Glassia Implementation Process

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Canadian Blood Services

BLOOD
PLASMA
STEM CELLS
ORGANS
& TISSUES

Disclaimer:

I have not received any financial support or compensation for this presentation.

Outline

- Overview of Canadian Blood Services' Plasma Protein and Related Products (PPRP) Program
- Glassia implementation process in all jurisdictions (Except QC)
- How to complete and submit the Request for Patient Designated PPRP form
- Who to contact for assistance and inquiries

Canadian Blood Services' Plasma Protein and Related Products Program

- Since 1998, Canadian Blood Services has been 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)
- Funded by the provincial and territorial ministries of health
- The PPRP Formulary program was established in 2019
- Providing a reliable, evidence-based and appropriate formulary of PPRP for patients
- a highly collaborative team of experts, including:
  - Clinical pharmacists
  - Physicians
  - Scientists
  - Procurement specialists
  - Supply chain professionals and
  - Leaders in stakeholder engagement.
- Currently, the PPRP Formulary includes around 50 products which are available through the national program.

Plasma Protein and Related Products Program

- Product selection process
- Special authorization program
- Utilization management
- Systems-wide approach to PPRP management

Glassia and the Canadian Blood Services Formulary

- **Why is Glassia being added to Canadian Blood Services' PPRP Formulary?**
- **How was Glassia chosen as the A1-PI product to be listed on the Canadian Blood Services' PPRP Formulary?**
- **Will patients currently on Prolastin-C be required to transition to Glassia?**

Eligibility criteria for Glassia

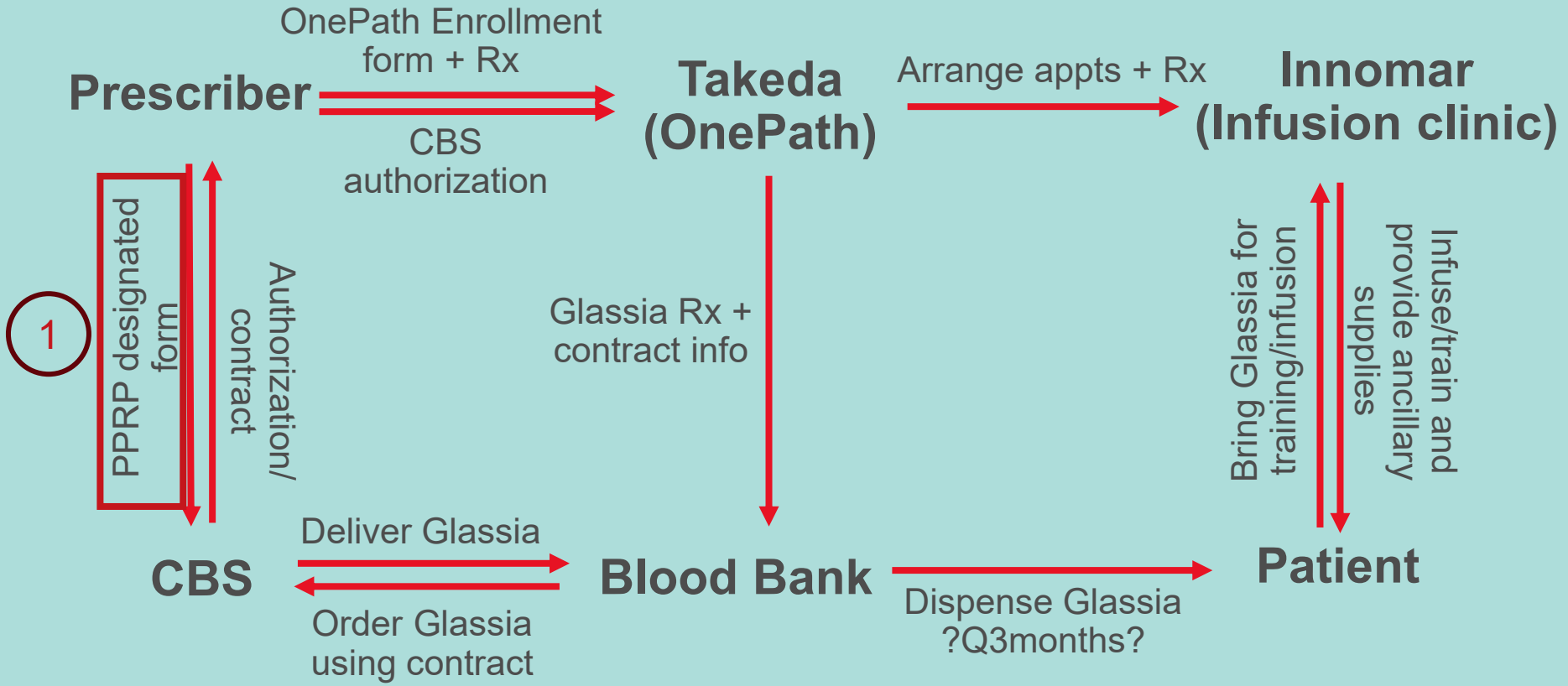
Glassia can be requested for adult patients with severe A1-PI deficiency and clinical evidence of emphysema who meet the following criteria*:

- Respirologist 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

Questions regarding eligibility can be directed to SAPPRPRequests@blood.ca.

