ALBERTA PRECISION LABORATORIES
Leaders in Laboratory Medicine

Glassia®
Alpha-1 Proteinase Inhibitor (Human)

APPLICABILITY: This document applies to APL, AHS, Covenant Health, and all other health care professionals involved in the transfusion of blood components and products in Alberta.	***OTHER NAMES:*** *Alpha-1 Proteinase Inhibitor (Human)* ***Company:*** *Takeda* ***Class:*** *Manufactured blood product, derived from human plasma*

In the event of discrepancy between APL Monograph and Manufacturer's documentation or patient resources, the APL Monograph will take precedence.

	INTRAVENOUS			OTHER		
ROUTES	**DIRECT IV****	**IV Infusion**	**Continuous Infusion**	**SC**	**IM**	**OTHER**
Acceptable Routes*	No	Yes	No	Yes***	No	N/A

***** Administration of blood components and blood products is a restricted activity. For specific conditions that apply to a profession's authorization to administer blood components and blood products, consult the applicable discipline-specific regulation under the Health Professions Act (Alberta). Health care professionals with this authorization require the applicable education, training, and competency.

** Direct IV administration of blood products may be performed by health care professionals that have authorization of administration of blood products within their scope of practice.

*** Subcutaneous administration is currently considered off-label and may only occur at the direction of the MRHP.

DESCRIPTION OF PRODUCT:

- Glassia® is a human-derived alpha-1 proteinase inhibitor (A1-PI).
- Available in single-use vials of 1000 mg (approx.) functionally active A1-PI, in 50 mL water for Injection.
- Viral inactivation/removal steps include nanofiltration and solvent/detergent treatment.
- May contain trace amounts of IgA.
- Glassia® is clear and colorless to yellow-green.
  - There may be protein particles present in the vial.
- Preservative-free
- Latex-free

AVAILABILITY:

- Routine distribution of Glassia® in Alberta will be handled through Bayshore Pharmacy.
- To request access of Glassia® for their patients, MRHPs must submit a Request for Patient Designated Plasma Protein and Related Products form to Canadian Blood Services (CBS): SAPPRPRequests@blood.ca
- Glassia® can be ordered from CBS using the patient's contract number through the Online Ordering Portal or by submitting the Order Form for Plasma Protein and Related Products Requiring Contracts.

INDICATIONS FOR USE:

- Glassia® is indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to alpha1-antitrypsin deficiency (AATD).

ELIGIBILITY CRITERIA:

- Confirmed diagnosis of severe AATD and clinically evident emphysema by Respirologist with indication that patient would benefit from treatment with A1-PI product.
- AATD: serum A1-PI levels <11µmol/L or <57 mg/dL before start of treatment.
- Clinical evidence of obstruction (FEV1 <80%).
- Non-smoker for at least 6 months.
- Has not received a lung transplant.

CONTRAINDICATIONS:

- IgA deficiency with antibodies against IgA.
- History of anaphylaxis or other severe systemic reaction to A1-PI.
- Hypersensitivity to this drug or to any ingredient in the formulation, including any non-medicine ingredient or component of the container.
- Lung disease in patients without AATD.
- Not authorized for use in pediatrics due to no established safety and efficacy in pediatric patients.

WARNINGS:

- Caution in patients over 65 years old.

DOSE:

- Recommended dose: 60 mg/kg weekly.

ADMINISTRATION:

Confirm signed consent has been obtained and documented prior to requesting blood components or products (human-source) from lab/transfusion service where possible.

The administration information below is intended for use by health care professionals when Glassia® is administered in an AHS health care facility (e.g. ambulatory IV clinic). For home-use of Glassia®, patients will be connected with an appropriate patient support program.

Refer to MRHP orders and instructions for off-label subcutaneous administration of Glassia®.

Pre-Infusion:

- Ensure recent patient weight and height is on file.
- Ensure pertinent labs are available as required.
- Ensure any ordered premedications have been given (e.g. antihistamines, antipyretics prn).
- Perform the appropriate pre-transfusion checks per AHS Transfusion Policy and Procedure.
- Report any new onset acute illness to the authorized prescriber prior to starting infusion.

Access:

- Peripheral IV or central venous access site.

