

# **Glassia Implementation FAQ**

## **VERSION 1.0**

Canadian Blood Services is responsible for securing and providing plasma protein and related products (PPRP) across Canada for use by clinicians and their patients in all provinces and territories (except Quebec). This document contains many common or important questions regarding the implementation of Glassia as a product on the Canadian Blood Services Plasma Protein and Related Products (PPRP) National Formulary.

Questions and Answers are grouped below by general interest, then by likely interested stakeholder audience types, and then by some specific topic sections. Checklists outlining the steps to access Glassia through transfusion medicine laboratories and through Bayshore Pharmacy in Alberta are located at the end of this document.

If you have a question that is not included in any of the sections below, please reach out to Canadian Blood Services at: [PPRPFormularyProgram@blood.ca](mailto:PPRPFormularyProgram@blood.ca).

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**This FAQ will be updated over time. Please note the version number above.**

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## General Information

### **What is Glassia?**

Glassia is a plasma-derived alpha-1-proteinase inhibitor (A1-PI). It is indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of A1-PI, also known as alpha-1 antitrypsin deficiency (AATD).

### **Why is Glassia being added to Canadian Blood Services' PPRP formulary?**

Since Glassia is a plasma-derived product, it has been listed on the Canadian Blood Services Plasma Protein and Related Products (PPRP) formulary. Canadian Blood Services is responsible for securing and providing PPRP to hospitals across Canada for use by clinicians and their patients in all provinces and territories (except Quebec)

### **How was Glassia chosen as the A1-PI product to be listed on the Canadian Blood Services PPRP Formulary?**

Glassia was the successful proponent of a Request for Proposals (RFP) for A1-PI products by Canadian Blood Services, which was open to all A1-PI products with a Health Canada Notice of Compliance (NOC). Provincial and territorial governments approved the listing of Glassia on the PPRP formulary.

### **When will Glassia be available?**

Glassia will be available for order by transfusion medicine laboratories (blood banks) from Canadian Blood Services on February 29, 2024. The availability of the product to be ordered for patients may vary between blood banks across the country.

Please note that in Alberta, Glassia will be dispensed and delivered to patients by Bayshore Pharmacy. It is expected that Glassia will be available in Alberta through Bayshore Pharmacy on March 18, 2024.

## Patients

### **Which patients will be eligible to access Glassia?**

Glassia is listed on the PPRP Formulary with specific eligibility criteria. Glassia can be requested for adult patients with severe A1-PI deficiency and clinical evidence of emphysema who meet the following criteria\*:

- Respiriologist has confirmed the diagnosis of severe A1-PI deficiency and clinical evidence of emphysema and indicated that patient would benefit from treatment with A1-PI product.
- A1-PI deficiency, defined as serum A1-PI levels  $<11 \mu\text{mol/L}$  or  $< 57 \text{ mg/dL}$  before start of the treatment.
- Clinical evidence of obstruction (FEV1  $<80\%$ ).
- Patients must be nonsmokers for at least 6 months.
- For patients who have not received a lung transplant.

\*Criteria are based on recommendations from CADTH

### **Will patients currently on Prolastin-C funded by the government be required to transition to Glassia?**

Patients currently receiving ministry-funded Prolastin-C who meet the eligibility criteria are expected to transition to Glassia. Patients are encouraged to contact their healthcare providers as soon as possible regarding the transition to Glassia.

### **How does a patient get approved for Glassia?**

Patients should reach out to their respirologist or primary healthcare provider to determine if Glassia is an appropriate treatment option and whether they meet the required eligibility criteria. As Glassia is listed on the PPRP formulary with specific eligibility criteria, the treating prescriber (a respirologist) must complete and submit a Request for Patient Designated PPRP form to Canadian Blood Services. The request will be reviewed to confirm that eligibility criteria are met, and a Named Patient Contract (NPC) will be created and provided to the prescriber if the patient is approved.

### **Once approved, how will patients get their medication?**

Like other products on the Canadian Blood Services PPRP Formulary, patients will receive the product through hospital transfusion medicine laboratories.

In the province of Alberta only, Glassia will be dispensed and delivered to patients by Bayshore Pharmacy (as part of a new Canadian Blood Services' pilot project).

