

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	✓	Medicare Part B
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)	Medical Benefit: Managed Medicaid		
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)	Medical Benefit: Add-on		
Advanced Control Specialty – Choice (ACSCF)	Value (VF)				

Reference #
5894-D

EXCEPTIONS CRITERIA FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: AFSTYLA AND KOVALTRY

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 Factor VIII products specified in this policy. 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 program applies to members who are new to treatment with the targeted product for the first time.

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

Table. Factor VIII Products

	Product(s)
Preferred*	<ul style="list-style-type: none"> • Afstyla (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant])
Targeted	<ul style="list-style-type: none"> • Advate (antihemophilic factor [recombinant]) • Kogenate FS (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Nuwiq (antihemophilic factor [recombinant]) • Recombinate (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant]) • Xyntha Solofuse (antihemophilic factor [recombinant])

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

II. EXCEPTION CRITERIA

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

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

A. Member has received treatment with the targeted product in the past 365 days.

This policy applies to the following:

Standard Control (SF)	Managed Medicaid Template (MMT)	ACSF Chart (ACSFC)	Medical Benefit	✓	Medicare Part B	Reference # 5894-D
Standard Control – Choice (SCCF)	Marketplace (MF)	SF Chart (SFC)	Medical: Advanced Biosimilars First	✓	Medicare Part B: Advanced Biosimilars First	
Preferred Drug Plan Design (PDPD)	Aetna Health Exchange (AHE)	VF Chart (VFC)	Medical Benefit: Managed Medicaid			
Advanced Control Specialty (ACSF)	IVL	New to Market (NTM)	Medical Benefit: Add-on			
Advanced Control Specialty – Choice (ACSCF)	Value (VF)					

- B. Member has a documented inadequate response, intolerable adverse event or contraindication to both of the preferred products.

REFERENCES

1. Advate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
2. Afstylia [package insert]. Kankakee, IL: CSL Behring LLC; June 2023.
3. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
4. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
5. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kovaltry [package insert]. Whippany, NJ: Bayer Healthcare LLC; December 2022.
7. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
8. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
9. Recombinate [package insert]. Lexington, MA: Takeda Pharmaceuticals U.S.A., Inc.; March 2023.
10. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.
11. Xyntha Solufuse [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals LLC; July 2022.