Reference number(s)
3445-D

This document applies to the following:

Product	Applies
Medicare Part B	☑
Medicare Part B: Advanced Biosimilars First	☑

Medicare Part B Step Therapy Alpha1-Proteinase Inhibitors

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

These criteria were developed to align with the following: Medicare Part B and Medicare Part B: Advanced Biosimilars First.

Plan Design Summary

This program applies to the alpha1-proteinase inhibitor products specified in this document. Coverage for non-preferred 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 non-preferred product for the first time.

Step therapy is applied in addition to any applicable National Coverage Determination (NCD), Local Coverage Determination (LCD), and Medicare Part B utilization management (UM) programs implemented for the client.

Table. Alpha1-Proteinase Inhibitor Products

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

	Products
Preferred	• **Prolastin-C** (alpha1-proteinase inhibitor [human]) • **Zemaira** (alpha1-proteinase inhibitor [human])
Non-preferred	• **Aralast NP** (alpha1-proteinase inhibitor [human]) • **Glassia** (alpha1-proteinase inhibitor [human])

Step Therapy Criteria

Coverage for a non-preferred product is provided when either of the following criteria are met:

- Member has received treatment with the non-preferred product in the past 365 days.
- 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.; October 2024.
2. Glassia [package insert]. Westlake Village, CA: Baxalta US 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.