### **How and where will patients get Glassia administered?**

Most patients will have Glassia administered at Innomar infusion clinics. Patients will also have the option of being trained to infuse at home. Once enrolled, patients will be contacted by Takeda's Patient Support Program (PSP), OnePath, to arrange appointments and receive instructions on how to transport their products for infusion appointments.

### **What services will be provided by Glassia's Patient Support Program (PSP)?**

Questions regarding Takeda's PSP should be directed to their provider, OnePath, through the following contact information:

Tel: 1-844-691-7284

Fax: 1-844-951-7284

E-mail: [support@onepathprogram.ca](mailto:support@onepathprogram.ca)

### **How much product will be provided to patients at a time?**

Patients will most often be provided with a three-month supply of Glassia. This may vary based on circumstances (e.g., trial period, travel).

### **Will patients incur any out-of-pocket drug costs if approved for Glassia?**

No, products are provided to patients (through transfusion medicine laboratories and Bayshore) at no cost.

### **How do patients need to store their product at home?**

The product monograph for Glassia states that it should be stored in the refrigerator at a temperature of 2°C to 8°C and should not be frozen.

### **Are there any differences between Prolastin-C and Glassia?**

The active ingredient in both Glassia and Prolastin-C is alpha1-proteinase inhibitor which is derived from pooled human plasma. Both products are approved by Health Canada and are considered therapeutically equivalent.

### **Will patients currently on Prolastin-C funded by the government be required to transition to Glassia?**

Yes - patients currently receiving government-funded Prolastin-C who meet the eligibility criteria for Glassia are expected to transition to Glassia.

**Will this transition cause a gap in therapy?**

No gap in therapy is anticipated for patients switching from Prolastin-C to Glassia.

**How does Canadian Blood Services protect Personal Health Information (PHI)?**

Canadian Blood Services provides a Privacy Notice for Patient Designated PPRP on our website. The notice is available here: [Privacy Notice for Patient Designated Plasma Protein and Related Products \(blood.ca\)](#).

For patients in Alberta receiving their products through Bayshore Pharmacy, the pharmacy will obtain consent to share their dispensing data with Canadian Blood Services (written or attestation by their health care provider).

*For any questions related to your respiratory health or testing, please contact your respirologist or primary healthcare provider.*

## Clinics and Clinicians

### **Are there any clinically relevant differences between Glassia and Prolastin-C?**

Through its review, CADTH looked at a non-inferiority trial comparing Glassia to Prolastin-C. This trial showed that Glassia is non-inferior to Prolastin-C and that no claim can be made that there is any difference between these products. Based on expert opinion and the non-inferiority trial, Prolastin-C and Glassia were found to be comparable.

### **What are the eligibility criteria for Glassia?**

Glassia can be requested for adult patients with severe A1-PI deficiency and clinical evidence of emphysema who meet the following criteria\*:

- Respiriologist has confirmed the diagnosis of severe A1-PI deficiency and clinical evidence of emphysema and indicated that patient would benefit from treatment with A1-PI product
- A1-PI deficiency, defined as serum A1-PI levels <11 µmol/L or < 57 mg/dL before start of the treatment
- Clinical evidence of obstruction (FEV1 <80%)
- Patients must be nonsmokers for at least 6 months
- For patients who have not received a lung transplant

\*Criteria is based on recommendations from CADTH

Questions regarding eligibility can be directed to [SAPPRPRequests@blood.ca](mailto:SAPPRPRequests@blood.ca).

### **How do prescribers request access to Glassia for their patients?**

As Glassia is listed on the PPRP formulary with specific eligibility criteria, the prescribing clinician must submit a Request for Patient Designated PPRP form to Canadian Blood Services at [SAPPRPRequests@blood.ca](mailto:SAPPRPRequests@blood.ca). Prescribers should also provide the [Privacy Notice for Patient Designated Plasma Protein and Related Products](#) to their patients.

The Request for Patient Designated PPRP form is available on the [Submitting Product Orders](#) webpage under the appropriate distribution site.

[A checklist outlining the required steps and contact information is provided at the end of this document.](#)

### **How will prescribers be informed of patient approval and Named Patient Contract (NPC)?**

If the request is approved, a Named Patient Contract (NPC) will be created. A notification will be sent to the designated contact on the request form. This notification will include the contract details (e.g., number, product name, approved quantities, expiry date).