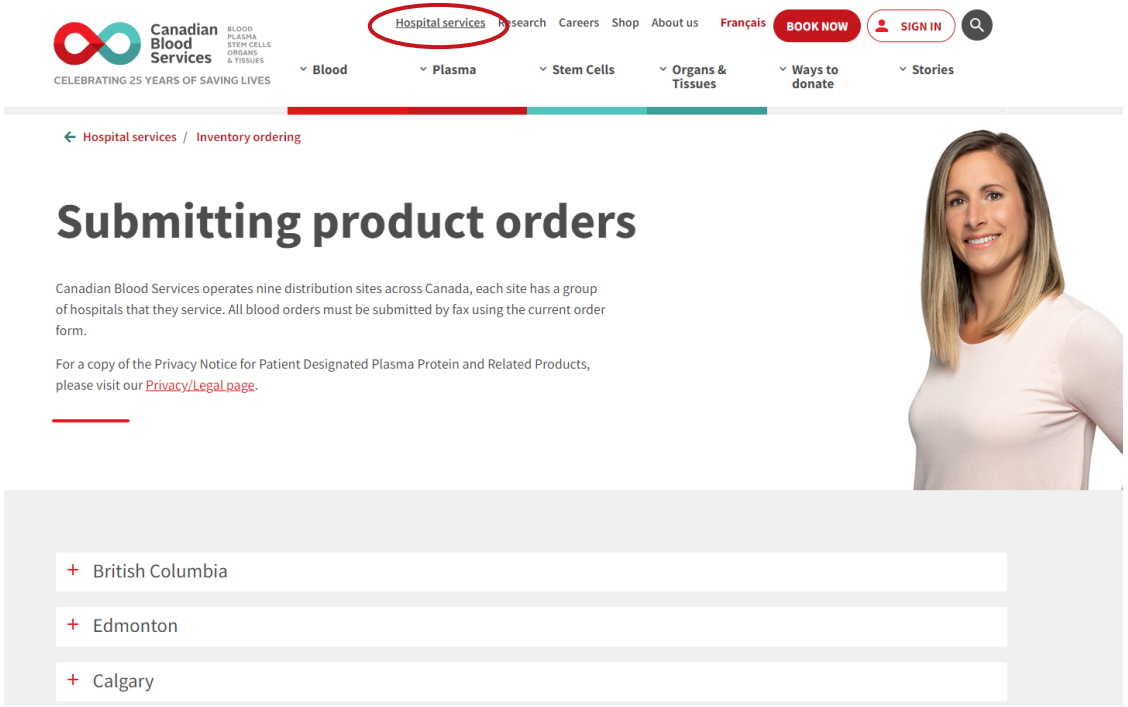
How to Access Glassia

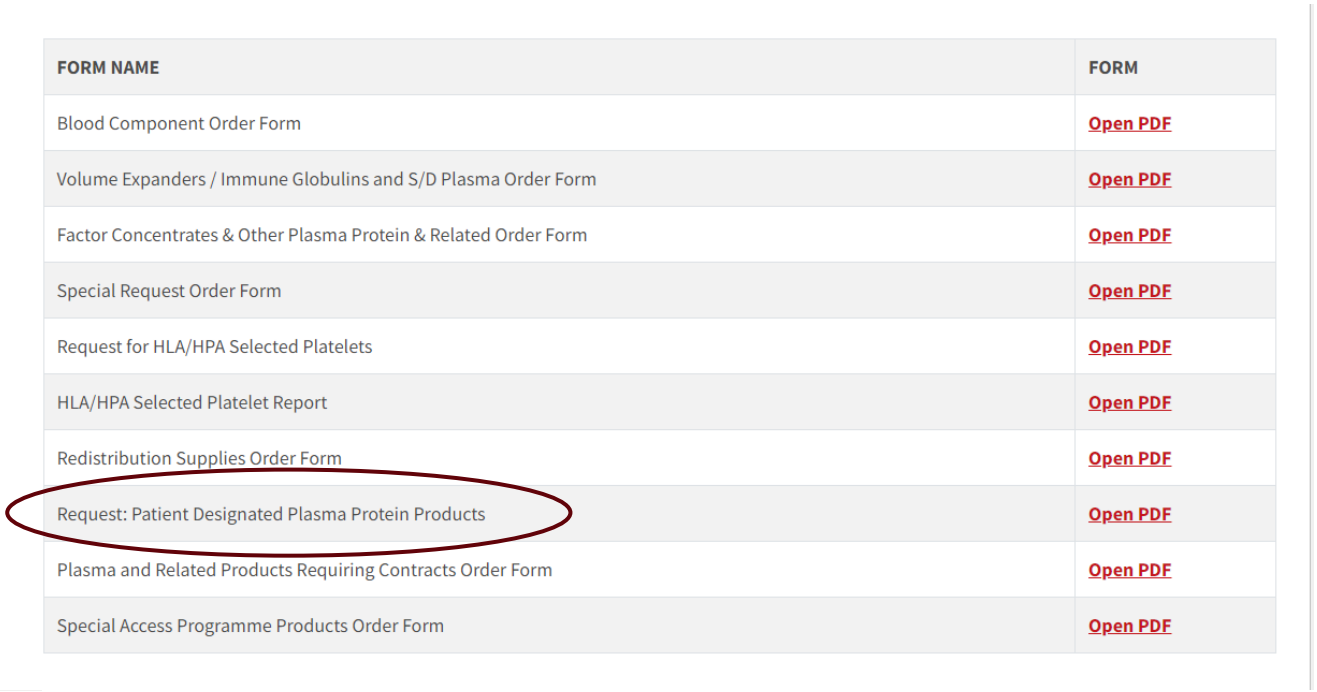
All Jurisdictions (except QC and AB)



How can prescribers access the form?

The form is available at: https://www.blood.ca/sites/default/files/F800135_Rev_1.pdf





FORM NAME	FORM
Blood Component Order Form	Open PDF
Volume Expanders / Immune Globulins and S/D Plasma Order Form	Open PDF
Factor Concentrates & Other Plasma Protein & Related Order Form	Open PDF
Special Request Order Form	Open PDF
Request for HLA/HPA Selected Platelets	Open PDF
HLA/HPA Selected Platelet Report	Open PDF
Redistribution Supplies Order Form	Open PDF
Request: Patient Designated Plasma Protein Products	Open PDF
Plasma and Related Products Requiring Contracts Order Form	Open PDF
Special Access Programme Products Order Form	Open PDF

www.blood.ca → Hospital services → Inventory ordering → Submitting product orders → Click on any Distribution Site and choose:

Request: Patient Designated Plasma Protein Products

How should the Request for Patient Designated PPRP form be filled out?