Administration Supplies:

- Intravenous administration set
  - Vented pump tubing (if infusing directly from vial)
- 5 micron in-line filter – not supplied by TM lab
- Infusion pump (as required)
- Normal saline (for flushing post-infusion)

Other Supplies:

- Antiseptic wipes or alcohol swabs
- If pooling into a sterile empty IV bag:
  - Sterile empty IV bag large enough to contain dose
  - Vented spike
  - 50mL sterile syringe
  - Blunt needle

  ] Not supplied by TM lab

Administration:

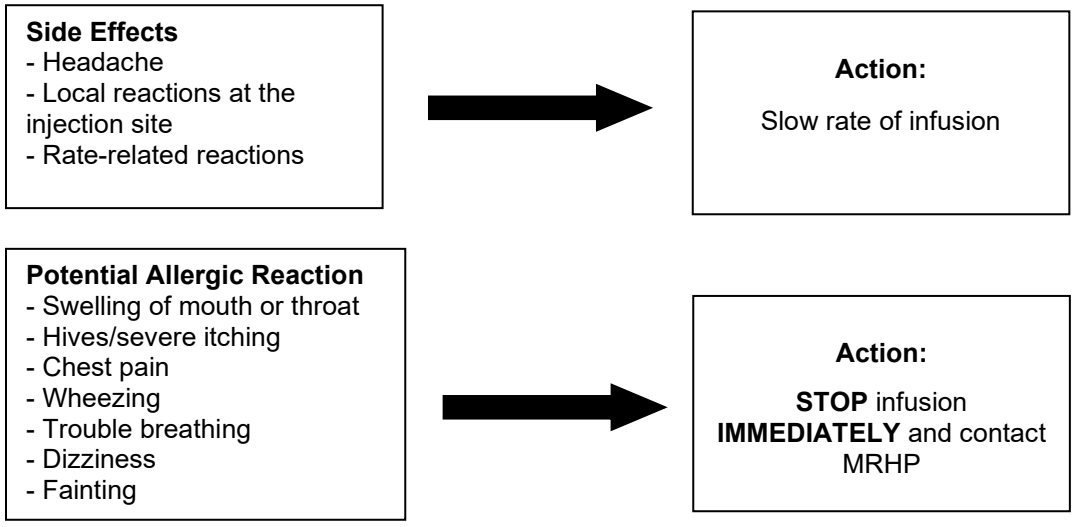
- Bring Glassia® to room temperature. Do not use heating devices.
- Visually inspect the product prior to administration. Do not use products that are cloudy.
- Do not mix with any other solutions or medications, except for normal saline for flushing post-infusion.
- Do not mix the Glassia® dual-vial units together.
- Administer within 3h of entering vial.

Infusion Rate:

- Max recommended rate: 0.2 mL/kg/min.
  - Nursing may titrate max rate determined by patient comfort and tolerability, no MRHP order required.

POTENTIAL HAZARDS WITH PARENTERAL ADMINISTRATION:

- Potential adverse events related to a blood product transfusion range in severity, from minor with no sequelae, to life-threatening. All adverse events occurring during a transfusion should be evaluated to determine whether or not the transfusion can be safely continued/restarted. Acute reactions need medical involvement.
- All adverse events suspected to be related to a product transfusion (whether during or after a transfusion) should be reported to your local transfusion service.
- The most common adverse reactions to Glassia® include: headache and upper respiratory infection.
- Other side effects include: cough, sinus infection, chest discomfort, shortness of breath, nausea, fatigue, and increased liver enzymes.



NURSING IMPLICATIONS:

Patient Vital Signs and Monitoring:

- Vital signs: Pre-administration and at least 20 min. post-infusion for any adverse effects.
  - If the patient has experienced previous adverse reactions to the product, or this is the first infusion of the product, monitor for 30 – 60 minutes post-infusion.

Note: Vital signs/patient monitoring may be conducted more frequently as determined by clinical condition of patient.

Patients receiving blood component or product transfusions must be observed closely for signs of any unexpected or untoward reactions. These reactions may occur during or after the infusion of blood component or blood products. For follow up instructions to a transfusion reaction, go to *Transfusion Reactions | Alberta Health Services*.

Documentation:

- Ensure documentation is completed as per the AHS *Transfusion of Blood Components and Products Policy*.
- The transfusion documentation should be double signed.
- Start and stop time of infusion and assessment of patient tolerability should also be documented in appropriate flow chart or clinical record (electronic or paper).
- Document vital signs as required in the appropriate flow chart or clinical record (electronic or paper).
- Provide patient notification of transfusion documentation where required.
- Documentation for home use of Glassia® must follow the policies of the clinical program.

STORAGE & STABILITY

- Store at 2-8°C until expiry.
- May be stored at room temperature (not to exceed 25°C) for up to one month after removal from the refrigerator. Do not return to refrigeration once removed.
- Product stored by the patient for home use must comply with manufacturer's recommendations. Product issued for home use and returned to Transfusion Medicine Laboratory will be discarded.
- Do not remove from carton until required for use.
- Do not use expired product.

COMMENTS:

Date Effective: 25 APR 2024
Revision #: 1.00
Document Number: TM40-01.02.044
Approved By: APL Transfusion Medicine Discipline Council

For questions or comments regarding this document please contact: Transfusion.SafetyTeam@aplabs.ca

REFERENCES

Glassia® manufacturer monograph. Available from www.takeda.com

Glassia® Implementation FAQ version 1.0. Available from Glassia Implementation FAQ CBS