

Clinical Policy: Factor IX Complex, Human (Bebulin, Profilnine)

Reference Number: CP.PHAR.219

Effective Date: 05.01.16

Last Review Date: 02.19

Line of Business: Medicaid, HIM-Medical Benefit

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

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

FDA Approved Indication(s)

Bebulin and Profilnine are indicated for the prevention and control of bleeding episodes in adult patients with hemophilia B (congenital factor IX deficiency or Christmas disease).

Limitation(s) of use: Bebulin and Profilnine are not indicated for use in the treatment of factor VII deficiency. They contain non-therapeutic levels of factor VII, and no clinical studies have been conducted to show benefit from this product for treating deficiencies other than factor IX 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.

It is the policy of health plans affiliated with Centene Corporation[®] that Bebulin and Profilnine are **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 \geq 18 years;
4. Request is for prevention and control of bleeding episodes;
5. 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 the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

II. Continued Therapy

A. Congenital Hemophilia B (must meet all):

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1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. 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 Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 3 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid and HIM-Medical Benefit.

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 – CP.PMN.53 for Medicaid and HIM-Medical Benefit 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

- Contraindication(s):
 - Bebulin: known history of hypersensitivity reactions to the product, known allergy to heparin, known history of heparin-induced thrombocytopenia
 - Profinilnine: none reported
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Factor IX complex (Bebulin)	Minor bleeding episodes: 25-35 IU/kg IV; repeat dose if there is evidence of further bleeding	90 IU/kg single dose or 75 IU/kg/repeated dose	Factor IX complex (Bebulin)
	Moderate bleeding episodes: 50-65 IU/kg IV every 24 hours		

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Drug Name	Indication	Dosing Regimen	Maximum Dose
	<p>Major bleeding episodes: initial 75-90 IU/kg IV followed by 50-60 IU/kg IV every 12-24 hours</p> <p>Minor surgery: 50-75 IU/kg IV one hour prior to surgery, followed by 25-65 IU/kg IV post-operatively every 12 hours</p> <p>Major surgery: 75-90 IU/kg IV one hour prior to surgery, followed by 25-75 IU/kg IV post-operatively every 12 hours for the first two weeks, then 25-35 IU/kg IV every 24 hours thereafter</p>		
Factor IX complex (Profilnine)	<p>Minor to moderate bleeding episodes: 20-30 IU/kg IV every 16-24 hours</p> <p>Major bleeding episodes: 30-50 IU/kg IV followed by 20 IU/kg IV every 16-24 hours</p> <p>Surgery: 30-50 IU/kg IV prior to surgery, followed by the same dose every 16-24 hours thereafter</p>	50 IU/kg	Factor IX complex (Profilnine)

VI. Product Availability

Drug Name	Availability
Factor IX complex (Bebulin)	Vial: 200-1,200 IU; Factor IX activity in IU is stated on the label of each vial
Factor IX complex (Profilnine)	Vial: 500, 1,000, 1,500 IU

VII. References

1. Bebulin Prescribing Information. Westlake Village, CA: Baxter Healthcare Corporation; September 2015. Available at http://www.shirecontent.com/PI/PDFs/BEBULIN_USA_ENG.pdf. Accessed November 8, 2018.
2. Profilnine Prescribing Information. Los Angeles, CA: Grifols Biologicals, Inc.; March 2017. Available at <http://www.grifolsusa.com/en/web/euu/bioscience/-/product/profilnine>. Accessed November 8, 2018.

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3. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia*. Jan 2013; 19(1): e1-47.
4. 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 September 26, 2018.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J7194	Factor IX complex, per IU

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy split from CP.PHAR.12.Blood Factors and converted to new template. Removed requests for documentation. Added age requirement per PIs. Neither drug is approved for prophylaxis so the “history of 2 or more episodes of bleeding into joints” is removed; approval period for non-prophylactic use is edited to provide 3 months on initial approval and one 3-month re-auth. Removed denial based on inhibitor titer of ≥ 5 BU/mL. Reviewed by specialist.	04.01.16	05.16
Safety information removed. Wording, approval periods, and use of “congenital” versus “acquired hemophilia descriptions made consistent across all blood factor policies. Efficacy statement added to renewal criteria. Reviewed by specialist- hematology/internal medicine.	04.01.17	05.17
1Q18 annual review: - Converted to new template - Changed age limit for Profilnine to 18 years, per PI - References reviewed and updated	11.28.17	02.18
1Q 2019 annual review: added HIM-Medical Benefit; no significant changes; references reviewed and updated.	09.26.18	02.19

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

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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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence.

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Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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