Clinical Policy: Factor IX Complex, Human (Profilnine)

Reference Number: LA.PHAR.219
Effective Date:
Last Review Date: 06.21
Line of Business: Medicaid

Coding Implications
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 adult 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

Prior authorization is required. 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 Louisiana Healthcare Connections 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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

II. Continued Therapy

A. Congenital Hemophilia B (must meet all):

1. **Currently receiving medication via Louisiana Healthcare Connections benefit 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 Louisiana Healthcare Connections 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 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): LA.PMN.53 for Medicaid.**

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 – LA.PMN.53 for Medicaid, 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): none reported**
- **Boxed warning(s): none reported**

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Factor IX complex (Profilnine)	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

Vial: 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 30, 2020.**
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.**

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
Converted corporate to local policy	06.2021

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. LHCC 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.

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 LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. 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. LHCC 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.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.

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