Generic Name: Alpha 1 Proteinase Inhibitor, human

Therapeutic Class or Brand Name: Alpha-1 Proteinase Inhibitors

Applicable Drugs: Aralast NP, Glassia, Prolastin-C, Zemaira

Date of Origin: 8/20/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of emphysema due to congenital alpha-1 antitrypsin (AAT) deficiency and must meet ALL criteria listed below:

A. Documentation of ONE of the following high-risk genotypes below:

i. PiZZ (ZZ-AATD)

ii. PiZ/null

iii. Pi null/null

B. Documented severe AAT deficiency with a serum level below 11 micromole/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry).

C. Documentation that the patient has never smoked, is currently attempting smoking cessation, or attestation that information regarding the harmful effects of smoking and behavioral and/or pharmacotherapy interventions to aid in smoking cessation have been discussed and encouraged.

D. Clinically evident emphysema confirmed by documentation of FEV1 between 35% and 80% predicted.

E. Continued optimal conventional treatment for emphysema (eg, bronchodilators, supplemental oxygen if necessary).

F. Documentation of one of the following:

i. Chronic cough with sputum production.

ii. Rapid decline in FEV1.

iii. Evidence of airflow obstruction (i.e., reduced FEV1/FVC ratio).

iv. Frequent respiratory infections.

v. Recurrent COPD exacerbations requiring systemic corticosteroids, antibiotics, ED visits, or hospitalization.

II. Minimum age requirement: 18 years of age

III. Prescribed by or in consultation with a pulmonologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Immunoglobin A (IgA) deficient patients with antibodies against IgA.
- PiMZ heterozygous or homozygous normal genotypes.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

Medication	Dose
Aralast NP (500 mg, 1000 mg SDV)	60mg/kg* IV once weekly
Glassia (1000 mg/50 mL, 4 g/200 mL, 5 g/250 mL SDV)	
Prolastin-C (1000 mg/20 mL SDV)	
Zemaira (1000 mg/20 mL, 4000 mg/76 mL, 5000 mg/95 mL SDV)	
*Not to exceed 60mg/kg dose Abbreviations: SDV, single dose vial	

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 12 months, with an updated letter of medical necessity or progress notes that initial approval criteria was met and documentation of adherence with treatment. If patient is currently a smoker, there must be documentation of an active smoking cessation attempt or continued regular and repeated counseling concerning the harmful effects of smoking and available smoking cessation options.

APPENDIX

N/A

REFERENCES

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2. American Thoracic Society and 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.. doi: 10.1164/rccm.168.7.818
3. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global strategy for the diagnosis, management, and prevention of COPD: Updated 2026. Accessed July 20, 2026. https://goldcopd.org/2026-gold-report-and-pocket-guide/
4. Aralast NP. Prescribing information. Takeda Pharmaceuticals U.S.A, Inc; 2025. Accessed July 20, 2026. https://www.shirecontent.com/PI/PDFs/ARALASTNP_USA_ENG.pdf
5. Glassia. Prescribing information. Takeda Pharmaceuticals U.S.A, Inc; 2025. Accessed July 20, 2026. Takeda Pharmaceuticals U.S.A, Inc; 2025. https://www.shirecontent.com/PI/PDFs/GLASSIA_USA_ENG.pdf
6. Prolastin-C. Prescribing information. Grifols Therapeutics LLC; 2020. Accessed July 20, 2026. https://www.prolastin.com/documents/7530511/7530662/Prolastin+Prescribing+Information.pdf/6b2c3082-7201-cc58-320f-29935328f762?t=1744034768380
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