

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input type="checkbox"/>
Standard Control – Choice (SCCF)	<input type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input 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"/>

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
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"/>
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

Factor VIII Products

Indications

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 Factor VIII products specified in this document. Coverage for targeted products 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 criteria 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) criteria implemented for the client.

Table. Factor VIII 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"> • Adynovate (antihemophilic factor [recombinant]) • Afstyla (antihemophilic factor [recombinant]) • Eloctate (antihemophilic factor [recombinant]) • Esperoct (antihemophilic factor [recombinant]) • Jivi (antihemophilic factor [recombinant]) • Nuwiq (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant]) • Xyntha Solufuse (antihemophilic factor [recombinant])
Target	<ul style="list-style-type: none"> • Advate (antihemophilic factor [recombinant]) • Alphanate (antihemophilic factor/von Willebrand factor complex [Human]) • Hemophil M (antihemophilic factor [human] monoclonal antibody purified) • Humate-P (antihemophilic factor/von Willebrand factor complex [Human]) • Koate (antihemophilic factor [human]) • Koate-DVI (antihemophilic factor [human]) • Kovaltry (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Recombinate (antihemophilic factor [recombinant]) • Wilate (von Willebrand factor/coagulation factor VIII complex [human])

Exception Criteria

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

Coverage for the targeted product is provided when either of the following criteria is met:

- Member is currently receiving treatment with the targeted product, excluding when the targeted product is obtained as samples or via manufacturer's patient assistance programs.
- Member has a documented inadequate response or intolerable adverse event with at least three of the preferred products.

References

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; March 2023.
2. Adynovate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; August 2023.
3. Afstylia [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
4. Alphanate [package insert]. Los Angeles, CA: Grifols Biologicals LLC; November 2022.
5. Eloctate [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; May 2023.
6. Esperoct [package insert]. Plainsboro, NJ: Novo Nordisk Inc.; July 2024.
7. Hemofil M [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
8. Humate-P [package insert]. Kankakee, IL: CSL Behring LLC; June 2020.
9. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
10. Koate [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; January 2022.
11. Koate-DVI [package insert]. Research Triangle Park, NC: Grifols Therapeutics LLC; August 2012.
12. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
13. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
14. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
15. Recombinate with 5 mL Sterile Water for Injection using BAXAJECT II [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
16. Wilate [package insert]. Paramus, NJ: Octapharma USA Inc.; March 2020.
17. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.
18. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.