

HEMOPHILIA MANAGEMENT**Effective Date: June 1, 2024****Review Dates: 2/10, 2/11, 2/12, 2/13, 2/14, 2/15, 2/16,
2/17, 2/18, 2/19, 2/20, 2/21, 2/22, 2/23, 5/23, 5/24, 5/25****Date Of Origin: February 10, 2010****Status: Current****I. POLICY/CRITERIA**

- A. The following criteria apply to all outpatient hemophilia drugs, including replacement factor, used for outpatient non-emergent treatment of hemophilia and related clotting disorders:
1. Member must be seen at least once a year in a participating, recognized hemophilia treatment center.
 2. Member must obtain their hemophilia drug/replacement factor from a preferred in-network hemophilia specialty pharmacy. Hemophilia drugs/replacement factors obtained from a preferred in-network hemophilia specialty pharmacy are covered under the pharmacy benefit. Hemophilia drugs/replacement factors administered by a home infusion company also must be obtained from a participating hemophilia specialty pharmacy.
 3. Member may continue care with a non-hemophilia treatment centers (HTC) affiliated hematologist if I.1 and I.2 above are satisfied.
- B. A preferred in-network hemophilia specialty pharmacy does not need to be utilized when the hemophilia drug/replacement factor is administered and billed as part of an emergency room visit or inpatient hospital admission.

Note: For cellular and gene therapy (e.g., Hemgenix and Roctavian) the provider and facility administering treatment must be participating, in-network, and in alignment with the Priority Health Infusion Services & Equipment policy (No. 91414) and/or Cellular and Gene Therapy policy (No. 91638).

II. MEDICAL NECESSITY REVIEW

Prior authorization is required only for outpatient hemophilia therapies billed to the medical benefit in non-emergent outpatient situations.

For Medicaid/Healthy Michigan Plan only: Priority Health staff should notify the Medicaid Operations CSHCS nurse when services are authorized as Hemophilia is a lifelong CSHCS qualifier.

For more information, please refer to the Priority Health Provider Manual.

III. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- ❖ **HMO/EPO:** *This policy applies to insured HMO/EPO plans.*
- ❖ **POS:** *This policy applies to insured POS plans.*
- ❖ **PPO:** *This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.*
- ❖ **ASO:** *For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.*
- ❖ **INDIVIDUAL:** *For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.*
- ❖ **MEDICARE:** *Coverage is determined by the Centers for Medicare and Medicaid Services (CMS) and/or the Evidence of Coverage (EOC); if a coverage determination has not been adopted by CMS, this policy applies.*
- ❖ **MEDICAID/HEALTHY MICHIGAN PLAN:** *For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.*

IV. DESCRIPTION

Hemophilia is a rare, inherited bleeding disorder in which the blood does not clot properly due to a lack or decrease in a protein called clotting factor (Factor VIII - hemophilia A or Factor IX – hemophilia B). There are three main levels of severity: mild, moderate and severe. Hemophilia primarily affects men, occurring in about 1 of every 5,000 male births for hemophilia A And 1 in every 25,000 male births for hemophilia B. In the 1970s, as many advances were made in hemophilia treatment, the focus of hemophilia care shifted from crisis and emergency management of bleeding episodes to long-term problems such as the prevention of joint disease, home treatment, education, employment, and other psychosocial factors. Federal legislation in 1976 established and provided funding for a network of comprehensive care centers.

These hemophilia treatment centers (HTCs) provide and coordinate a broad range of treatment and prevention services provided by a care team including physicians who specialize in hematology and other relevant specialties such as orthopedics,

social work, psychologists, and nurses with extensive training and experience with hemophilia, genetic counselors, dentists, dental hygienists, and dieticians.

In its first ten years, comprehensive care provided by HTC resulted in:

- An increase of 390% in the number of patients performing home infusions
- A decrease in the average number hospital admissions of 88%
- A decrease in the average days/year lost from work or school of 73% accompanied by a 74% decrease in adult unemployment
- A decrease in the average cost of care per patient per year of 74%

Data collected by the CDC confirms that, in addition to these benefits, receiving treatment from a federally funded HTC also decreases the risk of death and hospitalization for persons with hemophilia. Approximately 70% of people with hemophilia in the United States receive multidisciplinary, comprehensive care in HTC (Soucie, 2000).

V. CODING INFORMATION

ICD-10 Codes that may apply:

- D66 Hereditary factor VIII deficiency
- D67 Hereditary factor IX deficiency
- D68.0 Von Willebrand's disease
- D68.1 Hereditary factor XI deficiency
- D68.2 Hereditary deficiency of other clotting factors

CPT/HCPCS Codes:

This list is not all-inclusive. This policy applies to all hemophilia therapies, including products new to market not listed below.

