

This policy applies to the following:

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

EXCEPTIONS CRITERIA FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: ADYNOVATE, JIVI, KOGENATE FS, KOVALTRY, NOVOEIGHT

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"> • Adynovate (antihemophilic factor [recombinant], PEGylated) • Jivi (antihemophilic factor [recombinant], PEGylated-aucl) • Kogenate FS (antihemophilic factor [recombinant]) • Kovaltry (antihemophilic factor [recombinant]) • Novoeight (antihemophilic factor [recombinant])
Targeted	<ul style="list-style-type: none"> • Eloctate (antihemophilic factor [recombinant], Fc fusion protein) • Nuwiq (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 either of the following criteria is met:

- 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, intolerable adverse event, or has a contraindication to at least three of the preferred products.

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Balanced (BF)	New to Market (NTM)	IVL		Medical Benefit: Managed Medicaid	Aetna Health Exchange (AHE)

Reference #
2699-D

REFERENCES

1. Adynovate [package insert]. Westlake Village, CA: Baxalta US Inc.; June 2021.
2. Eloctate [package insert]. Cambridge, MA: Biogen Idec Inc.; December 2020.
3. Jivi [package insert]. Whippany, NJ: Bayer HealthCare LLC; August 2018.
4. Kogenate FS [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
5. Kogenate FS with BIO-SET [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
6. Kogenate FS with Vial Adapter [package insert]. Whippany, NJ: Bayer HealthCare LLC; December 2019.
7. Kovaltry [package insert]. Whippany, NJ: Bayer HealthCare LLC; January 2021.
8. Novoeight [package insert]. Plainsboro, NJ: Novo Nordisk Inc., July 2020.
9. Nuwiq [package insert]. Hoboken, NJ: Octapharma USA, Inc., September 2020.