Clinical Policy: Factor IX Complex, Human (Profilnine)

Reference Number: ERX.SPA.188
Effective Date: 01.11.17
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Factor IX complex (human) (Profilnine®) contains factor IX, II, X, and low levels of factor VII.

FDA Approved Indication(s)
Profilnine is indicated for the prevention and control of bleeding episodes in patients with hemophilia B (congenital factor IX deficiency or Christmas disease).

Limitation(s) of use: Profilnine contains non-therapeutic levels of factor VII and is not indicated for use in the treatment of factor VII deficiency.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Profilnine is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia B (must meet all)**:**

1. Diagnosis of congenital hemophilia B (factor IX deficiency);
2. Prescribed by or in consultation with a hematologist;
3. Age ≥ 18 years;
4. Request is for prevention and control of bleeding episodes;
5. Documentation of member's current body weight (in kg);
6. Dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Congenital Hemophilia B (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, new dose does not exceed the FDA approved maximum recommended dose for the relevant indication.

Approval duration: 3 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
Approval duration: Duration of request or 3 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Hemophilia B	Minor to moderate bleeding episodes: 20-30 IU/kg IV every 16-24 hours Major bleeding episodes: 30-50 IU/kg IV followed by 20 IU/kg IV every 16-24 hours Surgery: 30-50 IU/kg IV prior to surgery, followed by the same dose every 16-24 hours thereafter	50 IU/kg

VI. Product Availability

Vials: 500, 1,000, 1,500 IU

VII. References

1. Profilnine Prescribing Information. Los Angeles, CA: Grifols Biologicals, Inc.; June 2018. Available at http://www.grifolsusa.com/en/web/eeuu/bioscience/-/product/profilnine. Accessed November 23, 2021.
2. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. Haemophilia. Jan 2013; 19(1): e1-47.
3. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at https://www.hemophilia.org/Researchers-Healthcare-Providers/Medical-and-Scientific-Advisory-Council-MASAC/MASAC-Recommendations. Accessed November 30, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q18 annual review: Added efficacy statement to renewal criteria.	11.28.17	02.18
1Q 2019 annual review: no significant changes; clarified that disease must be congenital; references reviewed and updated.	09.26.18	02.19

Reviews, Revisions, and Approvals	Date	P&T Approval Date
1Q 2020 annual review: no significant changes; removed Bebulin from the policy as it is no longer available; references reviewed and updated.	11.27.19	02.20
1Q 2021 annual review: added requirement for documentation of body weight for calculation of appropriate dose; references reviewed and updated.	11.30.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.23.21	02.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.