



Government of Newfoundland and Labrador
Department of Health and Community Services
Provincial Blood Coordinating Program

GLASSIA GUIDANCE	NLBPCP-071
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Overview

Glassia is a plasma-derived alpha1-proteinase inhibitor (A1-PI), indicated for treatment in adults with clinically evident emphysema due to severe alpha1-antitrypsin deficiency.

Policy

1. Glassia is available to patients who meet specific eligibility criteria. The criteria for adult patients with severe A1-PI deficiency and clinical evidence of emphysema is as follows:
 - 1.1. Diagnosis of severe A1-PI deficiency and clinical evidence of emphysema confirmed by a Respiriologist, with the indication that the patient would benefit from treatment with A1-PI product;
 - 1.2. A1-PI deficiency, with serum A1-PI levels less than 11 $\mu\text{mol/L}$ or 57 mg/dL before start of treatment;
 - 1.3. A forced expiratory volume of less than 80 percent, clinical evidence of obstruction.
 - 1.4. Patients must be non-smokers for at least six (consecutive) months; and,
 - 1.5. Patients who have not received a lung transplant.
2. Approval for eligible patients shall be determined and confirmed by Canadian Blood Services (CBS).
3. Physicians with questions regarding eligibility shall be directed to SAPPRPRequests@blood.ca.
4. The prescriber shall obtain informed consent before initiating Glassia treatment. See attached [Informed Consent Policy](#).
5. Patients shall receive Glassia at Innomar Infusion clinics, receive home infusion by Innomar nurse or have the option to be trained to infuse Glassia at home.
6. Patients shall have appropriate training for home infusion before administering Glassia at home.
7. Training for home infusion shall be provided by OnePath through the Glassia Patient Support Program.
8. The home infusion program is a privilege for patients. Failure to comply with policies will require patients to revert to in clinic treatment.
9. All adverse events to Glassia shall be documented on either infusion log or issue/transfusion cards to return to Transfusion Medicine Laboratory (TML).
10. Glassia shall be issued by the TML to the patients or assigned designate.
11. Clinic infusion patients shall store Glassia at home and bring it with them to infusion appointments.

12. Patients shall receive an initial one month supply of Glassia upon start of treatment, after training is complete for self home infusion patients and up to a maximum of three (3) months' supply at TML discretion there after.
13. Infusion of Glassia shall be documented either by completing issue/transfusion cards or infusion log, which shall be returned to the TML when picking up next Glassia inventory.
14. Glassia discards or expiry shall be documented on either issue/transfusion cards or infusion log, to return to TML.

Guidelines

1. Glassia is stored at a temperature of 2°C to 8°C and not allowed to freeze. Once removed from refrigeration, Glassia shall be stored at room temperature, not exceeding 25°C for up to one month (four weeks).
2. Recommended dose of Glassia is 60 mg/kg, once weekly by intravenous infusion.
3. Glassia is contraindicated in:
 - 3.1. Individuals with immunoglobulin A (IgA) deficiency who have known anti-IgA;
 - 3.2. Individuals with a history of anaphylactic or severe adverse reaction to A1-PI products; and,
 - 3.3. Individuals who are hypersensitive to Glassia or any ingredient in the formulation, including any non-medical ingredient or component of the container.

Roles and Responsibilities

Physician:

1. Determine patient eligibility for Glassia based on the clinical criteria, contraindications, and the patient's ability to comply with guidelines for administration.
2. Obtain written informed consent from the patient for Glassia every 12 months.
3. Complete new Glassia order every 12 months.
4. Provide [Privacy Notice for Patient Designated Plasma Protein and Related Products](#) to patients.
5. Complete and submit CBS Request for Patient Designated Plasma Protein and Related Products form [here](#).
6. Receive confirmation of patient eligibility from CBS with patient's contract number.

7. Complete and submit Glassia Enrollment and Consent Form found [here](#), using patients contract number from CBS.

Note: Prescriber may send both CBS Request for Patient Designated Plasma Protein and Related Products and Enrollment and Consent Form to One Path if they choose.

8. Discuss with patients/families the potential adverse reactions and how to manage them.
9. Be available for telephone consultation in the event of severe adverse reactions or have an alternate physician available to address these issues.

Nurse Case Navigator

1. The Nurse Case Navigator works remotely and is the patients' first point of contact for all issues regarding Glassia and is the intermediary between the patient and the TML.
2. Prior to the patient running out of product (minimum 2 weeks), when notified by the patient, the Nurse Case Navigator will send the request the product pick up to the TML.

Nurse Educator

1. The Nurse Educator and provides all training and follow up clinic visits in-person.
2. For Self Home Infusion patients, the Nurse Educator:
 - 1.1. Reviews and completes, with the patient, the Patient Responsibility Agreement, maintains a record of the completed Agreement and a copy to the Nurse Case Navigator to provide to TML;
 - 1.2. Educates the patient on safe and appropriate self-administration of Glassia;
 - 1.3. Educates the patient on adverse reactions to Glassia and appropriate actions which include:
 - 1.3.1. Call Nurse Case Navigator (0800hrs to 2000hrs EST);
 - 1.3.2. Call the Newfoundland and Labrador Healthline at 811 or 1-888-709-2929; or,
 - 1.3.3. Call 911 or go to the closest emergency department for any emergency requiring immediate action;
 - 1.4. Organizes the provision of home infusion supplies;
 - 1.5. Advises patient/caregiver on proper transportation and storage of Glassia; and,
 - 1.6. Organizes clinic follow-up visits, if required.

