This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3445-D

POLICY Document for ARALAST NP, GLASSIA, PROLASTIN-C, ZEMAIRA

The overall objective of this policy is to support the appropriate and cost effective use of the medication, specific to use of preferred medication options, lower cost site of care and overall clinically appropriate use. This document provides specific information to each section of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

EXCEPTIONS CRITERIA
ALPHA1-PROTEINASE INHIBITORS

PREFERRED PRODUCT: PROLASTIN-C

POLICY

This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the alpha$_1$-proteinase inhibitor products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred product and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are new to treatment with a targeted product for the first time.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Alpha1-Proteinase Inhibitor Products

	Product(s)
Preferred	• **Prolastin-C** (alpha$_1$-proteinase inhibitor [human])
Targeted	• **Aralast NP** (alpha$_1$-proteinase inhibitor [human]) • **Glassia** (alpha$_1$-proteinase inhibitor [human]) • **Zemaira** (alpha$_1$-proteinase inhibitor [human])

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
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II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for a targeted product is provided when either of the following criteria are met:

A. Member has received treatment with the targeted product in the past 365 days.
B. Member has had a documented intolerable adverse event to the preferred product, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

DOCUMENT HISTORY

Created: Specialty Clinical Development (PS) 09/2018
Revised: IP 09/2019, 12/2019 (Separated Med B), JC 09/2020 (no change)
Reviewed: CDPR/ SD 10/2018, MMF 09/2019, EPA 12/2019
External Review: 10/2018, 02/2019

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3445-D

Section 2: Clinical Criteria

STANDARD MEDICARE PART B MANAGEMENT

Alpha$_1$-Proteinase Inhibitors

ARALAST NP (alpha$_1$-proteinase inhibitor [human])

GLASSIA (alpha$_1$-proteinase inhibitor [human])

PROLASTIN-C (alpha$_1$-proteinase inhibitor [human])

ZEMAIRA (alpha$_1$-proteinase inhibitor [human])

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. ARALAST NP
FDA-Approved Indication

Chronic augmentation therapy in adults with clinically evident emphysema due to severe congenital deficiency of alpha$_1$-proteinase inhibitor (alpha-antitrypsin deficiency)

B. GLASSIA

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
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FDA-Approved Indication

Chronic augmentation and maintenance therapy in adults with clinically evident emphysema due to severe hereditary deficiency of alpha$_1$-proteinase inhibitor (alpha$_1$-antitypsin deficiency)

C. PROLASTIN-C

FDA-Approved Indication

Chronic augmentation and maintenance therapy in adults with clinical evidence of emphysema due to severe hereditary deficiency of alpha$_1$- proteinase inhibitor (alpha$_1$- antitrypsin deficiency)

D. ZEMAIRA

FDA-Approved Indication

Chronic augmentation and maintenance therapy in adults with alpha$_1$-proteinase inhibitor (alpha$_1$-antitypsin) deficiency and clinical evidence of emphysema

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

Documentation of pretreatment serum alpha$_1$-antitrypsin (AAT) level must be available, upon request, for all submissions.

III. CRITERIA FOR INITIAL THERAPY

Alpha$_1$-proteinase inhibitor (alpha$_1$-antitrypsin) deficiency

Authorization of 12 months may be granted for treatment of alpha$_1$-antitrypsin deficiency when all of the following criteria are met:

A. Members display clinically evident emphysema.
B. The member's pretreatment serum AAT level is less than 11 micromol/L (80 mg/dL by radial immunodiffusion or 50 mg/dL by nephelometry).

This policy applies to the following:

	Standard Opt-in		**PDPD**		**Marketplace**		**Medical Benefit**	✓	**Medicare Part B**
	Standard Opt-out		**ACSF**		**MMT**		**Medical Benefit: Biosimilars First**		**Medicare Part B: Biosimilars First**
	VF		**Balanced**		**Medical Benefit: Managed Medicaid**		**Medical Benefit: Add-on**		**Medicare Part B: Add-on**

Reference #
3445-D

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving alpha$_1$-proteinase inhibitor therapy.

Authorization for 12 months may be granted when the following criteria are met:

A. The member is currently receiving therapy with an alpha$_1$-proteinase inhibitor.
B. The alpha$_1$-proteinase inhibitor is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy.

V. REFERENCES

SECTION 1

1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2018.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; June 2017.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; June 2018.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; April 2019.

SECTION 2

1. Aralast NP [package insert]. Westlake Village, CA: Baxalta US Inc.; December 2018.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; June 2017.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; August 2018.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; April 2019.
5. American Thoracic Society/European Respiratory Society statement: standards for the diagnosis and management of individuals with alpha-1 antitrypsin deficiency. *Am J Respir Crit Care Med*. 2003;168:818-900.
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.