CRITERIA FOR COVERAGE/NONCOVERAGE

ARALAST NP®, GLASSIA®, PROLASTIN®, PROLASTIN®-C, and ZEMAIRA® (alpha-1 proteinase inhibitors) will be considered for coverage under the pharmacy benefit program when the following criteria are met:

- The patient has a diagnosis of emphysema
- The patient has an alpha-1 proteinase inhibitor (alpha-1 antitrypsin) deficiency
- The patient has a high risk phenotype:
  - PiZZ
  - PiZ(null)
  - Pi(null)(null) OR
  - Other phenotypes associated with serum alpha-1 antitrypsin concentrations of less than 11 uM/L (80 mg/dL)
- The FEV1 level is between 30% and 65% of predicted or the patient has experienced a rapid decline in lung function (i.e., reduction of FEV1 more than 120 mL/year) that warrants treatment.
- The patient does not have IgA deficiency with known anti-IgA antibody.
- The patient is not a current smoker.

Approval duration is lifetime.

Alpha-1 protease inhibitor is considered experimental/investigational for conditions not listed in this coverage policy section.