Gateway Health℠ It's Wholecare.

Updated: 07/2021
PARP Approved: 09/2021

Prior Authorization Criteria

Alpha-1 Proteinase Inhibitors

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 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 alpha-1 proteinase inhibitor (A-1 PI) and the following criteria is met:

- Must be age-appropriate according to FDA-approved labeling, nationally recognized compendia, or evidence-based practice guidelines
- 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 AATD 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 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
- 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**
    - 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.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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DRUG NAME
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

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

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

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:	ICD Code:

Add questions or options for providing information as needed. If you add content to this section that increases the request form to two pages, please use the template for the 2nd page below.

☐ Yes ☐ No

☐ Yes ☐ No

☐ 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
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date

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DRUG NAME

PRIOR AUTHORIZATION FORM (CONTINUED)– PAGE 2 of 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

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

MEDICAL HISTORY (Complete for ALL requests)

Add questions or options for providing information as needed.

☐ Yes ☐ No

☐ Yes ☐ No

☐ 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
Please describe:

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date