EXCEPTIONS CRITERIA

FACTOR VIII PRODUCTS

PREFERRED PRODUCTS: 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 all members requesting treatment with a targeted product.

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

Table. Factor VIII Products

	Product(s)
Preferred*	• **Kovaltry** (antihemophilic factor [recombinant])
Targeted	• **Advate** (antihemophilic factor [recombinant]) • **Afstyla** (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.
B. Member has a documented inadequate response, intolerable adverse event or contraindication with the preferred product.

REFERENCES

1. Advate [package insert]. Lexington, MA: Baxalta US Inc.; December 2018.
2. Afstyla [package insert]. Kankakee, IL: CSL Behring LLC; April 2021.
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; October 2021.
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.