

PHARMACY POLICY STATEMENT

Ohio Medicaid

DRUG NAME	Aralast NP, Glassia, Prolastin C, Zemaira (alpha ₁ -proteinase inhibitor [human])
BILLING CODE	J0256 (J0257 for Glassia)
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office/Outpatient
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Products) QUANTITY LIMIT— See “Dosage allowed”
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Aralast NP, Glassia, Prolastin C, and Zemaira are **non-preferred** products and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

ALPHA₁-ANTITRYPSIN DEFICIENCY (AATD)

For **initial** authorization:

1. Member is 18 years old or older; AND
2. Medication must be prescribed by or in consultation with a pulmonologist; AND
3. Member has a diagnosis of clinically evident emphysema due to severe AATD; AND
4. Member is a never-smoker or has been a non-smoker for at least 3 months; AND
5. Member is in compliance with any prescribed supportive therapy (at least one)^{1,4} (e.g., bronchodilators, pulmonary rehabilitation, oxygen); AND
6. Chart notes must include lab reports showing ALL of the following¹:
 - a) Pre-treatment alpha₁-antitrypsin (AAT) serum level less than 11micromol/L or equivalent;
 - b) High risk genotype (e.g. Pi*ZZ, Pi*ZNull, Pi*NullNull);
 - c) Pre-treatment FEV₁ is 30-65%⁵ of predicted or has declined at a rate of 100mL/yr or more.
7. **Dosage allowed:** 60mg/kg IV once weekly.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Member continues to abstain from smoking; AND
2. At least ONE of the following:
 - a) AAT level at or above protective threshold (11 micromol/L);
 - b) Slowed rate of FEV₁ decline per spirometry results;
 - c) CT densitometry report or high resolution computed tomography (HRCT) demonstrates slowed progression of anatomic lung disease.^{3,4}

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers alpha₁-proteinase inhibitor not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
07/14/2020	Transferred to new template; revised and updated content.

References:

1. Stoller JK. Treatment of alpha-1-antitrypsin deficiency. *UpToDate*. <http://www.uptodate.com>. Updated July 13, 2020. Accessed July 13,2020.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease: 2020 Report. www.goldcopd.org (Accessed on July 14, 2020).
3. Miravittles M, Dirksen A, Ferrarotti I, et al. European Respiratory Society statement: diagnosis and treatment of pulmonary disease in α 1-antitrypsin deficiency. *Eur Respir J* 2017; 50: 1700610 [https://doi.org/10.1183/13993003.00610-2017].
4. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: a Canadian Thoracic Society clinical practice guideline [published correction appears in *Can Respir J*. 2012 Jul-Aug;19(4):272]. *Can Respir J*. 2012;19(2):109-116. doi:10.1155/2012/920918
5. Sandhaus RA, Turino G, Brantly ML, et al. The Diagnosis and Management of Alpha-1 Antitrypsin Deficiency in the Adult. *Chronic Obstructive Pulmonary Diseases: Journal of the COPD Foundation*. 2016;3(3):668-682. doi:10.15326/jcopdf.3.3.2015.0182
6. Gøtzsche PC, Johansen HK. Intravenous alpha-1 antitrypsin augmentation therapy for treating patients with alpha-1 antitrypsin deficiency and lung disease. *Cochrane Database of Systematic Reviews* 2016, Issue 9. Art. No.: CD007851. DOI: 10.1002/14651858.CD007851.pub3.

Effective date: 10/20/2020

Revised date: 07/14/2020