Reference number(s)
5584-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

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), Value Formulary (VF), and Value Formulary Chart (VFC).

Plan Design Summary

This program applies to the hereditary angioedema (HAE) 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 all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. 1. Products for the treatment of acute attacks of HAE (C1 esterase inhibitors)

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

	Products
Preferred	• Ruconest (C1 esterase inhibitor [recombinant])

	Products
Target	• Berinert (C1 esterase inhibitor [human])

Table 2. Products for the treatment of acute attacks of HAE (bradykinin B2 receptor antagonists)

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

	Products
Preferred	• icatibant (generic)
Target	• Firazyr (icatibant)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

C1 Esterase Inhibitors (C1INH)

Coverage for Berinert is provided when any of the following criteria is met:

- Member is using the targeted product for short-term preprocedural prophylaxis (i.e., prior to surgical or major dental procedures).
- Targeted product is being requested for treatment of laryngeal attacks.
- Member has a documented inadequate response to the preferred product, Ruconest.
- Member has a documented intolerable adverse event with the preferred product, Ruconest.
- Member has a documented contraindication to Ruconest (i.e., known or suspected allergy to rabbits or rabbit-derived products).
- Member is less than 13 years of age.

Bradykinin B2 Receptor Antagonists

Coverage for Firazyr is provided when the member has a documented intolerable adverse event with icatibant and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.

References

1. icatibant [package insert]. Weston, FL: Apotex Corp.; February 2024.

2. Ruconest [package insert]. Warren, NJ: Pharming Healthcare Inc.; April 2020.
3. Berinert [package insert]. Kankakee, IL: CSL Behring LLC; September 2021.
4. Firazyr [package insert]. Lexington, MA: Takeda Pharmaceuticals America Inc.; January 2024.