formulation), dextroamphetamine (immediate or sustained release formulation), or mixed salts amphetamine.

*Concerta and generics are now 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 September 2023



Health and Community Services

LIXISENATIDE (ADLYXINE 10 mcg/0.2 mL per dose, 20 mcg/0.2 mL per dose)

For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

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

Updated May 2022



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

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 $\geq 33\%$ 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 mecaseimerin 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

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

MEPOLIZUMAB (NUCALA 100 MG VIAL, NUCALA 100 MG/ML AUTO-INJECTOR, NUCALA 100 MG/ML SYRINGE)

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/ μ L AND has experienced two or more clinically significant asthma exacerbations in the past 12 months
 - blood eosinophil count of ≥ 150 cells/ μ L 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 Note:

Patients initiated on Nucala prior to July 19, 2019, the requirement for an ACQ baseline will be evaluated for renewal based on criteria (3) and (4) only. Such patients will be required to complete an ACQ at next available opportunity. Reimbursement should be discontinued if this ACQ score is not maintained subsequently.”

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

Methadone (Metadol 1mg, 5mg, 10mg, 25mg tablet)

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:

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

Updated July 2010



Health and Community Services

METHYLPHENIDATE (BIPHENTIN 10mg, 15mg, 20mg, 30mg, 40mg, 50mg 60mg, 80mg tablet)

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 extended release methylphenidate (Concerta and/or generics*), dexamphetamine 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 release formulation) or dexamphetamine (immediate release or sustained release formulation).

*Concerta and generics are now 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 February 2021



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:

- Must be eligibility for the disease specific 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



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 \(gov.nl.ca\)](http://www.health.gov.nl.ca/health/prescription/policies/Program-Claiming-Policies.pdf)

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

MOMETASONE/FORMOTEROL (ZENHALE 100ug-5ug, 200ug-5ug INHALER)

Reversible Obstructive Airway Disease (Asthma):

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control

OR

- In patients with **asthma/COPD (ACO) overlap** based on patient history and lung function studies indicating an ACO diagnosis
 - Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

Clinical Notes:

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

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 2023



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 treatment¹ of CAP in patients:

OR

- with co-morbidity² upon radiographic confirmation of pneumonia,
- who have failed first line therapies (macrolide, doxycycline, amoxicillin-clavulanate).
- For the treatment¹ of AECB in complicated patients³ 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**

- FEV₁ < 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 0.5mg, 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 June 2021



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 days¹

- 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).

¹Reimbursement 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 $\geq 10\%$ 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 $\geq 10\%$ 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 (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

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, OR
 - 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.

Discontinuation Criteria: For continued coverage, the patient must meet the following criteria:

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 response¹ 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).

¹Note that an inadequate response is defined as a patient who has used UDCA 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 $> \text{ULN}$ and $< 2 \times \text{ULN}$ **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 $1.67 \times \text{ULN}$; **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

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

Olanzapine Orally Disintegrating tablets (Zyprexa Zydis 5mg, 10mg, 15mg, 20mg tablets & generics)

Schizophrenia and related psychotic disorders:

- 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.

Bipolar Disorder:

- **Acute:** For the treatment of an acute episode of bipolar disorder following inadequate response or intolerance to another atypical antipsychotic.
- **Maintenance:** For maintenance therapy in those patients who have responded to acute treatment with olanzapine following inadequate response or intolerance to another atypical antipsychotic.

Coverage will be considered to a MAXIMUM daily dose of 30mg.

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

OLANZAPINE (ZYPREXA 2.5mg, 5mg, 7.5mg, 10mg, 15mg, 20mg and generics)

Schizophrenia and related psychotic disorders:

- 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.

Bipolar Disorder:

- **Acute:** For the treatment of an acute episode of bipolar disorder following inadequate response or intolerance to another atypical antipsychotic.
- **Maintenance:** For maintenance therapy in those patients who have responded to acute treatment with olanzapine.

Coverage will be considered to a MAXIMUM daily dose of 30mg.

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

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

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.

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.

¹Patients 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 January 2024



Health and Community Services

OMALIZUMAB (XOLAIR 150 MG VIAL, 150mg/ml prefilled syringe)

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.

Requirement for Initial Requests:

- Prescribed by a specialist (allergist, immunologist, dermatologist, etc.) or other authorized prescriber with knowledge of CIU treatment
- 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:

1. 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.
2. In patients who discontinue treatment due to temporary symptom control, re-initiation can be considered if CIU symptoms reappear.
3. Optimal management is defined as H1 antihistamines at up to 4 times the standard daily dose.

