

This policy applies to the following:

	Standard Opt-in		PDPD		Marketplace		Medical Benefit	✓	Medicare Part B	Reference # 3445-D
	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	

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 alpha₁-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

Preferred	Product(s)
Targeted	<ul style="list-style-type: none"> • Prolastin-C (alpha₁-proteinase inhibitor [human]) • Aralast NP (alpha₁-proteinase inhibitor [human]) • Glassia (alpha₁-proteinase inhibitor [human]) • Zemaira (alpha₁-proteinase inhibitor [human])

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.

REFERENCES

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.

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DOCUMENT HISTORY

Created: Specialty Clinical Development (PS) 09/2018
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