

Medical Policy:

Alpha 1-Proteinase Inhibitors (A₁-PI)

Last review date: 7/1/2025

Applicable Products:

Aralast NP (alpha.1-proteinase inhibitor human)
Glassia (alpha.1-proteinase inhibitor human)
Prolastin/Prolastin-C (alpha.1-proteinase inhibitor human)
Zemaira (alpha.1-proteinase inhibitor human)

Initial Approval Criteria:

Coverage may be approved if all of the following are met:

- Must be age 18 years or older; **AND**
- Must be prescribed by a pulmonologist; **AND**
- Must have a diagnosis of congenital alpha1-antitrypsin deficiency and clinical evidence of emphysema; **AND**
- Must not smoke; **AND**
- Must not have selective or severe immune globulin A (IgA) deficiencies; **AND**
- If applicable: Trial and failure, intolerance, or a contraindication to the preferred products as listed in the medical drug list

Renewal Criteria:

Coverage may be renewed if all of the following are met:

- Patient continues to meet Initial Approval Criteria; **AND**
- Improvement in the member's condition as evidenced by chart documentation showing a reduction in porphyria attacks requiring hemin administration, hospitalization, or urgent healthcare visits (e.g., emergency department visit); **AND**
- Absence of unacceptable toxicity

Length of Authorization:

12 months

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical or other circumstances may warrant individual consideration, based on review of applicable medical records, as well as other regulatory, contractual and/or legal requirements.

Medical policies do not constitute medical advice, nor are they intended to govern the practice of medicine. They are intended to reflect reimbursement and coverage guidelines. Coverage for services may vary for individual members, based on the terms of the benefit contract.