Claim Notes:

- Approvals will be for a maximum dose of 300mg every four weeks.
- Initial 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 November 2022



Health and Community Services

Ondansetron (Zofran 4mg, 8mg tablet and generics, 4mg ODT, 8mg ODT, 4mg/ml oral solution and generics)

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

Dolasetron 100mg tab: 1 tablet in a 24 hour period

The quantity limits above may only be filled as an open benefit for the first fill of any chemo anti-emetic 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.

Special Authorization criteria:

Coverage is considered for the treatment of emesis in patients who:

- are receiving **moderate to highly** emetogenic chemotherapy **OR**
- are receiving **mildly** emetogenic chemotherapy 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 chemo** for all patients (i.e. to a maximum of 9 tablets of ondansetron for a 1 day iv chemo regimen).
- Coverage will be limited to **one dose post-radiation** therapy.

In order to accurately assess requests for coverage, we require the following information:

For Chemotherapy:

- chemotherapy 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

Duration of approval will be for the full course of the chemotherapy regimen.

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 August 2011



Health and Community Services

OSELTAMIVIR (TAMIFLU 30mg, 45mg, 75mg capsules and generics)

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. *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.

* *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 January 2024



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 tumours 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:

- Patients must have a good performance status.
- 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.
- 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. 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. For the treatment of patients with locally advanced (not amenable to curative therapy) or metastatic EGFR T790M mutation-positive NSCLC who have progressed on EGFR tyrosine kinase inhibitor therapy.

Renewal Criteria:

- Written confirmation that the patient is responding to treatment.

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 first line therapy will be considered for patients with de novo EGFR T790M mutation-positive NSCLC.
- Requests will not be considered for patients who progress on, or within 6 months of, treatment with adjuvant EGFR targeted 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 September 2023



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 ≥ 40 mg 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

In combination with an aromatase inhibitor (e.g., letrozole) for the treatment of estrogen receptor positive, HER2 negative advanced breast cancer in postmenopausal women who:

- have not received prior therapy for advanced or metastatic disease, and
- are not resistant to (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:

- Sequential use of palbociclib and everolimus will not be reimbursed.
- Initial approval period: 1 year
- Renewal approval period: 1 year

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 progression on a CDK4/6 inhibitor, fulvestrant or everolimus.
- Initial approval period: 1 year
- Renewal approval period: 1 year

Updated February 2022



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 \leq 40mg daily (20mg and 40mg 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
	<p>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.</p> <p>Additional treatments within one year will require diagnostic confirmation of the continued presence of H. pylori.</p> <p>*A PPI at BID dosing will be reimbursed with special authorization as part of an approved H. pylori eradication regimen for 14 days.</p>	

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



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 III B, 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, 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 December 2021



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)

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 February 2023



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



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 $\geq 10\%$ 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 $\geq 10\%$ 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 tablets

For the treatment of patients with chronic phase, accelerated phase or blast phase chronic myeloid leukemia (CML) or Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL) and with ECOG performance status 0-2 for whom other tyrosine kinase inhibitor (TKI) therapy is not appropriate, including CML or Ph+ ALL that is T315i mutation positive or where there is resistance or intolerance to prior TKI therapy. Treatment should continue until unacceptable toxicity or disease progression.

Other TKI therapy is not considered appropriate in the following circumstances:

- for treatment of patients who have confirmed T315i mutation positive disease, independent of previous TKI therapy
- for the treatment of patients with chronic phase, accelerated phase or blast phase CML, or Ph+ ALL who have resistance/disease progression after at least two prior lines of TKI therapy where Iclusig would be available as third line TKI option, or who have intolerance to prior TKI therapy.

Initial Approval Period: 3 months

Approval Period with Hematological Response: 12 months

Recommended Starting Dose: 45mg once daily

Dose may be reduced to 15mg daily with major cytogenetic response (MCyR).

Renewal requests require assessment of hematologic and cytogenetic response.

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

PRASUGREL generic 10 MG TABLET

In combination with ASA for patients with:

- unstable angina (UA) or non-ST-segment elevation myocardial infarction (NSTEMI) managed with percutaneous coronary intervention (PCI); or
- ST-segment elevation myocardial infarction (STEMI) managed with primary or delayed PCI; or
- failure on clopidogrel and ASA therapy as defined by definite stent thrombosis, or recurrent STEMI, NSTEMI or UA after revascularization with PCI.

