

CARE VALUE POLICY

- POLICY:** Hemophilia – Recombinant Factor VIII Products Care Value Policy
- Standard Half-Life Products**
- Advate[®] (antihemophilic factor [recombinant] injection – Baxalta)
 - Afstyla[®] (antihemophilic factor [recombinant] single-chain injection – CSL Behring)
 - Kogenate[®] FS (antihemophilic factor [recombinant] injection – Bayer)
 - Kovaltry[®] (antihemophilic factor [recombinant] injection – Bayer)
 - Novoeight[®] (antihemophilic factor [recombinant] injection – Novo Nordisk)
 - Nuwiq[®] (antihemophilic factor [recombinant] injection – Octapharma)
 - Recombinate[®] (antihemophilic factor [recombinant] injection – Baxalta)
 - Xyntha[®]/Xyntha[®] Solofuse[™] (antihemophilic factor [recombinant] injection – Wyeth/Pfizer)
- Extended Half-Life Products**
- Adynovate[®] (antihemophilic factor [recombinant] injection, PEGylated – Baxalta)
 - Eloctate[®] (antihemophilic factor [recombinant] Fc fusion protein injection – Bioverative)
 - Esperoct[®] (antihemophilic factor [recombinant] glycopegylated exei injection – Novo Nordisk)
 - Jivi[®] (antihemophilic factor [recombinant] PEGylated-aucl injection – Bayer)
- Prolonged Half-Life Product**
- Altuviiiio[™] (antihemophilic factor [recombinant] Fc-VWF-XTEN fusion protein-ehtl injection – Bioverativ/Sanofi)

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OVERVIEW

All of the Factor VIII products are used for **hemophilia A**. Advate,¹ Adynovate,² Afstyla,³ Eloctate,⁴ Esperoct,⁵ Kogenate FS,⁶ Kovaltry,⁷ Novoeight,⁸ Nuwiq,⁹ Recombinate,¹⁰ Xyntha,¹¹⁻¹² Jivi,¹³ and Altuviiiio¹⁴ are recombinant Factor VIII products. Adynovate, Eloctate, Esperoct, and Jivi differ because they are modified agents that have an extended dosing interval in various clinical scenarios (e.g., routine prophylaxis).^{2,4,5,14} Most products are indicated in children and adults for control and prevention of bleeding episodes, perioperative management and routine prophylaxis to prevent or reduce the frequency of bleeding episodes. Jivi is only indicated for use in previously treated patients who are ≥ 12 years of age.¹³ In contrast to other Factor VIII therapies, Altuviiiio is independent of endogenous von Willebrand factor (VWF) in order to overcome the half-life limit imposed by Factor VIII-VWF interactions.¹⁴ Other components and/or modification of the molecule contribute to the half-life extension of Altuviiiio. Altuviiiio has demonstrated a 3- to 4-fold prolonged half-life relative to other standard and extended half-life Factor VIII products.

POLICY STATEMENT

This Care Value Policy has been developed to encourage the use of Preferred Products. For all Non-Preferred Products the patient is required to meet the respective standard *Hemophilia – Factor VIII Products Prior Authorization Policy* criteria. The program also directs the patient to try at least one Preferred Product prior to the use of Non-Preferred Products. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). All approvals are provided for 1 year in duration.

Automation: None.

Preferred Products: Adynovate, Advate, Afstyla, Altuviiiio, Eloctate, Esperoct, Jivi, Kogenate FS, Kovaltry, Novoeight, Xyntha

Non-Preferred Products: Nuwiq, Recombinate

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Products	Exception Criteria
Nuwiq and Recombinate	<p>1. Approve for 1 year if the patient meets the following (A <u>and</u> B):</p> <p>A) Patient meets the standard <i>Hemophilia – Factor VIII Products Prior Authorization Policy</i> criteria; AND</p> <p>B) Patient meets one of the following (i <u>or</u> ii):</p> <ul style="list-style-type: none"> i. Patient has tried at least one of Adynovate, Advate, Afstyla, Altuviiiio, Eloctate, Esperoct, Jivi, Kogenate FS, Kovaltry, Novoeight, or Xyntha; OR ii. Patient is currently receiving the requested Non-Preferred Product or has received the requested Non-Preferred Product in the past.

REFERENCES

1. Advate® intravenous injection [prescribing information]. Lexington, MA: Baxalta; December 2018.
2. Adynovate® intravenous injection [prescribing information]. Lexington, MA: Baxalta; June 2021.
3. Afstyla® intravenous injection [prescribing information]. Kankakee, IL: CSL Behring; April 2021.
4. Eloctate® intravenous injection [prescribing information]. Waltham, MA; Bioverativ; December 2020.
5. Esperoct® intravenous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; August 2022.
6. Kogenate® FS intravenous injection [prescribing information]. Whippany, NJ: Bayer; December 2019.
7. Kovaltry® intravenous injection [prescribing information]. Whippany, NJ: Bayer; October 2021.
8. Novoeight® intravenous injection [prescribing information]. Plainsboro, NJ: Novo Nordisk; July 2020.
9. Nuwiq® intravenous injection [prescribing information]. Hoboken, NJ: Octapharma; June 2021.
10. Recombinate™ intravenous injection [prescribing information]. Lexington, MA: Baxalta; June 2018.
11. Xyntha® intravenous injection [prescribing information]. Philadelphia, PA: Wyeth/Pfizer; July 2022.
12. Xyntha® Solofuse™ intravenous injection [prescribing information]. Philadelphia, PA: Wyeth/Pfizer; July 2022.
13. Jivi® intravenous injection [prescribing information]. Whippany, NJ: Bayer; August 2018.
14. Altuviiiio™ intravenous injection [prescribing information]. Waltham, MA: Bioverativ/Sanofi; February 2023.