

SPECIALTY GUIDELINE MANAGEMENT Alpha₁-Proteinase Inhibitors

ARALAST NP (alpha₁-proteinase inhibitor [human])
GLASSIA (alpha₁-proteinase inhibitor [human])
PROLASTIN-C (alpha₁-proteinase inhibitor [human])
ZEMAIRA (alpha₁-proteinase inhibitor [human])

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Aralast NP
Chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)
2. Glassia
Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)
3. Prolastin-C
Chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha₁-proteinase inhibitor (alpha₁-antitrypsin deficiency)
4. Zemaira
Chronic augmentation and maintenance therapy in adults with alpha₁-proteinase inhibitor deficiency and clinical evidence of emphysema

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Indefinite authorization may be granted for treatment of alpha₁-antitrypsin (AAT) deficiency when all of the following criteria are met:

1. The member has clinically evident emphysema.
2. The member's pretreatment serum AAT level is less than 11 micromol/L (80 mg/dl by radial immunodiffusion or 50 mg/dl by nephelometry).
3. The member's pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV₁) is greater than or equal to 25% and less than or equal to 80% of predicted.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2015.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; June 2016.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2016.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; September 2015.
5. American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med.* 2003;168:818-900.
6. 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.