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: 1 year.

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

<https://www.gov.nl.ca/hcs/files/Antiplatelet-Therapy-Form.pdf>

Updated October 2021



Health and Community Services

PREGABALIN generic 25mg, 50mg, 75mg, 150mg, 225mg, 300mg CAPSULE

- For the treatment of post-herpetic neuralgia, diabetic peripheral neuropathy, and post-traumatic neuropathic pain.
- For treatment of fibromyalgia.

Clinical Note:

- Treatment should be reassessed in six 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

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



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



Health and Community Services

RANIBIZUMAB (BYOOVIZ 10 mg/mL (0.23 mL/vial INTRAVITREAL, LUCENTIS 2.3 MG/0.23 ML VIAL, RANOPTO 10 mg/mL (0.23ml/vial), LUCENTIS 0.5 MG/0.05ML SYRINGE)

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.

Ranibizumab biosimilar(s) will be the preferred ranibizumab option for all ranibizumab-naïve patients prescribed a ranibizumab product. Preferred means the ranibizumab product to be considered for reimbursement for ranibizumab-naïve patients.

All Special Authorization (SA) requests for coverage of *ranibizumab* for **ranibizumab-naïve patients** requiring the drug for the indications listed below will be assessed for the biosimilar of *ranibizumab* only.

Patients will not be permitted to switch from Byooviz to Lucentis or another *ranibizumab* product or vice versa, if previously trialed and deemed unresponsive to therapy.

Please Note: patients presenting as new patients under NLPDP will be preferentially assessed for a ranibizumab biosimilar, regardless if the client had been using Lucentis prior to becoming an NLPDP patient.

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 April 2024



Health and Community Services

REGORAFENIB (STIVARGA) 40 MG TABLET

Advanced Hepatocellular Carcinoma

For the 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.
- Initial approval period: 4 months.
- Renewal approval period: 6 months.

Gastrointestinal Stromal Tumor

For the treatment of patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib and who have an 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 Note:

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

Claim Notes:

- 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 January 2021

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

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

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)
(DIN numbers 02412764, 02412772, 02412799, 02412802 and 02412810)**

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 June 2015



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)

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.
- Approvals will be for a maximum of 150 mg at weeks 0 and 4, then every 12 weeks thereafter.
- 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/Chronic-Plaque-Psoriasis-Medications.pdf>

UPDATED October 2023



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

Risedronate (Actonel 30mg tablets and generics)

- For the treatment of Paget's Disease.

Coverage will be limited to a 2 month approval.

Risedronate (Actonel 5mg and 35mg tablets and generics)

- For the treatment of osteoporosis associated with documented fracture.
- For the treatment of osteoporosis without documented fracture when a patient has a high 10 year fracture risk (based on age, sex and T-score, **see Appendix 1 below for fracture risk table**).
- As prophylaxis of corticosteroid induced osteoporosis in patient who will be or have been on systemic corticosteroid therapy for > 3 months.

Please note:

Alendronate 10mg & 70mg is open benefit for beneficiaries 65 years of age and older regardless of plan.

Appendix 1

10 Year Absolute Fracture Risk based on BMD

Age (yrs)	WOMEN			Age (yrs)	MEN		
	Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%		Low Risk < 10%	Moderate Risk 10% - 20%	High Risk > 20%
50	> - 2.3	- 2.3 to - 3.9	< - 3.9	50	>-3.4	≤-3.4	---
55	> - 1.9	- 1.9 to - 3.4	< - 3.4	55	>-3.1	≤-3.1	---
60	> - 1.4	- 1.4 to - 3.0	< - 3.0	60	>-3.0	≤-3.0	---
65	> - 1.0	- 1.0 to - 2.6	< - 2.6	65	>-2.7	≤-2.7	---
70	> - 0.8	- 0.8 to - 2.2	< - 2.2	70	>-2.1	-2.1 to -3.9	<-3.9
75	> - 0.7	- 0.7 to - 2.1	< - 2.1	75	>-1.5	-1.5 to -3.2	<-3.2
80	> - 0.6	- 0.6 to - 2.0	< - 2.0	80	>-1.2	-1.2 to -3.0	<-3.0
85	> - 0.7	- 0.7 to - 2.2	< - 2.2	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 January 2016



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

Risperidone (Risperdal M-tab 0.5mg, 1mg, 2mg, 3mg, 4mg & generics)

- For the treatment of schizophrenia and related psychotic disorders in patients unable to be treated with the regular oral risperidone 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 December 2016



Health and Community Services

RITUXIMAB (RUXIENCE 10 MG/ML VIAL, RIXIMYO 10 MG/ML VIAL, TRUXIMA 100 MG/10 ML VIAL)

For the treatment of patients with rheumatoid arthritis¹, vasculitis², or other autoimmune disease³.

