

Select Hemophilia A Products

Policy # 00822

Original Effective Date: 01/01/2023

Current Effective Date: 01/01/2026

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Factor IX products are addressed separately in medical policy 00863.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider select hemophilia products, including, but not limited to Jivi[®], Kovaltry[®], Novoeight[®], Advate[®], Adynovate[®], Afstyl[®], Elocate[®], Hemofil[®] M, Humate-P[®], Kogenate[®], Kogenate FS, Kovaltry[®], Nuwiq[®], Recombinate[®], Xyntha[®]/Xyntha Solufuse[®], Esperoct[®], and Altuviiio[™] to be **eligible for coverage**.**

Background/Overview

The hemophilia products mentioned in this policy (Jivi, Kovaltry, Novoeight, Advate, Adynovate, Afstyl, Elocate, Hemofil M, Humate-P, Kogenate, Kogenate FS, Kovaltry, Nuwiq, Recombinate, Xyntha/Xyntha Solufuse, Esperoct, and Altuviiio) are approved by the Food and Drug Administration for the treatment of hemophilia. The hemophilia products listed in this policy are covered at parity status. The lack of mention of a particular hemophilia product does not insinuate that there is no coverage for that product. This policy currently only lists Factor VIII products.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

The purpose of this policy is to reflect the coverage of the mentioned hemophilia products at parity status. It should be noted that these are not targeted medical drugs. This Medical Policy is informational in nature only.

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References

1. Jivi [package insert]. Bayer HealthCare, LLC. Whippany, New Jersey. Updated August 2018.
2. Kovaltry [package insert]. Bayer HealthCare, LLC. Whippany, New Jersey. Updated October 2021.
3. Novoeight [package insert]. Novo Nordisk. Bagsvaerd, Denmark. Updated July 2020.
4. Advate [package insert]. Baxalta US, Inc. Lexington, Massachusetts. Updated December 2018.
5. Afstylia [package insert]. CSL Behring, LLC. Kankakee, Illinois. Updated April 2021.
6. Eloctate [package insert]. Bioverativ Therapeutics, Inc. Cambridge, Massachusetts. Updated December 2020.
7. Hemofil M [package insert]. Baxalta US, Inc. Westlake Village, California. Updated June 2018.
8. Kogenate FS [package insert]. Bayer HealthCare, LLC. Whippany, New Jersey. Updated December 2019.
9. Nuwiq [package insert]. Octapharma AB. Elersvagen, Sweden. Updated September 2020.
10. Recombinate [package insert]. Baxalta US, Inc. Lexington, Massachusetts. Updated June 2018.
11. Xyntha & Xyntha Solofuse [package insert]. Wyeth Biopharma. Philadelphia, Pennsylvania. Updated August 2020.
12. Adynovate [package insert]. Baxalta US, Inc. Lexington, Massachusetts. Updated June 2021.
13. Esperoct [package insert]. Novo Nordisk. Bagsvaerd, Denmark. Updated August 2022.
14. Altuviiiio [package insert]. Bioverativ Therapeutics, Inc. Waltham, MA. Updated March 2023.
15. Humate-P [package insert]. CSL Behring. Kankakee, IL. Updated August 2020.
16. Kovaltry [package insert]. Bayer HealthCare LLC. Whippany, NJ. Updated December 2022.

Policy History

Original Effective Date: 01/01/2023

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| 12/01/2022 | Medical Policy Committee review |
| 12/14/2022 | Medical Policy Implementation Committee approval. New policy. |
| 12/07/2023 | Medical Policy Committee review |
| 12/13/2023 | Medical Policy Implementation Committee approval. Added new product, Altuviiiio to policy. |
| 12/05/2024 | Medical Policy Committee review |
| 12/11/2024 | Medical Policy Implementation Committee approval. Changed title from “Select Hemophilia Products” to “Select Hemophilia A Products”. Coverage eligibility unchanged. |
| 12/04/2025 | Medical Policy Committee review |
| 12/10/2025 | Medical Policy Implementation Committee approval. Updated product list to align with available products. |
- Next Scheduled Review Date: 12/2026

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****Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.