Reference number(s)
5883-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)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
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	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Hereditary Angioedema Prophylaxis

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: Value Formulary (VF).

Plan Design Summary

This program applies to the hereditary angioedema prophylaxis products specified in this document. 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. Products for the prevention of hereditary angioedema attacks

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

	Products
Preferred	• Orladeyo (berotralstat) • Takhzyro (lanadelumab-flyo)
Target	• Cinryze (C1 esterase inhibitor [human]) • Haegarda (C1 esterase inhibitor subcutaneous [human])

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 any of the following criteria is met:

- Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member is less than 12 years of age and has a documented inadequate response or intolerable adverse event with Takhzyro.
- Member is pregnant, breastfeeding, or planning pregnancy.
- Member has a documented inadequate response or intolerable adverse event with either of the preferred products: a) Orladeyo or b) Takhzyro.

References

1. Cinryze [package insert]. Lexington, MA: ViroPharma Biologics LLC, a Takeda company; February 2023.
2. Haegarda [package insert]. Kankakee, IL: CSL Behring LLC; January 2022.
3. Orladeyo [package insert]. Durham, NC: BioCryst Pharmaceuticals, Inc.; November 2023.
4. Takhzyro [package insert]. Lexington, MA: Dyax Corp., a Takeda company; February 2023.