### **How will Glassia be ordered from Canadian Blood Services?**

Transfusion medicine laboratories or Bayshore Pharmacy (for patients residing in Alberta) can order Glassia from Canadian Blood Services using the patient's contract number. Orders can be submitted through the Online Ordering Portal, or by faxing an order to the local Canadian Blood Services distribution site.

### **How will patients be onboarded to the Glassia Patient Support Program (PSP)?**

Prescribers can enroll patients by submitting enrollment form to Takeda's Patient Support (OnePath). Any questions regarding the program should be directed to OnePath through the following contact information:

Tel: 1-844-691-7284

Fax: 1-844-951-7284

E-mail: [support@onepathprogram.ca](mailto:support@onepathprogram.ca)

### **Are there any additional requirements to access Glassia through Bayshore in AB?**

Refer to the Alberta Distribution Modernization Pilot section below for details.

### **How does Canadian Blood Services protect patients' Personal Health Information (PHI)?**

The Privacy Notice for Patient Designated Plasma Protein and Related Products has been developed so that patients understand what personal information will be collected, the purposes for the collection and how it will be used, disclosed, and retained by Canadian Blood Services. The notice is available here: [Privacy Notice for Patient Designated Plasma Protein and Related Products](#). This notice applies to all patients receiving PPRP through the NPC program at Canadian Blood Services.

Specifics relating to PHI management for the Alberta Distribution Modernization Pilot are provided in the pertinent section below.

## Transfusion Medicine Laboratories

### **Where can I find the Customer Letter announcing the product highlights to enter Glassia into the hospital and lab information systems?**

Key product highlights to enter Glassia into the hospital and lab information systems can be found in [CL\\_2024-04](#).

### **What are the product details including storage modality and packaging dimensions?**

According to the Glassia product monograph:

- Each carton of Glassia contains a single-use vial containing approximately 1 gram of functional A1-PI in 50 mL of solution.
- Glassia vials should be kept in a carton until required for use. Glassia is to be stored at 2°C to 8°C (36°F to 46°F) and should not be frozen. Once removed from refrigeration, it can be stored at room temperatures not exceeding 25°C (77°F) for up to one month (4 weeks).
- Glassia contains no preservatives and no latex. Do not use after the expiration date printed on the label.

### **What is the refrigerated shelf-life of Glassia?**

According to Takeda, the manufacturer of Glassia, it is stable at refrigerated storage conditions (2 to 8°C) for 36 months from the date of manufacture. Glassia should not be frozen.



## **Alberta Distribution Modernization Pilot**

### **What is the “Alberta Distribution Modernization Pilot”?**

Canadian Blood Services is responsible for securing and providing plasma protein and related products (PPRP) to hospitals across Canada for use by clinicians and their patients in all provinces and territories (except Quebec). Currently, patients using products at home generally pick up their supply from the hospital and then administer the treatment at home.

Canadian Blood Services is piloting a program for home delivery to eligible patients in Alberta using Bayshore Pharmacy, a specialty pharmacy. The purpose of this pilot is to demonstrate that this is a feasible option for providing home care PPRP to patients, while increasing Canadian Blood Services’ access to product use data. Getting data from Bayshore Pharmacy on the use of PPRP will allow Canadian Blood Services to better manage PPRP access, demand planning, and inventory management.

### **Why is the pilot only being run in Alberta?**

This pilot is being implemented through financial support from the Alberta Ministry of Health.

### **How will patients approved for Glassia be onboarded to the pilot program in Alberta?**

The prescribing physician must submit a Request for Patient Designated PPRP form to Canadian Blood Services for review. If the listed criteria are met, the request will be approved, and a Named Patient Contract will be created by Canadian Blood Services.

Bayshore pharmacy will provide a form for patient enrollment and consent, as well as a prescription template for use by prescribers. The enrollment form and prescription should be sent to Bayshore Pharmacy in advance (~ 2-3 weeks) of the patient’s first fill. The Bayshore enrollment form only needs to be sent with the first prescription, to enroll the patient with Bayshore.

### **Who should patients contact if they have a problem?**

Patients should continue to report all clinical concerns to their respirologist or primary care provider.

Information on clinical issues reported directly to the pharmacy will be communicated by the pharmacy team to the prescriber/clinic as required. Patients should contact Bayshore Pharmacy for any issues with delivery or product quality.