Clinical Notes:

1. Severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent.
2. Severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide.
3. 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 October 2023



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 (EVENTY 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 \geq 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

RUFINAMIDE (BANZEL 100mg, 200mg, 400mg TABLET)

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 May 2014



Health and Community Services

RUXOLITINIB PHOSPHATE (JAKAVI 5mg, 10mg, 15mg, 20mg tablet)

Acute Graft Versus Host Disease (aGvHD)

For the treatment of steroid-refractory or steroid-dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older who meet the following criteria:

- Patients with clinically diagnosed grade II to IV aGvHD according to the NIH criteria (Harris et al. [2016]) and
- Patients with a confirmed diagnosis of corticosteroid-refractory or corticosteroid-dependent aGvHD

Renewal:

- Initial approval: 4 weeks. Renewal will be considered in patients who have achieved an overall response (i.e., CR, VGPR, PR, or stable disease with significant reduction in steroid doses), according to standard NIH criteria at day 28 (approximately 4 weeks).
- For subsequent renewals, patients should be assessed for treatment response every 2 to 3 months, until the occurrence of any of the discontinuation criteria

Discontinuation:

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

- Progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms;
- unacceptable toxicity;
- addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28; and/or
- recurrence or relapse of underlying hematological malignancy.

Prescribing:

- Must be prescribed by physicians with expertise with the diagnosis and management of aGvHD.
- Treatment with ruxolitinib must not be added to patients' concurrent treatment of systemic therapies for the treatment of aGvHD other than steroids ± calcineurin inhibitors.

Chronic graft-versus-host disease (cGvHD)

For the treatment of chronic graft-versus-host disease (cGvHD) in adults and pediatric patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies.

Initiation:

- Treatment should be initiated in patients who have clinically diagnosed cGvHD staging of moderate to severe based on NIH consensus criteria; and
- Patients should have a confirmed diagnosis cGvHD with inadequate response to corticosteroids or other systemic therapies.

Renewal:

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

Discontinuation:

Treatment 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; or
- recurrence or relapse of underlying hematological malignancy.

Prescribing:

- Must be prescribed by a physician with expertise in the diagnosis and management of cGvHD.
- Treatment must not be added to patients' concurrent treatment of systemic therapies other than steroids ± calcineurin inhibitors.

Myelofibrosis

- For patients with intermediate to high-risk symptomatic Myelofibrosis (MF) as assessed using the Dynamic International Prognostic Scoring System (DIPSS) Plus or patients with symptomatic splenomegaly. Patients should have ECOG performance status ≤ 3 and be either previously untreated or refractory to other treatment.

Polycythemia vera

- For the treatment of patients with polycythemia vera who have disease resistant to hydroxyurea (HU) or who are intolerant of HU according to the modified European LeukemiaNet Criteria used in the RESPONSE trial and have a good performance status.

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

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 care 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.

Updated July 2023



Health and Community Services

SALMETEROL (SEREVENT 50MCG DISKUS)

Reversible Obstructive Airway Disease (Asthma):

For treatment of moderate to severe asthma in patients in whom:

- are compliant with inhaled corticosteroids at optimal doses; and
- require additional symptom control, (e.g., cough, awakening at night, missing activities such as school, work or social activities because of asthma symptoms); and
- require increasing amounts of short-acting beta₂-agonists, indicative of poor control

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients:

- Experiencing persistent symptoms, as defined by a Medical Research Council (MRC) score of at least 3² or a COPD Assessment test (CAT) score ≥ 10 ³ and a post- bronchodilator FEV₁ < 80% predicted.

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids

OR

- At least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.

1. COPD diagnosis as defined by spirometry is a post-bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered. In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., MRC dyspnea scale score of at least Grade 3)
2. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
3. The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical notes

- Coverage for both a LAAC and LABA as two separate inhalers will not be considered.

Please visit the link below if you require our special authorization form:
<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



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.

