

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	✓	Medicare Part B	Reference # 3445-D
Preferred Drug Plan Design (PDPD)	Marketplace (MF)	SF Chart (SFC)	Medical Benefit: Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First	
Advanced Control Specialty (ACSF)	New to Market (NTM)	VF Chart (VFC)	Medical Benefit: Add-on			
Value (VF)	Aetna Health Exchange (AHE)		Medical Benefit: Managed Medicaid			
	IVL					

EXCEPTIONS CRITERIA ALPHA1-PROTEINASE INHIBITORS

PREFERRED PRODUCTS: PROLASTIN-C, ZEMAIRA

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

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

II. EXCEPTION CRITERIA

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 both of the preferred products (Prolastin-C and Zemaira), 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.; March 2023.

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	Value (VF)	Aetna Health Exchange (AHE)		Medical Benefit: Managed Medicaid		
		IVL				

Reference #
3445-D

2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2023.
3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; September 2022.