Pharmacy Drug Policy & Procedure

Policy Name:	AAT Deficiency	Policy #:	2383P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Aralast NP, Glassia, Prolastin-C and Zemaira.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Aralast NP, Glassia, Prolastin-C or Zemaira under the Specialty Medical benefit when ALL of the following criteria have been

Criteria

1. Coverage Criteria

1.1 Member has an alpha-1 antitrypsin (AAT) blood level less than 80 mg/dL or less than 11 uM/L.
- This is considered the blood level of the enzyme that protects against emphysema

1.2 Member has a genetic type associated with AAT deficiency or serum AAT concentrations of less than 80mg/dL.

1.3 Post-bronchodilation FEV1 (forced expiratory volume in one second) of 30% to 65%, OR a rapid decline in lung function

1.4 Ordered by a Pulmonologist (lung doctor)

1.5 Member is a non-smoker, meaning no nicotine products for at least 6 months

2. Exclusions

2.1 Member is IgA deficient with antibodies to IgA

2.2 Member has chronic obstructive pulmonary disease (COPD) and a genotype of PiMZ
- The COPD Foundation has found no evidence that alpha-1 antitrypsin augmentation is effective in this population

3. Approval Period

3.1 Initial Approval: 12 months

3.2 Subsequent Approvals: 12 months with documentation that deterioration of lung function has slowed substantially.

CPT Codes	
82103 – 82104	Alpha-1-antitrypsin; total phenotype
HCPCS Codes	
J0256	Injection, alpha 1 - proteinase inhibitor - (human), not otherwise specified, 10 mg
J0257	Injection, alpha 1 proteinase inhibitor - (human), (Glassia), 10 mg

References

1. Aralast NP (alpha1-proteinase inhibitor, human) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; March 2023.

2. Glassia (alpha1-proteinase inhibitor, human) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals USA Inc; September 2023.
3. Prolastin-C (alpha1-proteinase inhibitor, human) [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics, Inc; January 2022.
4. Zemaira (alpha1-proteinase inhibitor, human) [prescribing information]. Kankakee, IL: CSL Behring; September 2022.
5. Chapman KR, Stockley RA, Dawkins C, et al. Augmentation therapy for alpha1 antitrypsin deficiency: a meta-analysis. COPD. 2009;6(3):177-184.
6. Sandhaus RA, Turino G, Brantly ML, et al. The diagnosis and management of alpha-1 antitrypsin deficiency in the adult. Chronic Obstr Pulm Dis. 2016; 3(3): 668-682.
7. 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 Nov 30;50(5):1700610.

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