Respiratory Clinic (provide the name for your clinic to be created in our IT

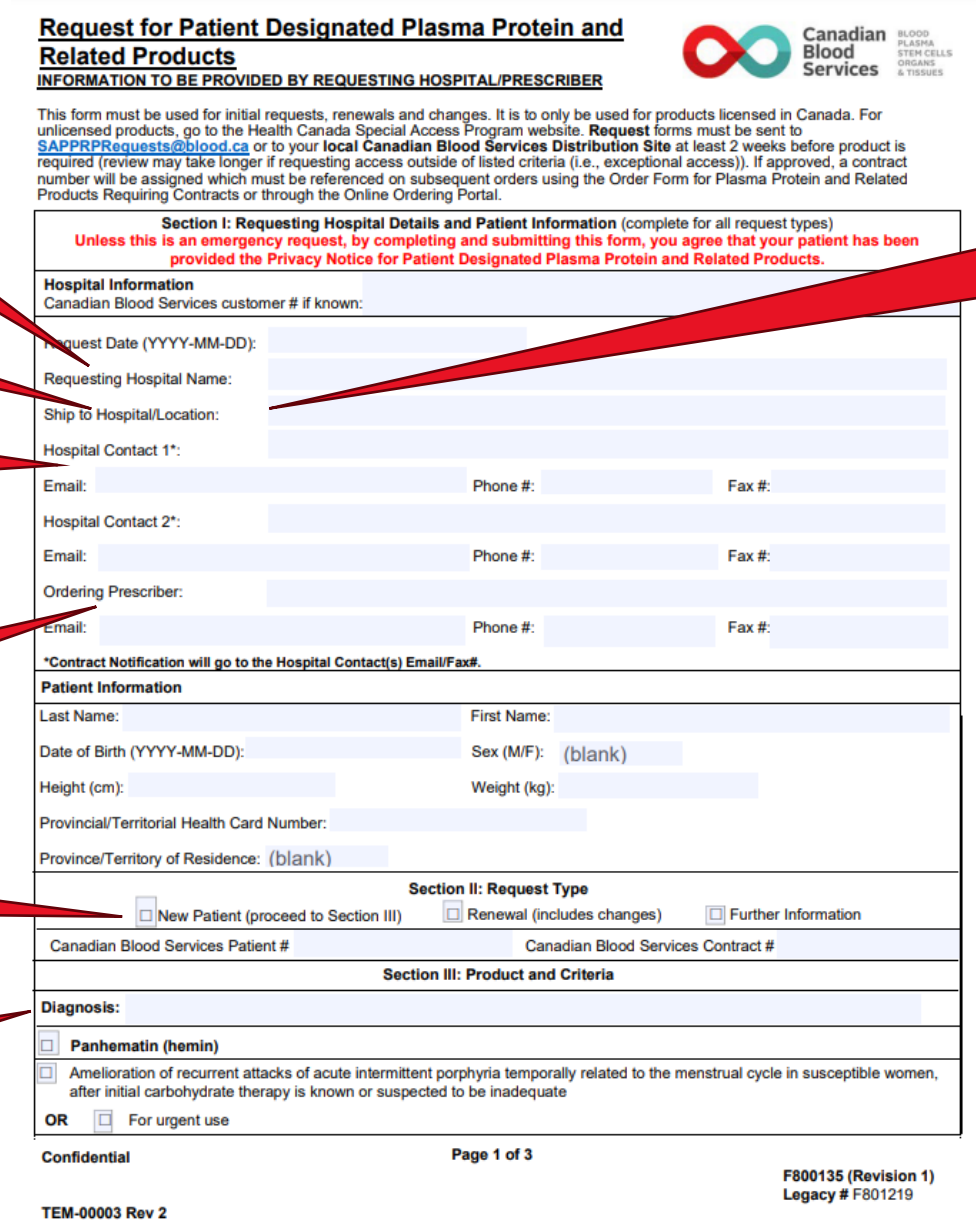
Blood bank where patient will pick up

Name and email of the person at the respiratory clinic who will be informed of the contract

Prescriber name and email (respirologist)

Request type (new patient or renewal)

Diagnosis (Alpha-1 Antitrypsin deficiency)



Request for Patient Designated Plasma Protein and Related Products

INFORMATION TO BE PROVIDED BY REQUESTING HOSPITAL/PRESCRIBER

Canadian Blood Services

This form must be used for initial requests, renewals and changes. It is to only be used for products licensed in Canada. For unlicensed products, go to the Health Canada Special Access Program website. **Request** forms must be sent to SAPPRPRequests@blood.ca or to your **local Canadian Blood Services Distribution Site** at least 2 weeks before product is required (review may take longer if requesting access outside of listed criteria (i.e., exceptional access)). If approved, a contract number will be assigned which must be referenced on subsequent orders using the Order Form for Plasma Protein and Related Products Requiring Contracts or through the Online Ordering Portal.

Section I: Requesting Hospital Details and Patient Information (complete for all request types)

Unless this is an emergency request, by completing and submitting this form, you agree that your patient has been provided the Privacy Notice for Patient Designated Plasma Protein and Related Products.

Hospital Information

Canadian Blood Services customer # if known:

Request Date (YYYY-MM-DD):

Requesting Hospital Name:

Ship to Hospital/Location:

Hospital Contact 1*:

Email: Phone #: Fax #:

Hospital Contact 2*:

Email: Phone #: Fax #:

Ordering Prescriber:

Email: Phone #: Fax #:

***Contract Notification will go to the Hospital Contact(s) Email/Fax#.**

Patient Information

Last Name: First Name:

Date of Birth (YYYY-MM-DD): Sex (M/F): (blank)

Height (cm): Weight (kg):

Provincial/Territorial Health Card Number:

Province/Territory of Residence: (blank)

Section II: Request Type

☐ New Patient (proceed to Section III) ☐ Renewal (includes changes) ☐ Further Information

Canadian Blood Services Patient # Canadian Blood Services Contract #

Section III: Product and Criteria

Diagnosis:

☐ **Panhematin (hemin)**

☐ Amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate

OR ☐ For urgent use

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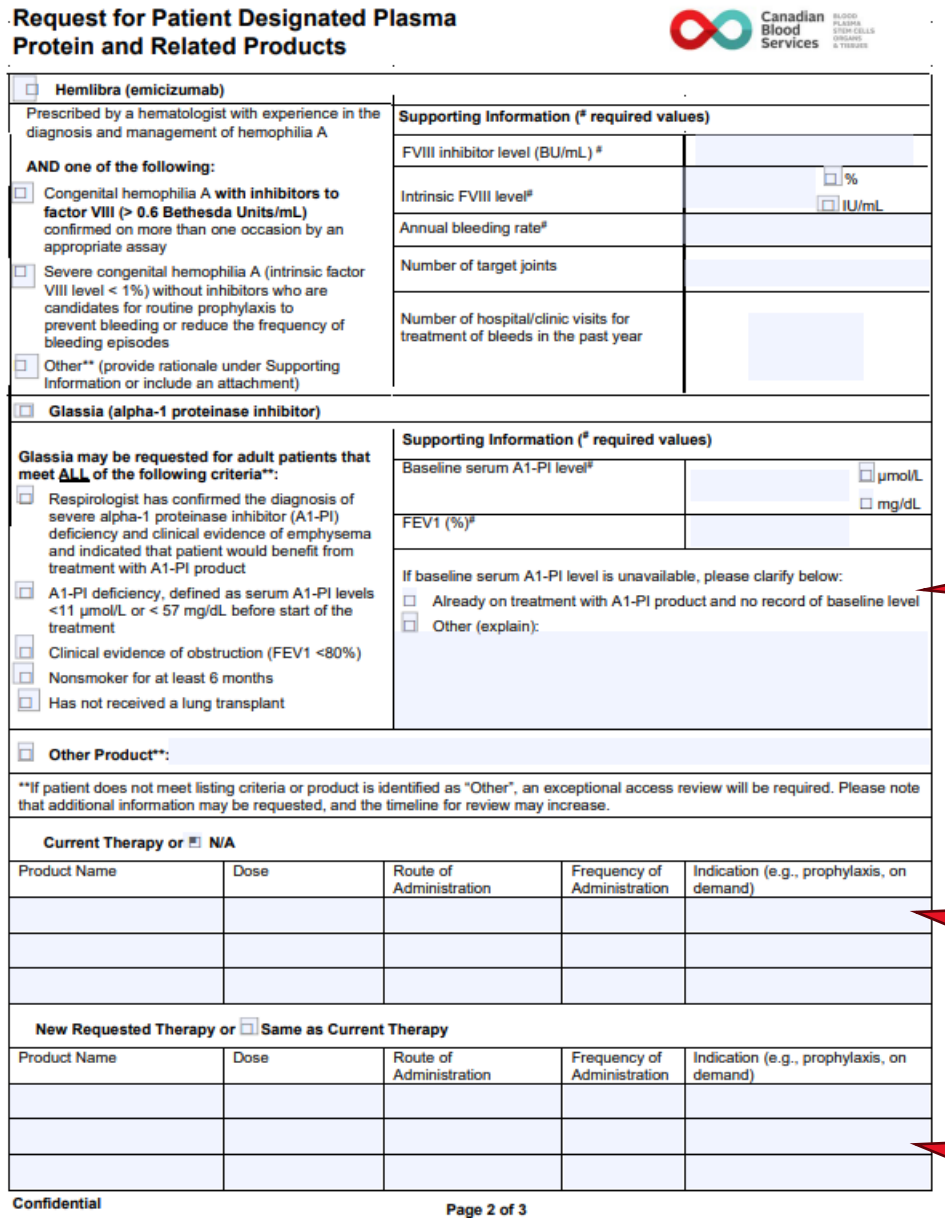
F800135 (Revision 1)
Legacy # F801219

