

Reference number(s) 7149-D

#### This document applies to the following:

Formulary	Applies
Standard Control (SF)	
Standard Control Choice (SCCF)	
Preferred Drug Plan Design (PDPD)	
Advanced Control Specialty (ACSF)	
Advanced Control Specialty Choice (ACSCF)	
Managed Medicaid Template (MMT)	V
Marketplace (MF)	V
Aetna Small Group Affordable Care Act (SG ACA)	
Aetna Health Exchange (AHE)	
Value (VF)	

Formulary	Applies
New to Market (NTM)	
Standard Formulary Chart (SFC)	
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	
Advanced Control Specialty Formulary Chart (ACSFC)	
Value Formulary Chart (VFC)	
Medical Benefit	
Medical Benefit: Advanced Biosimilars First	
Combined Benefit Management (CBM)	
Combined Benefit Management Pharmacy (CBMP)	
Medical Benefit Managed Medicaid (MMMB)	

# Exceptions Criteria Alpha1-Proteinase Inhibitors

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

These criteria were developed to align with the following: Managed Medicaid Template (MMT) and Marketplace Formulary (MF).

## **Plan Design Summary**

This program applies to the alpha1-proteinase inhibitor products specified in this document. Coverage for targeted product 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 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

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

Specialty Exceptions Alpha1-Proteinase Inh MMT-MF 7149-D P2026.docx

© 2026 CVS Caremark. All rights reserved.

This document contains confidential and proprietary information of CVS Caremark and cannot be reproduced, distributed or printed without written permission from CVS Caremark. This document contains prescription brand name drugs that are trademarks or registered trademarks of pharmaceutical manufacturers that are not affiliated with CVS Caremark.

Reference number(s)	
7149-D	

	Products
Preferred	Prolastin-C (alpha1-proteinase inhibitor [human])
Target	<ul> <li>Aralast NP (alpha1-proteinase inhibitor [human])</li> <li>Glassia (alpha1-proteinase inhibitor [human])</li> <li>Zemaira (alpha1-proteinase inhibitor [human])</li> </ul>

## **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.; October 2024.
- 2. Glassia [package insert]. Lexington, MA: Takeda Pharmaceuticals USA Inc; February 2025.
- 3. Prolastin-C [package insert]. Research Triangle Park, NC: Grifols Therapeutics Inc.; May 2022.
- 4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; January 2024.