SPECIALTY GUIDELINE MANAGEMENT
Alpha_{1}-Proteinase Inhibitors

ARALAST NP (alpha_{1}-proteinase inhibitor [human])
GLASSIA (alpha_{1}-proteinase inhibitor [human])
PROLASTIN-C (alpha_{1}-proteinase inhibitor [human])
ZEMAIRA (alpha_{1}-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 alpha_{1}-proteinase inhibitor (alpha_{1}-antitrypsin deficiency)

2. Glassia
   Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha_{1}-proteinase inhibitor (alpha_{1}-antitrypsin deficiency)

3. Prolastin-C
   Chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha_{1}-proteinase inhibitor (alpha_{1}-antitrypsin deficiency)

4. Zemaira
   Chronic augmentation and maintenance therapy in adults with alpha_{1}-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 alpha_{1}-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 (FEV_{1}) 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