TEM-00003 Rev 2

Ship to location: If unsure, choose the largest hospital in your area

Patient information

The form is available at:
https://www.blood.ca/sites/default/files/F800135_Rev_1.pdf



Request for Patient Designated Plasma Protein and Related Products

Canadian Blood Services

☐ **Hemlibra (emicizumab)**

Prescribed by a hematologist with experience in the diagnosis and management of hemophilia A

AND one of the following:

- ☐ Congenital hemophilia A **with inhibitors to factor VIII (> 0.6 Bethesda Units/mL)** confirmed on more than one occasion by an appropriate assay
- ☐ Severe congenital hemophilia A (intrinsic factor VIII level < 1%) without inhibitors who are candidates for routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes
- ☐ Other** (provide rationale under Supporting Information or include an attachment)

Supporting Information (# required values)

FVIII inhibitor level (BU/mL) #	
Intrinsic FVIII level#	☐ % ☐ IU/mL
Annual bleeding rate#	
Number of target joints	
Number of hospital/clinic visits for treatment of bleeds in the past year	

☐ **Glassia (alpha-1 proteinase inhibitor)**

Glassia may be requested for adult patients that meet ALL of the following criteria:**

- ☐ Respirologist has confirmed the diagnosis of severe alpha-1 proteinase inhibitor (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%)
- ☐ Nonsmoker for at least 6 months
- ☐ Has not received a lung transplant

Supporting Information (# required values)

Baseline serum A1-PI level#	☐ µmol/L ☐ mg/dL
FEV1 (%)#	

If baseline serum A1-PI level is unavailable, please clarify below:

- ☐ Already on treatment with A1-PI product and no record of baseline level
- ☐ Other (explain):

☐ **Other Product**:**

**If patient does not meet listing criteria or product is identified as "Other", an exceptional access review will be required. Please note that additional information may be requested, and the timeline for review may increase.

Current Therapy or ☐ N/A

Product Name	Dose	Route of Administration	Frequency of Administration	Indication (e.g., prophylaxis, on demand)

New Requested Therapy or ☐ Same as Current Therapy

Product Name	Dose	Route of Administration	Frequency of Administration	Indication (e.g., prophylaxis, on demand)

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Please make sure to check every box that applies to the patient and provide both required values under Supporting Information

If the A1-PI level is unknown as the patient is on Prolastin-C check the box. FEV1 still required

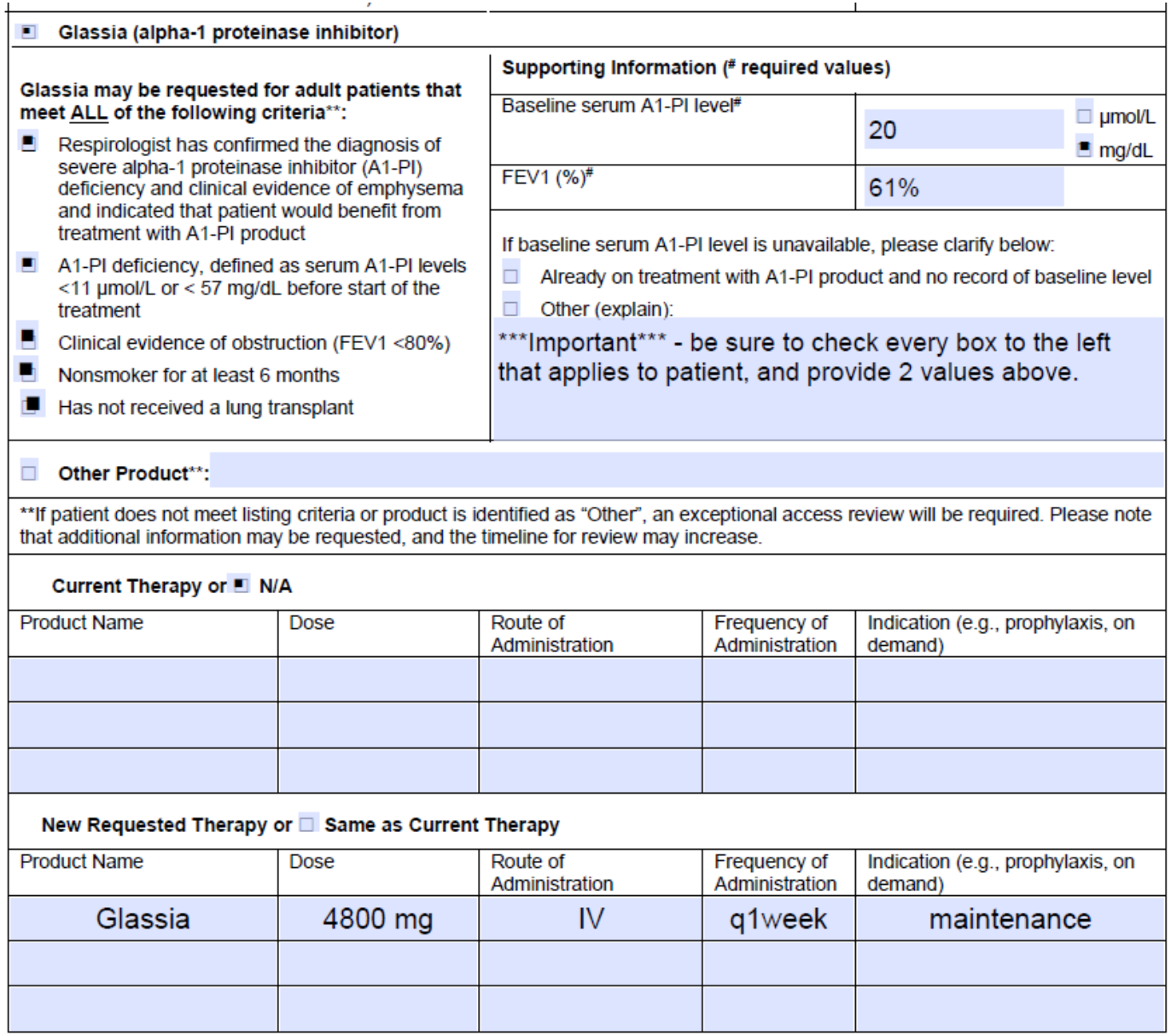
If the patient is on Prolastin-C, fill out the box (name, dose and frequency). If not, select N/A.