¹Pregnant 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 (≥ 15 mg 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 in patients with inadequate glycemic control on metformin and a sulfonylurea and who are not using insulin AND who are already stabilized on therapy with metformin, a sulfonylurea and saxagliptin to replace the individual components of saxagliptin and metformin in these patients.

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

<https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents.pdf>

Updated October 2023



Health and Community Services

SAXAGLIPTIN (ONGLYZA 2.5mg, 5mg and generics)

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

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.pdf>

Updated October 2023



Health and Community Services

SECUKINUMAB (COSENTYX 150mg/ml pre-filled syringe, pre-filled SensoReady 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 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.
- Initial approval for a maximum of 12 weeks.
- Coverage may be approved as follows: initial dosing of 300 mg doses at Weeks 0, 1, 2 and 3, followed by monthly maintenance dosing of 300 mg doses starting

at Week 4. If response criteria are met at 12 weeks, approval will be continued to a maximum dose of 300mg every month thereafter up to one year.

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>

SECUKINUMAB (COSENTYX 150mg/ml pre-filled syringe, pre-filled SensoReady pen)

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 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 October 2023



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

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 December 2023



Health and Community Services

SEMAGLUTIDE (OZEMPIC 2mg/1.5ml prefilled, 4mg/3ml prefilled pen, 0.68MG/ML SUBCUTANEOUS SOLUTION)

For the treatment of type 2 diabetes in combination with metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control.

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.

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.pdf>

Updated February 2024



Health and Community Services

SEMAGLUTIDE (RYBELSUS 3mg, 7mg, 14mg TABLET)

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes in either of the following:

- In addition to metformin in patients who do not achieve adequate glycemic control with metformin alone
- In addition to other antihyperglycemic agents
- Coverage will not be considered in combination with any other GLP-1 RA or with DPP-4 inhibitors.

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

<https://www.gov.nl.ca/hcs/files/Non-Insulin-Anti-Diabetic-Agents.pdf>

Updated February 2024



Health and Community Services

SEVELAMER CARBONATE (REVELA 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 arteriopathy)

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



Health and Community Services

Sildenafil (Revatio 20mg & generics)

Idiopathic Pulmonary Arterial Hypertension (IPAH) functional class III:

- For the treatment of patients with World Health Organization (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 and a sulfonylurea for patients with inadequate glycemic control on metformin and a sulfonylurea, in patients who are not using insulin.

Clinical Note:

- For patients who cannot take metformin and/or a sulfonylurea 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.pdf>

Updated October 2023



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 a sulfonylurea and who are not using insulin AND who are already stabilized on therapy with metformin, a sulfonylurea and sitagliptan, to replace the individual components of sitagliptan and metformin in these patients.

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

Updated October 2023



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 (CO₂) < 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



Health and Community Services

SODIUM PHENYLBUTYRATE and URSODOXICOLTAURINE (ALBRIOZA 3g/1g sachet)

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

- Adult patient with a diagnosis of definite ALS
- AND
- Has had ALS symptoms for 18 months or less
- AND
- Has a Forced Vital Capacity (FVC) of at least 60% of predicted value
- AND
- Does not require permanent noninvasive ventilation or invasive ventilation.

Discontinuation Criteria:

Treatment should be discontinued if any of the following are met:

- the patient requires invasive or permanent noninvasive ventilation.
- the patient becomes non-ambulatory and is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place.

Clinical Notes:

- The patient must be under the care of a specialist with experience in the diagnosis and management of ALS.
- FVC must be provided with initial request.
- Approval period: 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 August 2023



Health and Community Services

SOFOSBUVIR (SOVALDI 400 MG TABLET)

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative HCV RNA value within the last 6 months

	Approval Period and Regimen
Genotype 2 <ul style="list-style-type: none">• Without cirrhosis• With compensated cirrhosis	12 weeks in combination with ribavirin (RBV)
Genotype 3 <ul style="list-style-type: none">• 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 6 months.

