Priority Health

MEDICAL POLICY
No. 91569-R3

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

Date Of Origin: February 10, 2010

Status: Current

Summary of Changes

- Addition: Added reference to cellular and gene therapy treatments (Hemgenix and Roctavian) and related Priority Health medical policies.

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/Health Michigan 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 HTCs 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:

J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
J1412	Injection, valoctocogene roxaparvovec-rvox, per ml, containing nominal 2 x 10^13 vector genomes
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
J7183	Injection, von Willebrand factor complex (human), Wilate, 1 IU vWF: RCo
J7185	Injection, factor VIII (antihemophilic factor, recombinant) (Xyntha), per i.u.
J7186	Injection, antihemophilic factor VIII/von Willebrand factor complex (human), per factor VIII i.u.
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), per 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
J7193 Factor IX (antihemophilic factor, purified, nonrecombinant) per IU
J7194 Factor IX complex, per IU
J7195 Factor IX (antihemophilic factor, recombinant) per IU
J7198 Anti-inhibitor, per i.u
J7199 Hemophilia clotting factor, not otherwise classified (*Explanatory notes [drugname dose, route] must accompany claims billed with unlisted codes in addition to NDC code.)*
J7200 Injection, factor ix, (antihemophilic factor, recombinant), rixubis, per iu
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 iu
J7207 Injection, factor VIII, (antihemophilic factor, recombinant), PEGylated, 1 IU
J7208 Injection, factor viii, (antihemophilic factor, recombinant), pegylated-aucl, (jivi), 1 i.u.
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, 1 i.u.
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

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5. 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.
6. Roctavian [prescribing information]. Novato, CA: BioMarin Pharmaceutical Inc.; Accessed March 26,2024
7. Hemgenix [prescribing information]. King of Prussia, PA: CSL Behring LLC; Accessed March 26,2024