

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 an 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 congenital deficiency of alpha₁-antitrypsin (AAT) deficiency.

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); AND
- 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; December 2018.
2. Zemaira® intravenous infusion [prescribing information]. Kankakee, IL: CSL Behring; April 2019.
3. Prolastin®-C intravenous infusion [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics; June 2018.
4. Prolastin®-C Liquid intravenous infusion [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics; August 2018.
5. Glassia® intravenous infusion [prescribing information]. Lexington, MA: Shire; June 2017.
6. Brantly ML, Lascano JE, Shahmohammadi A. Intravenous alpha-1 antitrypsin therapy for alpha-1 antitrypsin deficiency: the current state of the evidence. *Chronic Obstr Pulm Dis*. 2018;6(1):100-114.
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8. 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).
9. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: A Canadian Thoracic Society clinical practice guideline. *Can Respir J*. 2012;19:109-116.
10. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. *Chronic Obstr Pulm Dis*. 2016;3(3):668-682.
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12. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. Updated 2021. Available at: <https://goldcopd.org/2021-gold-reports/>. Accessed on November 10, 2021.

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