Field Name	Field Description
Prior Authorization Group Description	**Alpha-1 Proteinase Inhibitors (Human)**
Drugs	**Preferred:** Prolastin-C **Non-Preferred:** Aralast NP Glassia Zemaira Or any other newly marketed agent
Covered Uses	Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria	**Members who have undergone liver transplantation** ~~None~~
Required Medical Information	None
Age Restrictions	18 years of age or older
Prescriber Restrictions	Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT
Coverage Duration	The request will be approved for up to a 12 month duration
Other Criteria	****Drug is being requested through the member's medical benefit**** **Initial Authorization:** • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] • Documentation was submitted (member's pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FE_{V1}] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) • Documentation of the member's current weight • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage

Revision/Review Date **<u>04/2024</u>** ~~01/2023~~	• If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition **Reauthorization:** • Documentation of the member's current weight • Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment) • Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life) • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage **Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.**