

ALPHA1-PROTEINASE INHIBITORS
Aralast NP, Glassia, **Prolastin-C**, Zemaira

Preferred Alpha1-Proteinase Inhibitor: Prolastin-C

Pre - PA Allowance

None

Prior-Approval Requirements**Age** 18 years of age and older**Diagnosis**

Patient must have the following:

1. Emphysema
 - a. Clinically documented alpha₁-antitrypsin (AAT) deficiency

AND ALL of the following for Aralast NP, Glassia, and Zemaira **ONLY**:

1. Patient has a pretreatment serum AAT level less than 11 µM/L (80 mg/dl by radial immunodiffusion or 50 mg/dl by nephelometry)
2. Patient must **NOT** be a current smoker
3. Documented progressive emphysema with **ONE** of the following:
 - a. Moderate airflow obstruction is evidenced by forced expiratory volume (FEV₁) of 30-65% of predicted value, prior to initiation of therapy
 - b. Individual has a rapid decline in lung function as measured by a change in FEV₁ greater than 120 ml/year
 - c. FEV₁ of >65% predicted with bronchiectasis with one or more severe exacerbations resulting in ED visit or hospitalization within the last year
4. Patient **MUST** have tried the preferred product (Prolastin-C), if adjudicated through the pharmacy benefit, unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval Limits**Duration** 3 months

Prior – Approval *Renewal* Requirements**Age** 18 years of age and older



Federal Employee Program.

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Diagnosis

Patient must have the following:

1. Emphysema

AND ALL of the following for Aralast NP, Glassia, and Zemaira **ONLY**:

1. Patient must **NOT** be a current smoker
2. Clinical evidence of efficacy with **ONE** of the following:
 - a. Elevation of AAT levels (above protective threshold)
 - b. Reduction in rate of deterioration of lung function with a reduction in FEV₁ rate of decline
3. Patient **MUST** have tried the preferred product (Prolastin-C), if adjudicated through the pharmacy benefit, unless the patient has a valid medical exception (e.g., inadequate treatment response, intolerance, contraindication)

Prior - Approval *Renewal* Limits

Duration 12 months