

**This document applies to the following:**

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input checked="" type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA)	<input type="checkbox"/>
Aetna Health Exchange (AHE)	<input type="checkbox"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input checked="" type="checkbox"/>
New to Market (NTM)	<input type="checkbox"/>

Formulary	Applies
Standard Formulary Chart (SFC)	<input type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input type="checkbox"/>
Medical Benefit	<input type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Combined Benefit Medical (CBM)	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<input type="checkbox"/>

# 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: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), and Value Formulary (VF).

## 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.

	Products
Preferred	<ul style="list-style-type: none"> <li>• Aralast NP (alpha1-proteinase inhibitor [human])</li> <li>• Glassia (alpha1-proteinase inhibitor [human])</li> <li>• Zemaira (alpha1-proteinase inhibitor [human])</li> </ul>
Target	<ul style="list-style-type: none"> <li>• Prolastin-C (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 the targeted product is provided when the member has had a documented intolerable adverse event to all of the preferred products, 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.; January 2022.
4. Zemaira [package insert]. Kankakee, IL: CSL Behring LLC; January 2024.