Provide Glassia dose, route of administration, frequency and indication

Example

- 80 kg patient
- Dose: 60 mg/kg/wk

Then 80kg × 60mg:
4800 mg/wk



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- ☑ 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%)
- ☑ Nonsmoker for at least 6 months
- ☑ Has not received a lung transplant

Supporting Information (# required values)

Baseline serum A1-PI level#	20	☐ µmol/L ☑ mg/dL
FEV1 (%)#	61%	

If baseline serum A1-PI level is unavailable, please clarify below:

- ☐ Already on treatment with A1-PI product and no record of baseline level
- ☐ Other (explain):

Important - be sure to check every box to the left that applies to patient, and provide 2 values above.

☐ **Other Product**:**

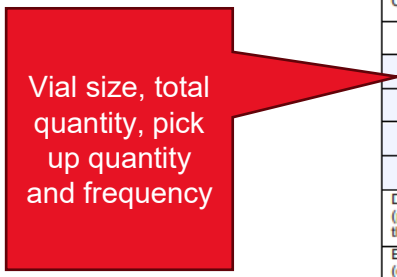
**If patient does not meet listing criteria or product is identified as "Other", an exceptional access review will be required. Please note that additional information may be requested, and the timeline for review may increase.

Current Therapy or ☑ N/A

Product Name	Dose	Route of Administration	Frequency of Administration	Indication (e.g., prophylaxis, on demand)

New Requested Therapy or ☐ Same as Current Therapy

Product Name	Dose	Route of Administration	Frequency of Administration	Indication (e.g., prophylaxis, on demand)
Glassia	4800 mg	IV	q1week	maintenance



Request for Patient Designated Plasma Protein and Related Products

Canadian Blood Services

Other Supporting Information (including rationale for change or initiation of therapy):

Section IV: Total Contract Quantities in Vials
(refer to order form for product and available sizes)

Contracts will be created up to a maximum of **12 months**, A renewal request will be required every 12 months

Vial Size	Total Contract Quantity	Pick Up Quantity	Frequency of Pick Up (e.g., every 3 months)	Duration of Contract (max 12 months)

Date of next product order (please comment if less than 1 week):	Comments (please include when next dose is due for STAT requests):
Expiry date of approved contract (optional to fill out for records following CBS notification):	

Section V: Urgent Medical Review and SAP Information (CBS Use Only)

The on-call medical officer can be contacted after hours to review urgent requests for **patients that meet listing criteria**. Exceptional access reviews cannot be completed by the on-call medical officer and should be sent to the PPRP Formulary team for regular review. Please forward the request form with all documentation of medical review to SAPPRPRequests@blood.ca.

Decision of urgent medical officer review: ☐ Approve 30-day supply (specify amount below) ☐ Deny

Comments:

If medical review was obtained verbally, indicate results of review in comment section above. Include: as per (physician name), initial and date (e.g., as per Dr. Jane Doe, LA 2019-07-27)

SAP Patient #:	SAP Contract #:	Completed/Entered by:	Date:

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F800135 (Revision 1)
Legacy # F801219

TEM-00003 Rev 2

Questions regarding the form can be directed to SAPPRPRequests@blood.ca.

Example

- 80 kg patient
- Dose: 60 mg/kg/wk
- Vial size: **1000mg/50ml**

So 4800mg ~ **5 vials/wk**

- Patient picks up every 3 months (13 weeks) supply: **65 vials**
- For 1-year contract approval: **260 vials**

Other Supporting Information (including rationale for change or initiation of therapy):

Section IV: Total Contract Quantities in Vials
(refer to order form for product and available sizes)

Contracts will be created up to a maximum of **12 months**, A renewal request will be required every 12 months

Vial Size	Total Contract Quantity	Pick Up Quantity	Frequency of Pick Up (e.g., every 3 months)	Duration of Contract (max 12 months)
1000 mg/50 mL	260	65	q3months	12 months

Date of next product order (please comment if less than 1 week):

Expiry date of approved contract (optional to fill out for records following CBS notification):

Comments (please include when next dose is due for STAT requests):
(can add appointment date if this has been arranged or leave blank)

Once complete, where should the Request for Designated PPRP be sent to request access to Glassia?