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions on different days.
- 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 November 2023



Health and Community Services

SOFOSBUVIR/VELPATASVIR (EPCLUSA 400 MG-100 MG TABLET)

For treatment-naïve or treatment-experienced adult patients with chronic hepatitis C virus (HCV) who meet the following criteria:

- Prescribed by a hepatologist, gastroenterologist, or infectious disease specialist (or other physician experienced in treating a patient with hepatitis C infection).
- Lab-confirmed hepatitis C genotype 1, 2, 3, 4, 5, 6 or mixed genotypes
- Quantitative HCV RNA value within the last 6 months

Approval Period and Regimen	
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes <ul style="list-style-type: none">• Patients with compensated cirrhosis• Patients without cirrhosis	12 weeks
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes <ul style="list-style-type: none">• Patients with decompensated cirrhosis	12 weeks in combination with ribavirin

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 a patient who has been previously treated with a peginterferon/ribavirin regimen, including regimens containing HCV protease inhibitors 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) 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 6 months.

- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions on different days.
- 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 November 2023



Health and Community Services

SOFOSBUVIR/VELPATASVIR/VOXILAPREVIR (VOSEVI) 400MG/100MG/100MG TABLET)

For treatment-experienced¹ adult patients with chronic 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 6 months;

Approval Period	
Genotypes 1, 2, 3, 4, 5, 6 or mixed genotypes <ul style="list-style-type: none"> • Patients with compensated cirrhosis • Patients without 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: daclatasvir (Daklinza), elbasvir (as part of Zepatier), ledipasvir (as part of Harvoni), velpatasvir (as part of Epclusa)
- 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 6 months.
- Claims that exceed the maximum claim amount of \$9,999.99 must be divided and submitted as separate transactions on different days.

- **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 October 2023



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 atezolizumab in combination with bevacizumab, 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 January 2022



Health and Community Services

STIRIPENTOL (DIACOMIT 250mg, 500mg CAPSULE, 250mg, 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 arteriopathy)

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 days¹

- 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).

¹Reimbursement 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 days¹

- 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).

¹Reimbursement 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



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



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



Health and Community Services

TERBINAFINE (LAMISIL and generic brands)

250mg tablet

- Treatment of onychomycosis
- Treatment of dermatophyte infection unresponsive to other treatments or unlikely to respond to other treatments due to the site or severity of the infection.

Claim Notes:

- Approval limits payment for 6 weeks for the treatment of fingernail mycosis.
- Approval limits payment for 12 weeks for the treatment of toenail mycosis.

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

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, orchiectomy, 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, orchiectomy, 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 ICSs, defined as ≥ 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., 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 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/Standard-Special-Authorization-Form.pdf>

Updated January 2024



Health and Community Services

Thyrotropin alpha (Thyrogen 0.9mg/ml)

For preparation prior to radioiodine ablation in patients who have undergone thyroidectomy 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 (NSTEMACS) 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 NSTEMACS), 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 NSTEMACS 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)

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.
- Approvals will be for a 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 12 weeks thereafter.
- Initial Approval: 16 weeks.
- 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 December 2023



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



Health and Community Services

TIOTROPIUM / OLODATEROL (INSPIOLTO RESPIMAT 2.5-2.5ug)

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients who have inadequate control² while being treated with either along-acting beta₂ agonist (LABA) or long-acting anticholinergic (LAAC).

1. COPD diagnosis, as defined by spirometry, is a post bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered.

In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms after at least 1 month of LAAC or LABA; and an MRC score of at least 3 or a COPD Assessment test (CAT) score ≥ 10).
 - MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
 - The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical Notes

- Coverage for LABA and LAAC as two separate inhalers will not be considered.
- LAAC/LABA inhalers are not intended to be used in combination with an inhaled corticosteroid (ICS) unless criteria for triple therapy is fulfilled.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

TIOTROPIUM (SPIRIVA 18ug CAPSULES, SPIRIVA RESPIMAT 2.5ug INHALER)

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients:

- Experiencing persistent symptoms, as defined by a Medical Research Council (MRC) score of at least 3² or a COPD Assessment test (CAT) score ≥ 10 ³ and a post- bronchodilator FEV₁ < 80% predicted.

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids

OR

- At least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.

1. COPD diagnosis as defined by spirometry is a post-bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered. In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., MRC dyspnea scale score of at least Grade 3)
2. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
3. The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Triple therapy:

COPD:

- Patients should not be started on triple inhaled therapy as initial therapy for COPD.
- Combination therapy with LAAC/LABA/ICS will be considered for the treatment of COPD as defined by spirometry in patients who have inadequate control while being treated with a LAAC/LABA combination for at least 2 months.
- Inadequate control is defined as persistent symptoms or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 severe exacerbation of COPD requiring hospitalization.

