HIGHMARK HEALTH OPTIONS

Updated: 07/2025
DMMA Approved: 07/2025

Request for Prior Authorization for Alpha-1 Proteinase Inhibitors
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

All requests for Alpha-1 Proteinase Inhibitors require a Prior Authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Alpha-1 Proteinase Inhibitors Prior Authorization Criteria:

Alpha-1 Proteinase Inhibitors include Aralast NP™, Glassia™, Prolastin®-C 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 has a diagnosis of congenital alpha-1-antitrypsin deficiency (AATD) confirmed by **ONE** of the following:
  - A high risk AATD genetic variant [e.g., 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 a baseline circulating serum concentration of AATD < 11 µmol/L using rocket immunoelectrophoresis (which corresponds to < 80 mg/dl if measured by radial immunodiffusion or < 57 mg/dl if measured by nephelometry).
- Member has a diagnosis of clinically evident 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 or ex-smoker
- Member must not have a contraindication to therapy such as an Immunoglobulin A (IgA) deficiency with antibodies against IgA.
- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- 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 documentation of improvement or stabilization of the signs and symptoms of emphysema associated with alpha-1 antitrypsin deficiency including slowed progression of emphysema as evidenced by

annual spirometry testing or a decrease in frequency, duration or severity of pulmonary exacerbations

- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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ALPHA-1 PROTEINASE INHIBITORS
PRIOR AUTHORIZATION FORM- Page 1 of 2

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 8:00am to 7:00pm

PROVIDER INFORMATION

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

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
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, 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)

Diagnosis: ☐ Emphysema due to congenital deficiency of A-1 PI ☐ Other: _____

Does the member have a diagnosis of congenital alpha-1-antitrypsin deficiency (AATD) confirmed by ONE of the following?

- A high risk AATD genetic variant [e.g., Pi*ZZ, Pi*Z(null), Pi*(null)(null), or Pi*SZ protein phenotypes (homozygous)] ☐ Yes ☐ No
- Other rare AATD disease-causing alleles associated with serum AAT level < 11 µmol/L ☐ Yes ☐ No

What is the member's baseline circulating serum concentration of AATD? _____
Does the member have any contraindications to therapy? ☐ Yes ☐ No
Does the member have a diagnosis of emphysema confirmed by any 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

Does the prescriber attest the member will continue to be on optimal conventional treatment for emphysema (e.g., bronchodilators, supplemental oxygen, etc.)? ☐ Yes ☐ No
Is the member currently a nonsmoker or ex-smoker? ☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

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ALPHA-1 PROTEINASE INHIBITORS
PRIOR AUTHORIZATION FORM- Page 2 of 2

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PHONE: (844) 325-6251 Monday through Friday 8:00am to 7:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REAUTHORIZATION

Is there documentation of improvement or stabilization of the signs and symptoms of emphysema associated with alpha-1 antitrypsin deficiency including slowed progression of emphysema as evidenced by annual spirometry testing or a decrease in frequency, duration or severity of pulmonary exacerbations? ☐ Yes ☐ No
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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This page is only to be used if the form extends to a second page.

DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

MEDICAL HISTORY (Complete for ALL requests)

*****Fill in questions as needed****** If you add content to this section that increases the request form to two pages, please have a section on page two that identifies which member the request is being submitted.

☐

☐ Yes ☐ No

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Add questions as needed

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

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date