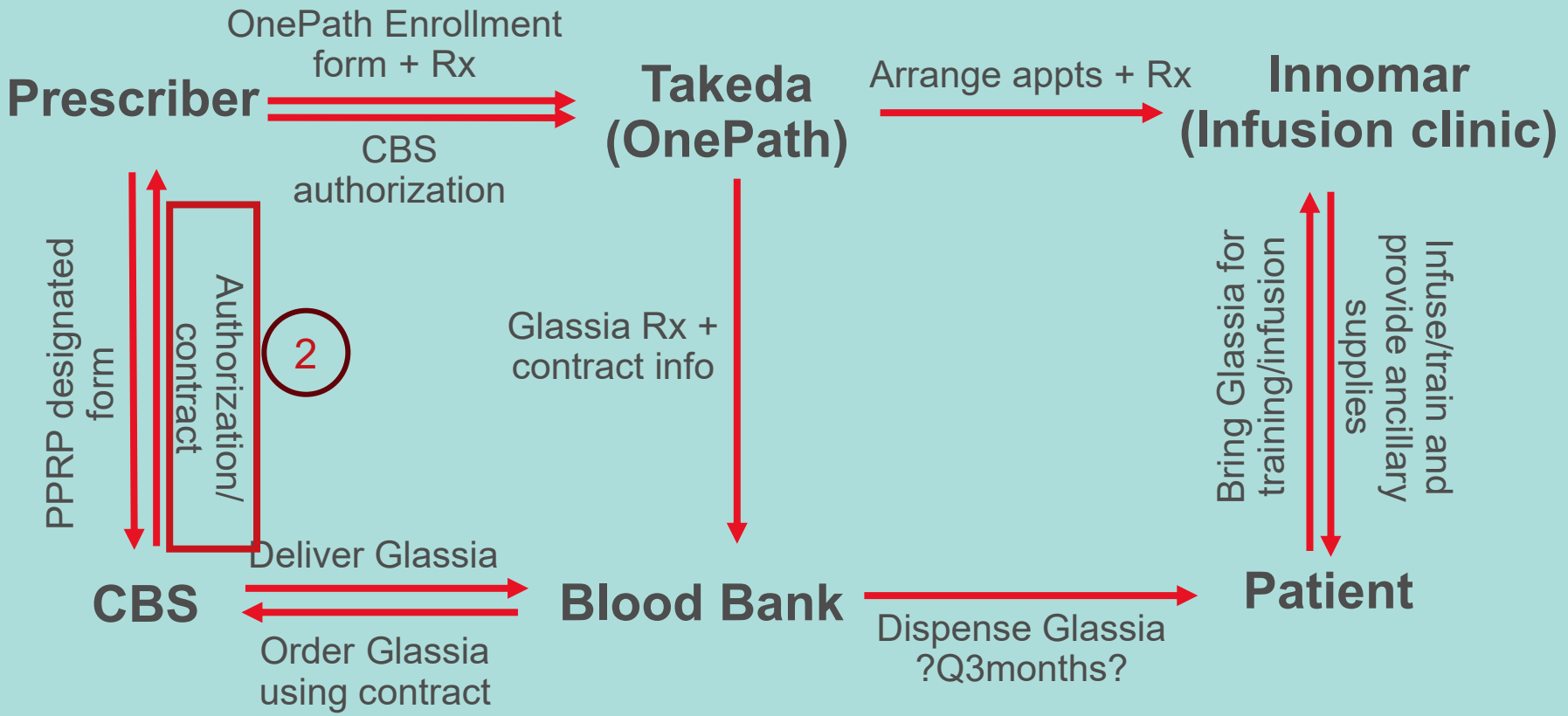
The prescribing clinician must submit a Request for Patient Designated PPRP form to Canadian Blood Services at SAPPRPRequests@blood.ca.

The request form can also be faxed to your local Canadian Blood Services Distribution site (see table).

Prescribers should also provide the Privacy Notice for Patient Designated Plasma Protein and Related Products to their patients (found here): https://www.blood.ca/sites/default/files/IM-00053_rev_1.pdf

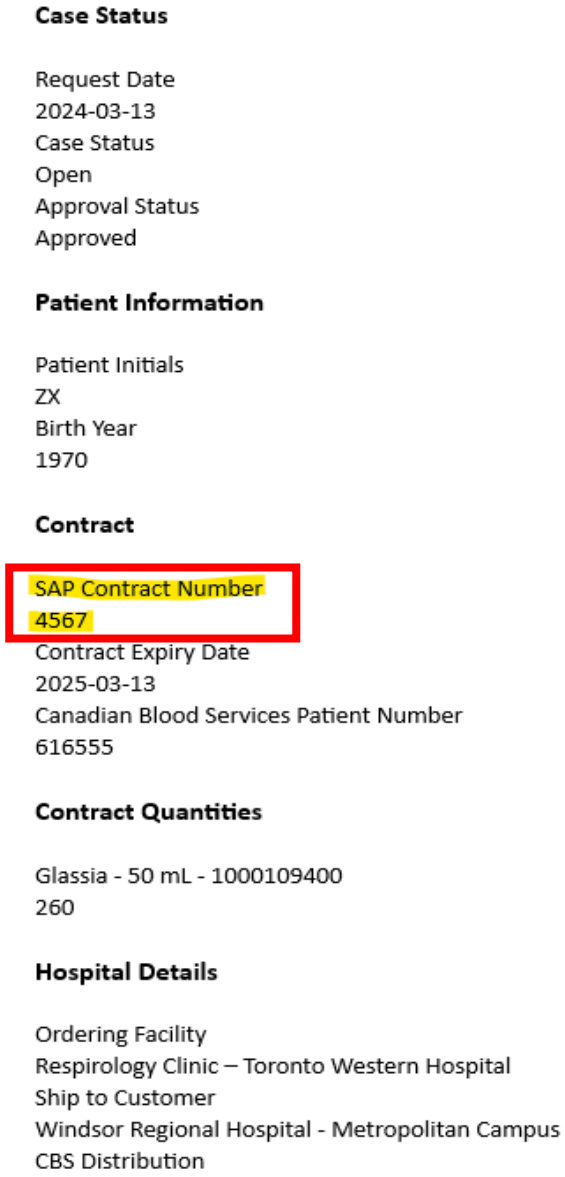
Distribution Site	Fax Number
British Columbia	604-879-6669
Alberta Edmonton Calgary	 780-433-4478 403-410-2791
Saskatchewan	306-347-1551
Manitoba	204-774-2956
Ontario Brampton Ottawa	 1-888-334-4554 613-560-7199
Atlantic Provinces (NB/NS/PEI)	1-855-305-6904
Newfoundland/Labrador	709-758-5322

All Jurisdictions (except QC and AB)



How will prescribers be informed of patient approval and the patient's contract number?

An approval notification, containing the patient's contract number, expiry date and approved quantities will be sent to the respirology contact noted on the request form.



Case Status

Request Date
2024-03-13
Case Status
Open
Approval Status
Approved

Patient Information

Patient Initials
ZX
Birth Year
1970

Contract

SAP Contract Number
4567
Contract Expiry Date
2025-03-13
Canadian Blood Services Patient Number
616555

