

**Factor IX Concentrates – Hemophilia B
Effective January 1, 2021**

Plan	<input type="checkbox"/> MassHealth <input checked="" type="checkbox"/> MassHealth (PUF) <input type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
Specialty Limitations	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Hemophilia A (factor VIII [factor 8] deficiency) and hemophilia B (factor IX [factor 9] deficiency) are X-linked inherited coagulation factor deficiencies that result in lifelong bleeding disorders. The availability of factor replacement products has dramatically improved care for individuals with these conditions. Factor XI products are used to control and prevent bleeding episodes in adults and children with Hemophilia B, for perioperative management in adults and children with Hemophilia B, and for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and children with Hemophilia B

Hemophilia B
Rebiny (coagulation factor IX [recombinant], glycoPEGylated)
Idelvion (coagulation factor IX [recombinant], albumin fusion protein)
Alprolix (coagulation factor IX [recombinant], Fc fusion protein)
Benefix (coagulation factor IX [recombinant]) *
Ixinity (coagulation factor IX [recombinant])
Rixubis (coagulation factor IX [recombinant])
Alphanine SD (coagulation factor IX [human])
Mononine (coagulation factor IX [human])
Hemophilia B Complex
Bebulin (factor IX complex [human])
Profilnine (factor IX complex [human])

* Preferred Drug



Coverage Guidelines

Hemophilia B

Authorization may be granted when the following criteria are met, and documentation is provided:

1. Member has diagnosis of hemophilia B

Hemophilia B Complex

Authorization may be granted when ONE of the following criteria are met, and documentation is provided:

1. Member has diagnosis of hemophilia B or bleeding due to low levels of liver dependent coagulation factors
2. Member is using medication for treatment of factor X deficiency (Bebulin only)
3. Member is using medication for treatment of factor II deficiency (Profilnine only)

Continuation of Therapy

All members (including new members) requesting authorization for continuation must meet initial authorization criteria.

Limitations

Approvals will be granted for 36 months.

References

1. Alprolix [package insert]. Waltham, MA: Bioverativ Therapeutics Inc.; July 2019.
2. BeneFIX [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; July 2019.
3. Ixinity [package insert]. Seattle, WA: Aptevo BioTherapeutics LLC, December 2018.
4. Rixubis [package insert]. Lexington, MA: Baxalta US Inc.; May 2018.
5. AlphaNine SD [package insert]. Los Angeles, CA: Grifols Biologicals LLC; June 2018.
6. Mononine [package insert]. Kankakee, IL: CSL Behring LLC; December 2018.
7. Idelvion [package insert]. Kankakee, IL: CSL Behring LLC; October 2019.
8. Rebinyn [package insert]. DK-2880 Bagsvaerd, Denmark: Novo Nordisk A/S; June 2017.
9. Srivastava A, Brewer AK, Mauser-Bunschoten EP, et al. Guidelines for the management of hemophilia. *Haemophilia*. 2013;19(1):e1-e47.
10. National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised April 2018. MASAC Document #253. Accessed December 3, 2019.
11. Bebulin [package insert]. Westlake Village, CA: Baxalta US Inc.; September 2015.
12. Profilnine [package insert]. Los Angeles, CA: Grifols Biologicals, LLC; June 2018.

Review History

11/18/2020 – Updated and reviewed at Nov P&T Mtg: Moved from SGM to custom template, Separated Comm/Exch vs. MassHealth; reflected Benefix as preferred, changed approval dates from indefinite to 36 months

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