

Policy Name:	AAT Deficiency	Policy #:	2383P
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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
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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. 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 Nov 30;50(5):1700610.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.