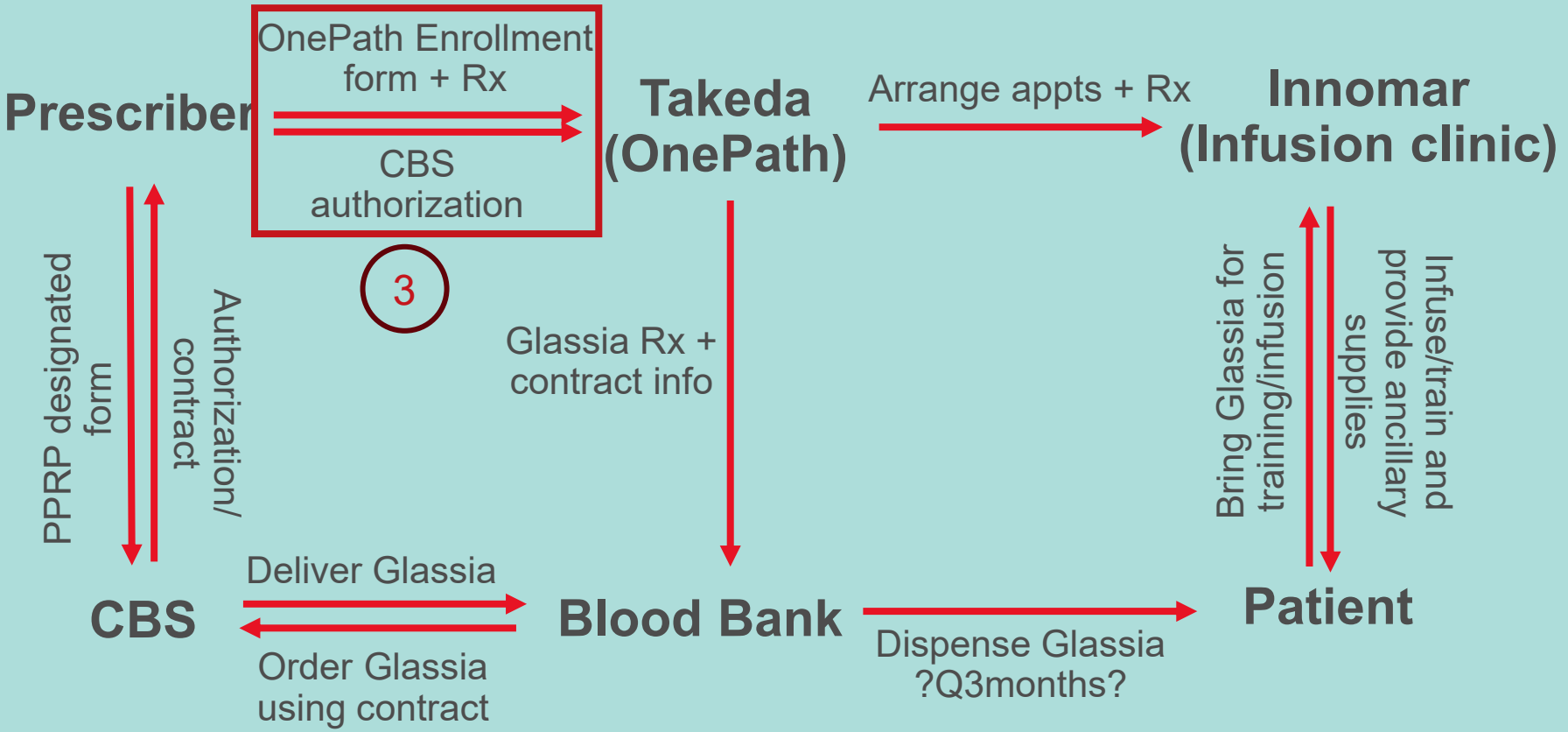
Contract Quantities

Glassia - 50 mL - 1000109400
260

Hospital Details

Ordering Facility
Respirology Clinic – Toronto Western Hospital
Ship to Customer
Windsor Regional Hospital - Metropolitan Campus
CBS Distribution

All Jurisdictions (except QC and AB)



Patient Support Program (PSP) onboarding

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

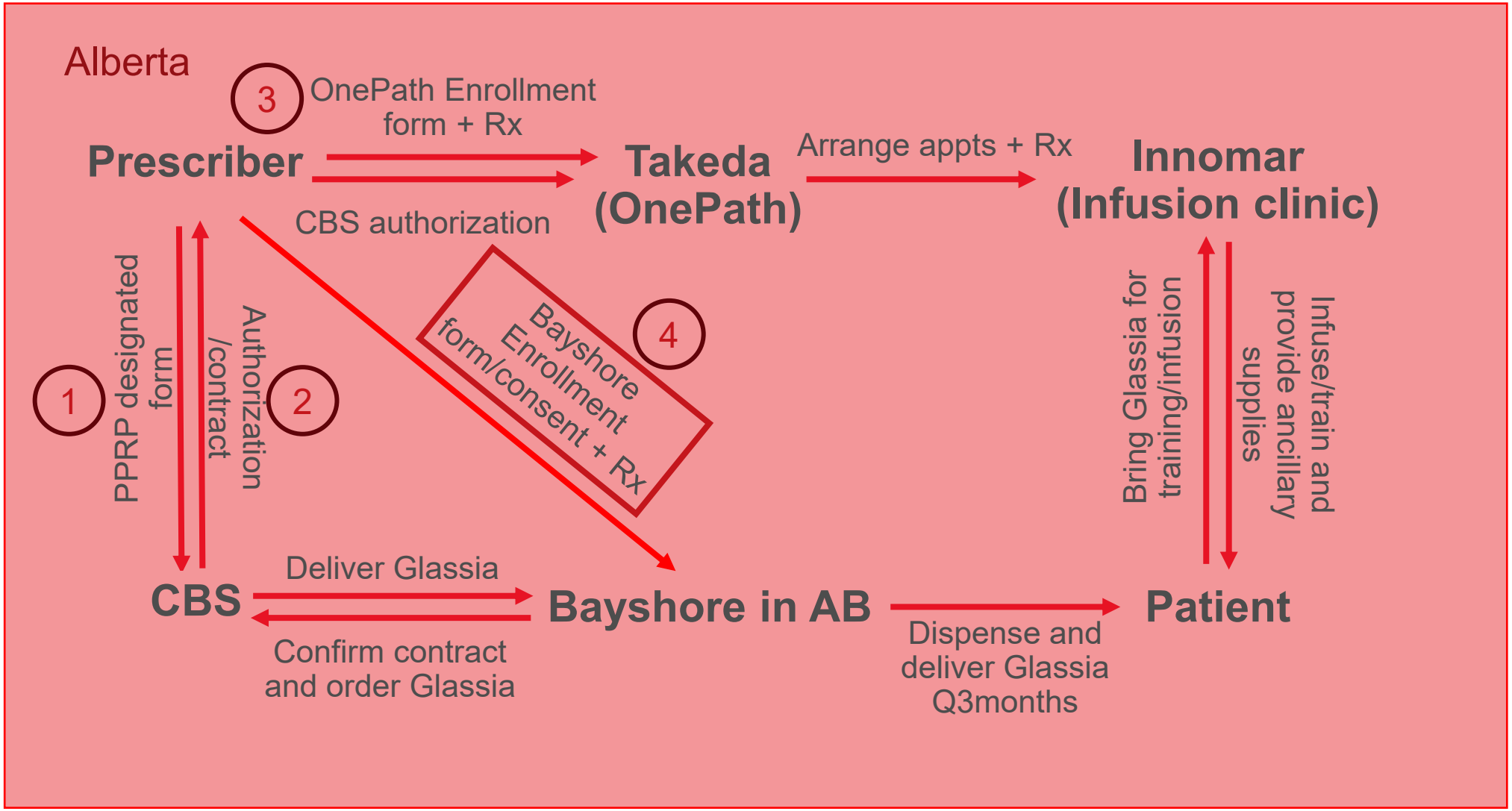
Prescribers can enroll patients by submitting the enrollment form to Takeda's Patient Support (OnePath). Any questions regarding the program should be directed to OnePath through the following contact information:

Tel: 1-844-691-7284

Fax: 1-844-951-7284

E-mail: support@onepathprogram.ca

How is access to Glassia different in Alberta?



