Effective: July 1, 2023

Prior Authorization Required
If REQUIRED, submit supporting clinical documentation pertinent to service request.

 Applies to:

Commercial Products
☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988
☐ Tufts Health Plan Commercial products; Fax 617-673-0988
 CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products
☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939
☑ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956
  *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products
☑ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956
☑ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☑ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☑ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview
Hemophilia is a congenital condition caused in which there is a deficiency in a clotting factor, Hemophilia A by a deficiency of coagulant factor VIII and Hemophilia B by coagulant factor IX, both intrinsic pathway (contact activation) coagulation factors. Clotting factors are necessary to stop bleeding and allow wounds to close and heal. Acquired hemophilia is a sub-type that is caused by an autoimmune disorder disrupting clotting factor production rather than a genetic disorder. Von Willebrand Disease is a failure to produce the primary hemostasis (platelet activation) coagulation factor von Willebrand factor. Antihemophilic factors can be produced recombinantly, by a culture of cells into which the human gene for production of the factor has been grafted or produced by extraction from healthy human plasma.

Food and Drug Administration (FDA) Approved Indications:
Alprolix® is a recombinant DNA derived coagulation Factor IX concentrate indicated in adults and children with hemophilia B for:
• On-demand treatment and control of bleeding episodes,
• Perioperative management of bleeding,
• Routine prophylaxis to reduce the frequency of bleeding episodes.

Limitation of Use: Alprolix is not indicated for induction of immune tolerance in patients with hemophilia

BeneFIX® is a recombinant human blood coagulation factor IX indicated for adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for:
• On-demand treatment and control of bleeding episodes,
• Perioperative management of bleeding,
• Routine prophylaxis to reduce the frequency of bleeding episodes.
Limitations of Use: BeneFIX is not indicated for induction of immune tolerance in patients with hemophilia B.

Idelvion® is a recombinant DNA-derived coagulation Factor IX concentrate, indicated for use in children and adults with Hemophilia B (congenital Factor IX deficiency) for:

- On-demand treatment and control of bleeding episodes,
- Perioperative management of bleeding,
- Routine prophylaxis to reduce the frequency of bleeding episodes,

Limitations of Use: Idelvion is not indicated for immune tolerance induction in patients with Hemophilia B.

Ixinity® is a human blood coagulation factor indicated for the treatment of:

- Adults and children ≥ 12 years of age with hemophilia B for:
- On-demand treatment and control of bleeding episodes
- Perioperative management
- Adults with hemophilia B for:
- Routine prophylaxis to reduce the frequency of bleeding episodes

Limitations of use: Ixinity is not indicated for induction of immune tolerance in patients with hemophilia B.

Rebinyn® is a recombinant DNA-derived coagulation Factor IX concentrate indicated for use in adults and children with hemophilia B for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding

Limitations of Use: Rebinyn is not indicated for routine prophylaxis in the treatment of patients with hemophilia B. Rebinyn is not indicated for immune tolerance induction in patients with hemophilia B

Rixubis® is an antihemophilic factor indicated in adults and children with hemophilia B for:

- On-demand treatment and control of bleeding episodes
- Perioperative management of bleeding
- Routine prophylaxis to reduce the frequency of bleeding episodes.

Limitations of use: Rixubis is not indicated for induction of immune tolerance in patients with Hemophilia B.

NATIONAL COVERAGE DETERMINATION

Covered Indications
Medicare provides coverage of these factor products through Part A and B coverage. In Part B, Medicare provides coverage in two manners, one of an 'incident to' event where the provider has a cost of the factor and administers, whereby the claim will demonstrate the factor product code and administration codes. Medicare also provides coverage for self-administered blood-clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision. Medicare covers blood-clotting factors for the following conditions:

- Factor VIII deficiency (classic hemophilia, hemophilia A).
- Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component).
- Congenital factor XI deficiency (Hemophilia C).
- Von Willebrand's disease.
- Acquired hemophilia (acquired Factor VIII autoantibodies most frequently) and other coagulation factor deficiencies, intrinsic circulating anticoagulants, antibodies or inhibitors.
- Congenital deficiencies of other clotting factors (such as congenital afibrinogenemia and others).

Other diagnoses may be applicable based on U.S. Food and Drug Administration (FDA) label but the list above indicates CMS designation of add-on payment for inpatient care and additional coverage would not be acceptable to the system for Part A.

Note: Refer to Center for Medicare and Medicaid Local Coverage Determination (LCD) for Hemophilia Factor Products (L35111) at https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35111.

Clinical Guideline Coverage Criteria
The Plan may authorize Alprolix, BeneFIX, Idelvion, Ixinity, Rebinyn or Rixubis when all the following clinical criteria is met:
1. The Member has a documented diagnosis of Hemophilia B

Reauthorization Criteria
The Plan may authorize coverage of Alprolix, BeneFIX, Idelvion, Ixinity, Rebinyn or Rixubis when the following criteria are met:
1. Documentation confirms therapeutic response from the requested factor IX product with reduced frequency or severity of
Limitations

- Authorization is limited to 12-month intervals when coverage criteria are met
- Reauthorization is limited to 12-month intervals when reauthorization criteria are met
- All other indications other than those listed above are considered experimental/investigational and not medically necessary
- Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the Plan

Codes

The following code(s) require prior authorization:

**Table 1: HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>J7193</td>
<td>Factor ix (antihemophilic factor, purified, non-recombinant) per i.u.</td>
</tr>
<tr>
<td>J7194</td>
<td>Factor ix, complex, per i.u.</td>
</tr>
<tr>
<td>J7195</td>
<td>Injection, factor ix (antihemophilic factor, recombinant) per i.u, not otherwise specified</td>
</tr>
<tr>
<td>J7200</td>
<td>Injection, factor IX, Fc fusion protein (recombinant), Alprolix, per iU</td>
</tr>
<tr>
<td>J7201</td>
<td>Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU</td>
</tr>
<tr>
<td>J7202</td>
<td>Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1iu</td>
</tr>
<tr>
<td>J7213</td>
<td>Injection, coagulation factor IX (recombinant), Ixinity, 1 IU</td>
</tr>
</tbody>
</table>

References:

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)
September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:
- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: June 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS codes have been added: J7213

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better
understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.