	<b>Johns Hopkins HealthCare LLC</b> <b>Pharmacy Public</b> <b>Medical Management Drug Policies</b>	<i>Policy Number</i>	MMDP076
		<i>Effective Date</i>	05/01/2023
		<i>Review Date</i>	04/19/2023
	<i>Subject</i> <b>Alpha1-Proteinase Inhibitors: Aralast NP, Glassia, Prolastin-C, Zemaira</b>	<i>Revision Date</i>	04/19/2023
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This document applies to the following Participating Organizations:

US Family Health Plan

**Keywords:** Alpha1-Proteinase Inhibitors , Aralast NP, Glassia, Prolastin-C, Zemaira

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## **I. POLICY**

Alpha<sub>1</sub>-Proteinase Inhibitors (Aralast NP, Glassia, Prolastin-C, Zemaira) will require prior authorization for medical benefit coverage to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.

## **II. POLICY CRITERIA**


- A. Aralast NP, Glassia, Prolastin-C, or Zemaira may be approved for patients who meet the following:
  1. Documentation has been submitted showing that the Alpha1-Proteinase Inhibitor will be used for treatment of emphysema due to alpha1-antitrypsin (AAT) deficiency AND the following:
    - a. Patient's pretreatment serum AAT level is less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry)
    - b. Patient's pretreatment post-bronchodilation forced expiratory volume in 1 second (FEV1) is greater than or equal to 25% and less than or equal to 80% of the predicted value
    - c. Laboratory has a documented PiZZ, PiZ (null), or Pi (null, null) (homozygous) AAT deficiency or other phenotype or genotype associated with serum AAT concentrations of less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry)

## **III. AUTHORIZATION PERIOD/LIMITATIONS**

- A. Initial approval will be limited to 12 months of therapy
- B. Continuation of therapy may be approved in 12-month intervals with documentation showing the member is experiencing a beneficial clinical response from therapy

## **IV. EXCLUSIONS**

- A. Alpha<sub>1</sub>-Proteinase Inhibitors will not be covered for the following:
  1. Patients documented to have the PiMZ or PiMS AAT deficiency
  2. Any indications that are not FDA-approved, or guideline-supported

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## V. RECOMMENDED DOSAGE

Please refer to the FDA-approved prescribing information, or clinical guidelines, for indication-specific dosing details.

## VI. CODES

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**Note: The following CPT/HCPCS codes are included below for informational purposes. Inclusion or exclusion of a CPT/HCPCS code(s) below does not signify or imply member coverage or provider reimbursement. The member's specific benefit plan determines coverage.**

Medication	HCPCS/CPT Code
Injection, alpha 1 proteinase inhibitor (human), not otherwise specified, 10 mg	J0256
Injection, alpha 1 proteinase inhibitor (human), (glassia), 10 mg	J0257

## VII. REFERENCES

1. Aralast NP [prescribing information]. Westlake Village, CA: Baxalta US Inc.; December 2018.
2. Glassia [prescribing information]. Westlake Village, CA: Baxalta US Inc.; June 2017.
3. Prolastin-C [prescribing information]. Research Triangle Park, NC: Grifols Therapeutics Inc.; May 2020.
4. Zemaira [prescribing information]. Kankakee, IL: CSL Behring LLC; April 2019.
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6. Marciniuk DD, Hernandez P, Balter M, et al. Alpha-1 antitrypsin deficiency targeted testing and augmentation therapy: a Canadian Thoracic Society clinical practice guideline. Can Respir J. 2012;19:109- 116.
7. 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):668-82.

## VIII. APPROVALS

Signature on file at JHHC

DATE OF REVISION	SUMMARY OF CHANGE
04/19/2023	Policy Creation

Review Dates: 04/19/2023

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