- J1411 Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
- J1412 Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2×10^{13} vector genomes
- J1414 Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose
- J7170 Injection, emicizumab-kxwh, 0.5 mg
- J7175 Injection, factor X, (human), 1 IU
- J7179 Injection, von Willebrand factor (recombinant), (Vonvendi), 1 IU VWF: RCo
- J7180 Injection, factor XIII (antihemophilic factor, human), 1 IU
- J7181 Injection, factor xiii a-subunit, (recombinant), per iu
- J7182 Injection, factor viii, (antihemophilic factor, recombinant), (novoeight), per IU
- J7183 Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF: RCo
- J7185 Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per IU
- J7186 Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII IU
- J7187 Injection, von Willebrand factor complex (Humate-P), per IU VWF-RC0
- J7188 Injection, factor VIII (antihemophilic factor, recombinant), (Obizur), per IU
- J7189 Factor VIIa (antihemophilic factor, recombinant), (NovoSeven RT), 1 mcg
- J7190 Factor VIII (antihemophilic factor, human) per IU

J7191	Factor VIII (antihemophilic factor (porcine)), per IU
J7192	Factor VIII (antihemophilic factor, recombinant) per IU , not otherwise specified
J7193	Factor IX (antihemophilic factor, purified, nonrecombinant) per IU
J7194	Factor IX complex, per IU
J7195	Factor IX (antihemophilic factor, recombinant) per IU , not otherwise specified
J7198	Anti-inhibitor, per iIU
J7199	Hemophilia clotting factor, not otherwise classified (<i>Explanatory notes [drugname dose, route] must accompany claims billed with unlisted codes in addition to NDC code.</i>)
J7200	Injection, factor ix, (antihemophilic factor, recombinant), rixubis, per iIU
J7201	Injection, factor ix, fc fusion protein (recombinant), per IU
J7202	Injection, factor IX, albumin fusion protein, (recombinant), Idelvion, 1 IU
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 IU
J7204	Injection, factor viii, antihemophilic factor (recombinant), (esperoct), glycopegylated-exei, per IU
J7205	Injection, factor viii fc fusion (recombinant), per iIU
J7207	Injection, factor VIII, (antihemophilic factor, recombinant), PEGylated, 1 IU
J7208	Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 IU
J7209	Injection, factor VIII, (antihemophilic factor, recombinant), (Nuwiq), 1 IU
J7210	Injection, Factor VIII, (antihemophilic factor, recombinant), (Afstyla), 1 IU
J7211	Injection, Factor VIII, (antihemophilic factor, recombinant), (Kovaltry), 1 IU
J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram
J7213	Injection, coagulation factor ix (recombinant), ixinity, 1IU.
J3590,	Alhemo (Injection, concizumab-mtci solution)
C9399	Unclassified drugs or biologicals (All claims submitted with unclassified or unlisted codes must include explanatory notes (i.e., drug name, dose, route) and the national drug code (NDC) that was dispensed)
J3590,	Hympavzi (Injection, marstacimab-hncq, 0.5 mg)
C9304	Injection, marstacimab-hncq, 0.5 mg
J3590	Unclassified biologics (All claims submitted with unclassified or unlisted codes must include explanatory notes (i.e., drug name, dose, route) and the national drug code (NDC) that was dispensed)
C9399	Unclassified drugs or biologicals (All claims submitted with unclassified or unlisted codes must include explanatory notes (i.e., drug name, dose, route) and the national drug code (NDC) that was dispensed.)

For Commercial & Individual plans: *Products represented by the above CPT/HCPCS codes are pharmacy benefit only and must be processed through the pharmacy benefits manager for all non-emergent outpatient situations.*

For Medicaid/Healthy Michigan: *Products represented by the above CPT/HCPCS codes, other than gene therapies, must be processed through the pharmacy benefit for all maintenance doses. For planned outpatient procedures (e.g., surgery, scope, etc.), Priority Health may authorize one dose to be billed to the medical benefit.*

For Medicare: *Products represented by the above CPT/HCPCS codes must be processed through the medical (Part B) benefit. Hemophilia therapies are excluded under the pharmacy (Part D) benefit.*

VI. REFERENCES

1. Centers for Disease Control and Prevention. [Hemophilia Treatment Centers \(HTCs\)](#) (Accessed April 4, 2025).
2. Schieve LA, Byams VR, Dupervil B, et al. Evaluation of CDC's Hemophilia Surveillance Program — Universal Data Collection (1998–2011) and Community Counts (2011–2019), United States . MMWR Surveill Summ 2020;69 (No. SS-5):1–18. DOI: <http://dx.doi.org/10.15585/mmwr.ss6905a1>
3. Soucie JM et al. Mortality among males with hemophilia: relations with source of medical care. Blood (2000) 96 (2): 437–442.
4. Soucie JM et al. Occurrence rates of haemophilia among males in the United States based on surveillance conducted in specialized haemophilia treatment centres. Haemophilia. 2020 May;26(3):487-493. doi: 10.1111/hae.13998.
5. Roctavian [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; Accessed March 26,2024
6. Hemgenix [prescribing information]. King of Prussia, PA: CSL Behring LLC; Accessed March 26,2024

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