NO. 91569

HEMOPHILIA MANAGEMENT

Effective: 06/01/2026
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Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

Policy scope: This policy establishes medical necessity criteria for outpatient, non-emergent hemophilia therapies, including factor replacement, non-factor agents, and gene therapies, for members with hemophilia and related clotting disorders.

Related policies:

- Priority Health Infusion Services & Equipment policy # 91414
- Cellular and Gene Therapy policy # 91638

I. MEDICAL NECESSITY 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 Reimbursement Requirements for Outpatient Medical Drugs billing policy and/or Cellular and Gene Therapy policy (No. 91638).

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

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the CMS Online Manual System (IOMs) and Transmittals.
For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to CMS Medicare Coverage Database.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)	
NCD 110.3 - Anti-Inhibitor Coagulant Complex (AICC)	
Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

III. BACKGROUND

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's resulted in:

- An increase of 390% in the number of patients performing home infusions
- A decrease in the average number of hospital admissions by 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).

Traditional treatments for hemophilia have largely worked by directly replacing the missing coagulation factor, but face challenges due to the short half-life of factor VIII and factor IX, the need for frequent intravenous access and development of neutralizing antibodies to coagulation factors (inhibitors). Recent advances in hemophilia therapy have worked to eliminate these challenges. Half-life extension of factor concentrates has lengthened the time needed between infusions, enhancing quality of life. Subcutaneous administration of therapeutics utilizing alternative mechanisms to overcome inhibitors have expanded the options to prevent bleeding. Finally, initial successes with gene therapy offer a cautious hope for durable cure. (Fassel et al., 2021)

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
National Bleeding Disorders Foundation	MASAC Document 267 - MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors
National Bleeding Disorders Foundation	MASAC Document 282 - MASAC Recommendations on Hemophilia Treatment Center Preparedness for Delivering Gene Therapy for Hemophilia
International Society on Thrombosis and Haemostasis	Clinical practice guideline for treatment of congenital hemophilia A and B based on the Grading of Recommendations Assessment, Development, and Evaluation methodology
World Federation of Hemophilia	WFH Guidelines for the Management of Hemophilia, 3rd edition

National Bleeding Disorders Foundation	MASAC Document 269- Standards and Criteria for the Care of Persons with Congenital Bleeding Disorders

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See U.S. Food & Drug Administration (FDA) Medical Device Databases for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date

VI. CODING

ICD-10 Codes that may support medical necessity

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 x 10^13 vector genomes
J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose
J7170	Injection, emicizumab-kxwh, 0.5 mg
J7172	Injection, marstacimab-hncq, 0.5 mg (Hympavzi)
J7173	Injection, concizumab-mtci, 0.5 mg (Alhemo)
J7174	Injection, fitusiran, 0.04 mg (Qfitlia)
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 *(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 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.
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 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)*

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.*

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not

be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

To access Evicore guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into Priority Health Prism → Authorizations → Authorization Criteria Lookup.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the 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); 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. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

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SUMMARY OF CHANGES

Clarifications:

- Updated background and references

Past committee review dates: 02/2010, 02/2011, 02/2012, 02/2013, 02/2014, 02/2015, 02/2016, 02/2017, 02/2018, 02/2019,0 2/2020, 02/2021, 02/2022, 02/2023, 05/2023, 05/2024, 05/2025, 05/2026

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