

This policy applies to the following:

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

Reference #
4224-D

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 all members requesting treatment with a targeted product.

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

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

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 the 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]. Lexington, MA: Baxalta US Inc.; December 2022.
2. Glassia [package insert]. Lexington, MA: Takeda Pharmaceuticals USA Inc; September 2022.

Specialty Exceptions Alpha1-Proteinase Inh VF-MMT-MF-SFC-ACSFC-VFC-Medical-MMMB 4224-D P2024
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Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on	
Advanced Control Specialty – Choice (ACSCF)	✓	Value (VF)					

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3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; May 2020.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; September 2022.