How is access to Glassia different in Alberta?

In Alberta, eligible patients will have Glassia dispensed and delivered to their homes by Bayshore Pharmacy, a specialty pharmacy, instead of picking it up from Transfusion Medicine Laboratories (blood banks).

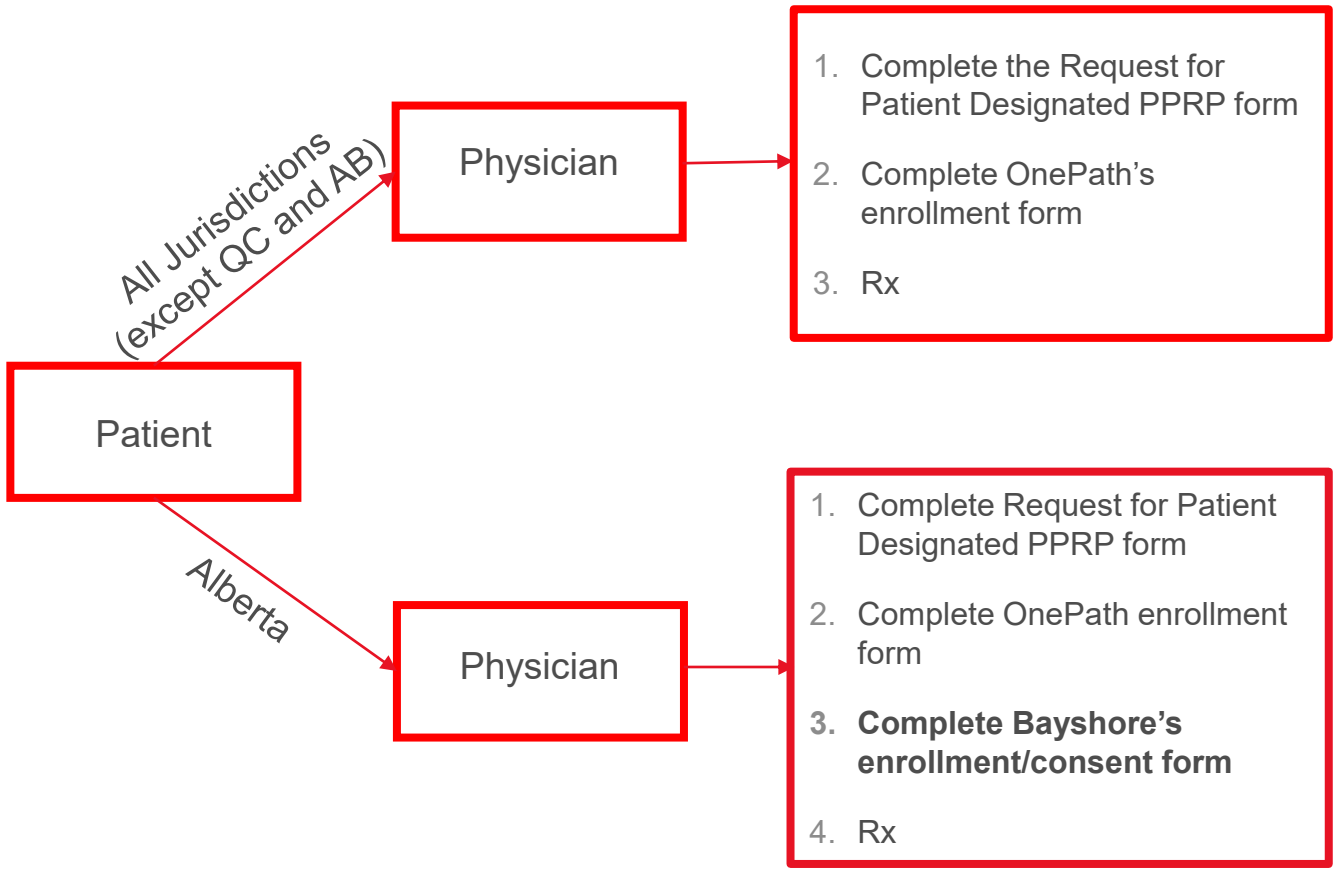
Patients enrolled in OnePath, Glassia's patient support program (PSP), will receive their Glassia infusion administered at an Innomar clinic (same as in other jurisdictions).

Extra Step:

Prescribers must complete the Bayshore enrollment/consent form and provide it along with a Glassia Rx to Bayshore Pharmacy

- Tel: 1-855-430-0730
- Fax: 1-855-307-2929
- Email: bsrxab@bayshore.ca

Summary


All Jurisdictions (except QC and AB)
Physician
1. Complete the Request for Patient Designated PPRP form
2. Complete OnePath's enrollment form
3. Rx
Patient
Alberta
Physician
1. Complete Request for Patient Designated PPRP form
2. Complete OnePath enrollment form
3. Complete Bayshore's enrollment/consent form
4. Rx

As a prescriber, who should I contact if I have…

- Any questions regarding eligibility and completing the Request for Patient Designated PPRP form: SAPPRPRequests@blood.ca.
- Any questions regarding the Rx, enrollment forms, infusion appointment or dispensing of product should be directed to **OnePath**:
  - Tel: 1-844-691-7284
  - Fax: 1-844-951-7284
  - E-mail: support@onepathprogram.ca
- Any questions regarding the dispensing and delivery of Glassia to patients' homes (**Only Alberta**) should be directed to **Bayshore**:
  - Tel: 1-855-430-0730
  - Fax: 1-855-307-2929
  - Email: bsrxab@bayshore.ca

Who should patients contact if they have a problem?

- The FAQ instructs patients to direct any clinical questions regarding the disease and eligibility criteria to their prescriber(s).
- Any questions regarding the infusion appointment or dispensing of product should be directed to **OnePath**:
  - Tel: 1-844-691-7284
  - Fax: 1-844-951-7284
  - E-mail: support@onepathprogram.ca
- Any questions regarding the dispensing and delivery of Glassia to patients' homes (**Only Alberta**) should be directed to **Bayshore**:
  - Tel: 1-855-430-0730
  - Fax: 1-855-307-2929
  - Email: bsrxab@bayshore.ca

Emily,
blood donor

Charles,
blood recipient

Thank you