### **How will patients contact the pharmacy for information?**

After the initial prescription is sent to Bayshore Pharmacy by the clinic/prescriber, the pharmacy will contact the patient directly with additional information. This information package will include pharmacy contact information for patients.

### **How does Canadian Blood Services protect Personal Health Information (PHI)?**

As noted above, Canadian Blood Services provides a Privacy Notice for Patient Designated PPRP on our website. This is applicable nationwide (except Quebec) to patients receiving PPRP through the NPC program at Canadian Blood Services, and it has been updated to reflect data sharing with the specialty pharmacy in the pilot. The notice is available here: [Privacy Notice for Patient Designated Plasma Protein and Related Products](#).

Bayshore Pharmacy requires express consent from patients to share their dispensing data with Canadian Blood Services. Bayshore Pharmacy will be obtaining this consent as part of their enrollment form.

### **What information is being shared by Bayshore Pharmacy with Canadian Blood Services?**

Personal information shared with Canadian Blood Services will be limited to information related to the dispensing of Glassia. Other personal information required by the pharmacist as part of their standard practice, such as other medications being taken or other medical conditions, will not be shared. Bayshore Pharmacy has prepared a Privacy Notice that will be shared with patients to outline the information being shared.

### **How will personal information be shared between Canadian Blood Services and Bayshore Pharmacy for this pilot?**

For the purposes of this pilot, personal Information will be shared between Canadian Blood Services and the specialty pharmacy (Bayshore) via a secure site managed by Canadian Blood Services. Access schema is based on need to know, least access and least privilege. Access is limited to those approved by Canadian Blood Services to review eligibility information, to upload and/or review dispensing data or to provide technical support. If a user leaves or changes roles, their access will be revoked.

Canadian Blood Services' contract with Bayshore pharmacy requires that Bayshore Pharmacy safeguard personal information in accordance with applicable law.

### **How and where will prescriptions for Glassia be sent in Alberta?**

Prescriptions will be sent directly to Bayshore Pharmacy using a dedicated fax line at 1-855-307-2929. Connect Care prescriptions can also be sent electronically to this fax line.

**Will Bayshore Pharmacy be monitoring for patient adherence to the prescribed therapy?  
How will this be done?**

Yes - pharmacy staff will be proactively monitoring for expected upcoming refills and will contact patients in advance (2 – 3 weeks) to confirm when the product is needed and to monitor for adherence. Any issues noted by pharmacy staff will be communicated to prescribers/clinics for management, as required.

**Will blood banks in Alberta ever be required to place orders for Glassia?**

There may be circumstances in which blood banks will need to order Glassia (e.g., hospitalized patient without home supply, patients with no fixed address). In these cases, the blood bank should contact Canadian Blood Services at [SAPPRPRequests@blood.ca](mailto:SAPPRPRequests@blood.ca) to discuss the circumstances and have the contract updated as required. Canadian Blood Services will coordinate the communication between the clinic, the blood bank, and the distribution site to ensure everyone is aware the blood bank will be ordering Glassia for that patient contract.

**What happens if a patient requests a refill when running out of product at the last minute?**

The aim is to minimize late refill requests by having the specialty pharmacy proactively monitor upcoming refills and contact patients in advance. There will be a minimum turnaround time for requests, which is likely to be at least several business days (to account for ordering and arranging delivery).

If contacted by a patient for a last-minute refill request, clinics should call Bayshore Pharmacy at 1-855-430-0730 to inform them of the urgency and ensure the order is appropriately prioritized.

**Who can clinics contact at the specialty pharmacy for any questions or issues?**

Clinics can contact Bayshore Pharmacy staff via the following:

Tel: 1-855-430-0730

Fax: 1-855-307-2929

Email: [bsrxab@bayshore.ca](mailto:bsrxab@bayshore.ca)

