

Aralast™ NP, Glassia™, Prolastin-C®, and Zemaira® (alpha₁-proteinase inhibitor [human])

When requesting Aralast NP, Glassia, Prolastin-C, and Zemaira (alpha₁-proteinase inhibitor [human]), the individual requiring treatment must be diagnosed with the following FDA-approved indication or approved compendial use and meet the specific coverage guidelines and applicable safety criteria for the covered indication.

FDA-Approved Indication

Aralast NP, Glassia, Prolastin-C and Zemaira are alpha₁-proteinase inhibitors indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha₁-antitrypsin (AAT).

Approved Off-label Compendial Use

Panniculitis due to alpha₁-antitrypsin (AAT) deficiency

Coverage Guidelines

Emphysema due to AAT deficiency

The individual must meet **all** of the following criteria for authorization:

- Is 18 years of age or older;
- Has a baseline (pretreatment) AAT serum concentration less than 11 micromol/L (less than 80 mg/dL if measured by radial immunodiffusion or less than 57 mg/dL if measured by nephelometry);
- Is currently a nonsmoker.

Panniculitis due to AAT deficiency

The individual must be 18 years of age or older for authorization.

Approval duration: 12 months

Dosing Recommendation

The recommended dose is 60 mg/kg administered once weekly by intravenous infusion.

References

1. Aralast NP® intravenous infusion [prescribing information]. Lexington, MA: Shire; October 2024.
2. Zemaira® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; January 2024.

3. Prolastin®-C intravenous infusion [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics; January 2021.
4. Prolastin®-C Liquid intravenous infusion [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics; May 2020.
5. Glassia® intravenous infusion [prescribing information]. Lexington, MA: Shire; September 2023.
6. Miravittles M, Dirksen A, Ferrarotti I, et al. European Respiratory Society statement: diagnosis and treatment of pulmonary disease in alpha1-antitrypsin deficiency. *Eur Respir J*. 2017;50(5).
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10. American Thoracic Society and the European Respiratory Society. Standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med*. 2003;168:818-900.
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14. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2024. Available at: <https://goldcopd.org/2024-gold-report/>. Accessed on January 9, 2024.