Asthma/COPD overlap (ACO):

- Inadequate control is defined as persistent symptoms (ex. cough, sputum, dyspnea) or experiencing 2 or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least 1 exacerbation of COPD requiring hospitalization.
- Please provide details to support the ACO diagnosis (patient symptoms, risk factors, spirometry etc).

Clinical Notes:

- Coverage for LABA and LAAC as two separate inhalers will not be considered.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

Tipranavir (Aptivus 250mg capsule)

To be used as an alternate Protease Inhibitor (PI's) as part of a HIV treatment regimen in the treatment of adult patients with HIV-1 infection who are:

- treatment experienced and
- have demonstrated failure to multiple PI's and in whom no other PI is 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 July 2010



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 (ACTEMRA 162 MG/0.9 ML SYRINGE)

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 (≥ 15 mg 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: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- 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.*

Please visit the following link 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>

TOCILIZUMAB (ACTEMRA 80mg/4ml, 200mg/10ml, 400mg/20ml intravenous infusion) 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 (≥ 15 mg 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: 6 months
- Renewal Approval: 1 year. Confirmation of continued response is required.
- Maximum Dosage Approved:

- Tocilizumab: 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.

Please visit the following link 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>

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 period: 16 weeks
- Renewal period: 1 year

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.

Please visit the following link 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>

TOCILIZUMAB (ACTEMRA 162mg/0.9ml SYRINGE, ACTEMRA 162 MG/0.9 ML Autoinjector)

Giant Cell Arteritis (GCA):

For the treatment of adult patients with new onset or relapsed giant cell arteritis (GCS) in combination with glucocorticoids (at initiation of therapy, or with relapse)

Initial coverage will be for 16 weeks.

- Reassessment should occur after between 12 weeks and 16 weeks of therapy to determine response.

Renewal requests:

- Confirmation of response to treatment (i.e absence of flares¹ AND normalization of C-reactive protein (CRP) to <1mg/dL).

Clinical Note:

- Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA.

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
- Approval is for a 52-week period. Requests for extension may be considered and must include:
 - description of response to treatment, and
 - description of progress of glucocorticoid taper
- Authorization may be granted following any new episode of the disease, according to the treatment terms and conditions previously mentioned for the initial episode.

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 2023



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 (≥ 15 mg 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

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.

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 III or IV 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

**TRIAMCINOLONE HEXACETONIDE INJECTABLE SUSPENSION (TRIAMCINOLONE
HEXACETONIDE 20 MG/ML)**

For the symptomatic treatment of juvenile idiopathic arthritis.

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 2020



Health and Community Services

TRIENTINE (WAYMADE-TRIENTINE 250mg 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 June 2023



Health and Community Services

TRIFLURIDINE-TIPIRACIL (LONSURF) 15 MG/6.14 MG, 20 MG/8.19 MG TABLET

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.
- 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 April 2021



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



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. Kadcyca, 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 62.5-25ug INHALER)

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients who have inadequate control² while being treated with either along-acting beta₂ agonist (LABA) or long-acting anticholinergic (LAAC).

1. COPD diagnosis, as defined by spirometry, is a post bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered.

In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., Medical Research Council (MRC) dyspnea scale score of at least Grade 3. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.

2. Inadequate control is defined as persistent symptoms after at least 1 month of LAAC or LABA; and an MRC score of at least 3 or a COPD Assessment test (CAT) score ≥ 10).
 - MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
 - The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical Notes

- Coverage for LABA and LAAC as two separate inhalers will not be considered.
- LAAC/LABA inhalers are not intended to be used in combination with an inhaled corticosteroid (ICS) unless criteria for triple therapy is fulfilled.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

UMECLIDINIUM BROMIDE (INCRUSE ELLIPTA 62.5 MCG INHALATION DEVICE)

Chronic Obstructive Pulmonary Disease (COPD):

For the treatment of chronic obstructive pulmonary disease (COPD) as defined by spirometry¹ in patients:

- Experiencing persistent symptoms, as defined by a Medical Research Council (MRC) score of at least 3² or a COPD Assessment test (CAT) score ≥ 10 ³ and a post-bronchodilator FEV₁ < 80% predicted.

OR

- Experiencing 2 or more moderate exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids **OR** at least 1 acute severe exacerbation of COPD (AECOPD) requiring hospital admission.

