

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

Reference #
2699-D

EXCEPTIONS CRITERIA FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: ADVATE, AFSTYLA, KOGENATE FS, KOVALTRY, NOVOEIGHT, NUWIQ, XYNTHA

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 a 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"> • Advate (antihemophilic factor [recombinant]) • Afstyla (antihemophilic factor [recombinant]) • Kogenate FS (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant]) • Nuwiq (antihemophilic factor [recombinant]) • Xyntha (antihemophilic factor [recombinant])
Targeted	<ul style="list-style-type: none"> • Recombinate (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 products.

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

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	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)	✓	Medical Benefit		Medicare Part B	Reference #
	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First	2699-D
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First	
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on			
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)							

- A. Member is currently receiving treatment with a targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- B. 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. Afstyla [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. Nuwiq [package insert]. Paramus, NJ: Octapharma USA, Inc., June 2021.
8. Recombinate [package insert]. Lexington, MA: Baxalta US Inc.; June 2018.
9. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.