Infusion Nurse

1. Administer Glassia to patients either in clinic or at home.
2. Report adverse events through Innomar process and document on either issue/transfusion cards or infusion log, to inform TML.

3. Document infusion and/or discard of each vial of Glassia.

Note: Nursing support is provided by OnePath/Innomar

Transfusion Medicine Laboratory:

1. Receive Glassia order requests from One Path/Innomar case navigator.
2. Order Glassia from CBS using patient's contract number.
3. Notify One Path case manager when orders are ready for pick up, when possible.
4. Issue Glassia to the patient/caregiver as per facility policy in the lab information system (LIS).
5. Document the appropriate transportation and storage temperature of Glassia on the transport container.
6. Update infusion information from returned infusion log or issue/transfuse cards into the LIS.
7. Notify Transfusion Safety Officer (TSO) or designate of any adverse reactions noted on the returned infusion log or issue/transfusion cards.
8. Complete Adverse Events form if required (TSO or designate).

Patient:

1. For Self Home Infusions:
 - 1.1. Complete home infusion training; demonstrate competence prior to initiation of self-administration regimen.
 - 1.2. Follow the instructions for home infusion as per the patient education materials or written modified program provided by Nurse Educator/physician.
 - 1.3. Store Glassia in a temperature-controlled environment according to instructions provided in the product monograph.
 - 1.4. Administer doses as scheduled by the attending physician.
 - 1.5. Ensure an adult (who is not undergoing the infusion) is present for the duration of the infusion and for 60 minutes following the completion of the infusion.
 - 1.6. Maintain and dispose of equipment as instructed.
 - 1.7. Contact the Nurse Educator when questions regarding supplies or the home infusion process arise.
 - 1.8. Contact the Nurse Case Navigator a minimum of two (2) weeks before additional product will be required, to arrange product pick-up.

- 1.9. Complete a letter of authorization for product pick-up for any person retrieving product from the TML.
 - 1.10. Document all adverse reactions on issue/transfusion cards to return to TML. (Any adverse reaction that requires emergency medical attention should be reported to the patient's physician before administering any other doses).
 - 1.11. Attend all scheduled clinic appointments.
 - 1.12. Complete the infusion log or issue/transfusion cards for the Glassia and return them to the TML when retrieving the next Glassia inventory.
2. For in-clinic infusion/home infusion by Innomar nurse patients:
- 2.1. Store Glassia in a temperature controlled environment according to instructions provided in the product monograph.
 - 2.2. Contact the Nurse Case Navigator a minimum of two (2) weeks before additional product will be required, to arrange product pick-up.
 - 2.3. Complete a letter of authorization for product pick-up for any person retrieving product from the TML when necessary.
 - 2.4. Attend all scheduled clinic appointments.
 - 2.5. Complete the infusion log or issue/transfusion cards for the Glassia and return them to the TML when retrieving the next Glassia inventory.

Key Words

Glassia, alpha1-proteinase inhibitor, A1-PI, alpha1-antitrypsin deficiency

Supplemental Materials

Forms

NLG-001 Glassia Home Infusion Responsibility Agreement
NLG-002 Letter of Authorization for Product Pick-up
NLG-003 Transfusion Medicine Laboratory Product Pick-up Record

Product Monograph

<https://www.takeda.com/en-ca/glassiapm>

Appendices

Appendix A: Roles and Responsibilities

Note: Patient and health care provider education and training is provided by OnePath. These resources are separate from the NLBBCP.

References

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Appendix A:

Roles and Responsibilities

Physician	Complete and submit CBS Request for Patient Designated Plasma Protein and Related Products
	Complete and submit the enrolment form
	Obtain informed consent from patient
	Renew Glassia prescription every 12 months
Nurse Case Navigator	Act as intermediary between patient and TML
	Notify TML of Glassia pick-up
Nurse Educator	Provide training and education to patient
	Complete Patient Responsibility Agreement with patient
	Organize the provision of home infusion supplies
	Organize clinic follow-up visits, if required.
Infusion Nurse	Administer Glassia to patient
	Report all adverse events
	Document infusion and discards of Glassia
Transfusion Medicine Lab (TML)	Receive order for Glassia pick up from Nurse Case Navigator
	Order Glassia for specific patient from CBS using contract number
	Prepare Glassia for patient pick-up
	Notify Nurse Case Navigator when Glassia is ready for pick-up, if possible
	Update LIS when Infusion Log or issue/transfusion cards are returned
Patients	Pick-up Glassia inventory from TML
	Store Glassia according to requirements
	If self-infusing Glassia at home, complete training
	Contact Nurse Case Navigator at least two weeks before additional Glassia is required
	Return completed Infusion Log or issue/transfusion cards to TML when retrieving next Glassia inventory