Updated: 03/2020
DMMA Approved: 05/2020

Request for Prior Authorization for Alpha1-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C and Zemaira®)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Alpha1-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C and Zemaira®) require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Alpha1-proteinase inhibitors (Aralast NP™, Glassia™, Prolastin®-C and Zemaira®)Prior Authorization Criteria:

Alpha1-proteinase include Aralast NP, Glassia, Prolastin, and Zemaira. New products with this classification will require the same documentation.

Coverage may be provided with a diagnosis of Emphysema due to congenital deficiency of alpha1-proteinase inhibitor (A1-PI) and the following criteria is met:

- Member is 18 years of age or older
- Member has a diagnosis of congenital alpha-1-antitrypsin (AAT) deficiency confirmed by **ONE** of the following:
    - Pi*ZZ, Pi*Z(null), Pi*(null)(null), or Pi*SZ protein phenotypes (homozygous)
    - Other rare AAT deficiency disease-causing alleles associated with serum AAT level < 11 µmol/L
- Member has circulating serum concentration of AAT < 11 µmol/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry).
- Member has a diagnosis of emphysema confirmed by **ONE** of the following:
    - Forced expiratory volume in one second (FEV1) from ≥ 30% to ≤ 65% of predicted, post-bronchodilator
    - FEV1 from > 65% to < 80% of predicted, post-bronchodilator, and a rapid decline in lung function showing a change in FEV1 > 100 mL/year
- Medication is prescribed by or in consultation with a pulmonologist.
- Prescriber attests that member will continue to be on optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen, etc.)
- Member is currently a nonsmoker.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Reauthorization benefit will be approved if there is documented, significant improvement with prior courses of treatment.
- **Reauthorization Duration of Approval:** 12 months

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Alpha1-proteinase Inhibitors
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Highmark Health Options Pharmacy Services. **FAX:** (855) 476-4158
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (844) 325-6251 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:
Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Is member 18 years of age or older?
   ☐ Yes ☐ No

2. Does the member have a diagnosis of congenital alpha-1-antitrypsin (AAT) deficiency confirmed by any of the following:
   a. Pi*ZZ, Pi*Z(null), Pi*(null)(null), or Pi*SZ protein phenotypes (homozygous)
      ☐ Yes ☐ No

   b. Other rare AAT deficiency disease-causing alleles associated with serum AAT level < 11 µmol/L
      ☐ Yes ☐ No

3. Does the member have circulating serum concentration of AAT < 11 µmol/L (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry)?
   ☐ Yes ☐ No

4. Does the member have a diagnosis of emphysema confirmed by any of the following:

a. Forced expiratory volume in one second (FEV1) from ≥ 30% to ≤ 65% of predicted, post-bronchodilator
☐ Yes ☐ No

b. FEV1 from > 65% to < 80% of predicted, post-bronchodilator, and a rapid decline in lung function showing a change in FEV1 > 100 mL/year
☐ Yes ☐ No

5. Will the medication be prescribed by or in consultation with a pulmonologist?
☐ Yes ☐ No

6. Does the prescriber attest that member will continue to be on optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen, etc.)?
☐ Yes ☐ No

7. Is the member currently a nonsmoker?
☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY			
Medication Name	**Strength/ Frequency**	**Dates of Therapy**	**Status (Discontinued & Why/Current)**

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date