1. COPD diagnosis as defined by spirometry is a post-bronchodilator FEV₁/FVC < 0.7. Spirometry from any point in time will be considered. In the rare occasion when spirometry cannot be obtained, reasons must be clearly explained and other evidence regarding COPD severity must be provided for consideration (i.e., MRC dyspnea scale score of at least Grade 3)
2. MRC Grade 3 is described as: walks slower than people of the same age on the level because of shortness of breath from COPD or has to stop for breath when walking at own pace on the level because of COPD.
3. The COPD assessment test is an 8-item tool for measuring health status impairment with scores from 0-40. It is available online at <http://www.catestonline.org/images/pdfs/CATest.pdf>

Clinical notes

- Coverage for both a LAMA and LABA as two separate inhalers will not be considered.

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

<https://www.gov.nl.ca/hcs/files/Chronic-Obstructive-Pulmonary-Disease-Form.pdf>

Updated October 2023



Health and Community Services

UPADACITINIB (RINVOQ 15mg, 30mg TABLET)

Rheumatoid Arthritis:

For the treatment of moderate to severely active rheumatoid arthritis, alone or 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 (≥ 15 mg 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:

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

For the treatment of adults and adolescents 12 years of age and older with refractory moderate to severe atopic dermatitis (AD) who are not adequately controlled with a systemic treatment (e.g., steroid or biologic) or when use of those therapies is inadvisable.

Initiation Criteria

Patients must have had an adequate trial (with a documented refractory disease), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies:

- Maximally tolerated medical topical therapies for atopic dermatitis combined with phototherapy (where available), and
- Maximally tolerated medical topical therapies for atopic dermatitis combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine)

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.
- Patients will not be permitted to switch back to Rinvoq if they were deemed unresponsive to therapy.

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

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)

Plaque psoriasis

For the treatment of patients with 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 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 is defined as:

- 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.
- Approvals will be for 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter.
 - Initial Approval: 16 weeks.
 - Renewal Approval: 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.
- Approvals will be for 45 or 90 mg given at weeks 0, 4 and 16, then every 12 weeks thereafter.
- Initial Approval: 6 months.
- Renewal Approval: Long term. Confirmation of response is required as defined as 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 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>

USTEKINUMAB (WEZLANA 45MG/0.5ML PREFILLED SYRINGE, 90mg / 1.0mL Prefilled Syringe, 45mg/0.5ml Single-use Vial, 130mg / 26mL Single-use Vial)

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.

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
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- 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.
 - Initial Approval: 16 weeks.
 - Renewal Approval: Long term. Confirmation of continued response is required.
 - 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 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.)

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.
- Consideration will be given for patients who have not received a four-week trial of aminosaliclates 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.

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.
- Initial Approval: 16 weeks
- Renewal Approval: Long term. Confirmation of response is required.

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

VALGANCICLOVIR (VALCYTE 50 MG/ML SOLUTION)

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 May 2019



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 advanced 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

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 ≥ 40 mg 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

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.

Updated March 2023

VENETOCLAX (VENCLEXTA) 10MG, 50MG, 100MG TABLETS, AND STARTER PACK

Chronic Lymphocytic Leukemia/Small Cell Lymphoma

1. As monotherapy for the treatment of patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (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.
 - Initial approval period: 1 year
 - Renewal approval period: 1 year
2. In combination with rituximab for the treatment of adult patients with CLL/SLL who have received at least one prior therapy, irrespective of their 17p deletion status.

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.
4. Re-treatment with Venetoclax plus Rituximab is funded as an option at the time of relapse if the progression-free interval was at least 12 months for patients who responded and completed 2 years of Venetoclax therapy.

Claim Notes:

- Initial approval period: 1 year
 - Renewal approval period: 1 year
3. In combination with obinutuzumab for the treatment of adult patients with previously untreated CLL/SLL whom fludarabine-based treatment is inappropriate.

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 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 not be considered.
- 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.
- Initial approval period: 1 year.
- Renewal 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 $\leq 50\%$, or chronic stable angina
 - DLCO $\leq 65\%$ or FEV₁ $\leq 65\%$
 - Creatinine clearance ≥ 30 mL/min to 45 mL/min
 - Moderate hepatic impairment with total bilirubin >1.5 to ≤ 3.0 ULN

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

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 \leq 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

Wet Nebulization Coverage Criteria (Ipratropium, salbutamol, ipratropium/salbutamol, sodium cromoglycate, budesonide nebulers 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 nebulers 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 CAPSULE

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.

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

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 days¹

- 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).

¹Reimbursement 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