# How to Access Glassia through Transfusion Medicine Laboratories (Blood Banks)

## Process Checklist

<input checked="" type="checkbox"/>	<b>Steps to access Glassia</b>
<input type="checkbox"/>	<p><b>1. Apply for patient eligibility</b></p> <ul style="list-style-type: none"> <li>✓ Complete the Request for Patient Designated Plasma Protein and Related Products form, which is available on the <a href="#">Submitting Product Orders</a> webpage under the appropriate distribution site.</li> <li>✓ Email the form to <a href="mailto:SAPPRPRequests@blood.ca">SAPPRPRequests@blood.ca</a> or fax it to your local Canadian Blood Services distribution site.</li> <li>✓ Please provide the <a href="#">Privacy Notice for Patient Designated Plasma Protein and Related Products</a> to your patient.</li> </ul>
<input type="checkbox"/>	<p><b>2. Receive confirmation of patient eligibility</b></p> <ul style="list-style-type: none"> <li>✓ If the patient is approved, Canadian Blood Services will send a notification email containing the patient's <u>contract number</u> to the designated clinic contact on the request form.</li> <li>✓ Keep a record of the contract number and expiry date.</li> </ul>
<input type="checkbox"/>	<p><b>3. Enroll patient in Takeda's Patient Support Program (PSP), OnePath</b></p> <ul style="list-style-type: none"> <li>✓ Complete and submit the OnePath enrollment form, including infusion order.</li> <li>✓ OnePath will organize infusion appointments with Innomar</li> <li>✓ OnePath contact information:        Tel: 1-844-691-7284        Fax: 1-844-951-7284        Email: <a href="mailto:support@onepathprogram.ca">support@onepathprogram.ca</a></li> </ul>
<input type="checkbox"/>	<p><b>4. Prescribe/Order Glassia</b></p> <ul style="list-style-type: none"> <li>✓ Glassia prescription/order should be submitted to the Transfusion Medicine Laboratory (blood bank) where the patient will pick up product.</li> <li>✓ Please also provide them with the patient's Canadian Blood Services contract number to facilitate product ordering.</li> </ul>

## How to Access Glassia in Alberta

### Process Checklist

<input checked="" type="checkbox"/>	<b>Steps to access Glassia</b>
<input type="checkbox"/>	<p><b>1. Apply for patient eligibility</b></p> <ul style="list-style-type: none"> <li>✓ Complete the Request for Patient Designated Plasma Protein and Related Products form, which is available on the <a href="#">Submitting Product Orders</a> webpage under the appropriate distribution site.</li> <li>✓ Email the form to <a href="mailto:SAPPRPRequests@blood.ca">SAPPRPRequests@blood.ca</a> or fax it to your local Canadian Blood Services distribution site.</li> <li>✓ Please provide the <a href="#">Privacy Notice for Patient Designated Plasma Protein and Related Products</a> to your patient.</li> </ul>
<input type="checkbox"/>	<p><b>2. Receive confirmation of patient eligibility</b></p> <ul style="list-style-type: none"> <li>✓ If the patient is approved, Canadian Blood Services will send a notification email containing the patient's <u>contract number</u> to the designated clinic contact on the request form.</li> <li>✓ Keep a record of the contract number and expiry date.</li> </ul>
<input type="checkbox"/>	<p><b>3. Enroll patient in Takeda's Patient Support Program (PSP), OnePath</b></p> <ul style="list-style-type: none"> <li>✓ Complete and submit OnePath enrollment form, including infusion order.</li> <li>✓ OnePath will organize infusion appointments with Innomar</li> <li>✓ OnePath contact information:            Tel: 1-844-691-7284            Fax: 1-844-951-7284            Email: <a href="mailto:support@onepathprogram.ca">support@onepathprogram.ca</a></li> </ul>
<input type="checkbox"/>	<p><b>4. Enroll patient with Bayshore Pharmacy</b></p> <ul style="list-style-type: none"> <li>✓ Complete and submit Bayshore Pharmacy.</li> <li>✓ Bayshore Pharmacy contact information:            Tel: 1-855-430-0730            Fax: 1-855-307-2929            Email: <a href="mailto:bsrxab@bayshore.ca">bsrxab@bayshore.ca</a></li> </ul>
<input type="checkbox"/>	<p><b>5. Prescribe Glassia</b></p> <ul style="list-style-type: none"> <li>✓ Glassia prescriptions can be sent through your electronic medical record (EMR) to Bayshore Pharmacy via electronic fax to 1-855-307-2929.</li> <li>✓ Alternatively, the Glassia Prescription Template can be completed and faxed to Bayshore Pharmacy at 1-855-307-2929.</li> </ul>