

Federal Employee Program.

### **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 alpha<sub>1</sub>-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 (FEV<sub>1</sub>) 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 FEV<sub>1</sub> greater than 120 ml/year
  - c. FEV<sub>1</sub> 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



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Preferred Alpha1-Proteinase Inhibitor: Prolastin-C

### **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 FEV<sub>1</sub> 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