CareSource

PHARMACY POLICY STATEMENT
North Carolina Marketplace

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.

ALPHA$_1$-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 following[1]:
   a) Pre-treatment alpha$_1$-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 FEV_1 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 FEV_1 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 alpha$_1$-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. Miravitlles M, Dirksen A, Ferrarotti I, et al. European Respiratory Society statement: diagnosis and treatment of pulmonary disease in α1-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.

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