

# 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 alpha<sub>1</sub>-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

	Product(s)
Preferred*	<ul style="list-style-type: none"><li>• Prolastin-C (alpha<sub>1</sub>-proteinase inhibitor [human])</li></ul>
Targeted	<ul style="list-style-type: none"><li>• Aralast NP (alpha<sub>1</sub>-proteinase inhibitor [human])</li><li>• Glassia (alpha<sub>1</sub>-proteinase inhibitor [human])</li><li>• Zemaira (alpha<sub>1</sub>-proteinase inhibitor [human])</li></ul>

\*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:

- Member has received treatment with the targeted product in the past 365 days.
- 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 2022.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US Inc.; March 2022.
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.