

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 an alpha₁-proteinase inhibitor indicated for chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe congenital deficiency of alpha₁-antitrypsin deficiency.

Approved Off-label Compendial Use

Panniculitis due to alpha₁-antitrypsin (AAT) deficiency

Coverage Guidelines

The individual must have a diagnosis of emphysema due to alpha₁-antitrypsin (AAT) deficiency OR panniculitis due to AAT deficiency.

For emphysema due to AAT deficiency:

The individual must meet BOTH of the following criteria for approval:

- Baseline (pretreatment) AAT serum concentration is less than 11 micromol/L (less than 80 mg/dL)
- Currently a nonsmoker

Approval duration: 12 months

Dosing Recommendation

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

References

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2. Zemaira™ [prescribing information]. Kankakee, IL: CSL Behring; September 2015.
3. Prolastin®-C [prescribing information]. Research Triangle Park, NC: Talecris Biotherapeutics; February 2017.
4. Prolastin®-C Liquid [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics; September 2017.
5. Glassia® [prescribing information]. Lexington, MA: Shire; June 2017.
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