

Preemptive policy: This is a P&T approved policy and can be used after the drug is FDA approved until it is superseded by an updated policy



Clinical Policy: Denecimig (Mim8)

Reference Number: CP.PHAR.781

Effective Date: **FDA Approval Date**

Last Review Date: 08.26

Line of Business: Commercial, HIM/ICHRA, Medicaid

[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Denecimig (Mim8^{®/™}) is a factor VIIIa mimetic bispecific antibody.

FDA Approved Indication(s) **[Pending]**

Mim8 is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients aged 12 years or older with hemophilia A (congenital factor VIII [FVIII] deficiency) with or without FVIII inhibitors.

Limitation(s) of use: [XXX]

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Mim8 is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Congenital Hemophilia A (must meet all):

1. Prescribed for routine prophylaxis of bleeding episodes in members with congenital hemophilia A (FVIII deficiency);*
2. Prescribed by or in consultation with a hematologist;
3. Age $\geq$ 12 years;*
4. Member's weight meets both of the following (a and b) ;*
 - a. Documentation of member's current body weight in kg;
 - b. Current weight $\geq$ 30 kg;
5. Member meets one of the following (a or b):*[^]

[^]For Illinois HIM requests, the step therapy requirements below do not apply as of 1/1/2026 per IL HB 5395

- a. Failure of a bypassing agent or FVIII product[†] (see Appendix B) used for routine prophylaxis as assessed and documented by prescriber (see Appendix D), unless clinically significant adverse effects are experienced or all are contraindicated;
- b. Member had $\geq$ 5 acute bleeding episodes in the previous 6 months treated with a FVIII product or bypassing agent;

[†]Prior authorization may be required for bypassing agents and FVIII products

6. For members who are new to Mim8 therapy and have not previously used bypassing agents or FVIII products for routine prophylaxis: Member meets one of the following (a or b):*
 - a. Member has severe hemophilia (defined as FVIII level of < 1%);
 - b. Member has experienced at least one serious spontaneous bleed (*see Appendix D*);
7. For hemophilia A with inhibitors: Member has inhibitor level ≥ 5 Bethesda units (BU);*
8. Mim8 is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., bypassing agents and FVIII products as prophylactic therapy, ^ Hemlibra[®], Qfitlia[®], Hympavzi[™], Alhemo[®]);*
^On-demand usage of a bypassing agent or FVIII product may be continued
9. Dose does not exceed FDA-labeled maximum dosing.*

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy*

**Criteria will mirror the clinical information from the prescribing information once FDA-approved*

A. Congenital Hemophilia A (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
 - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
2. Member is responding positively to therapy (e.g., reduction in number of all bleeds, joint bleeds, and/or target joint bleeds over time);*
3. Mim8 is not prescribed concurrently with another hemophilia prophylaxis agent (e.g., bypassing agents and FVIII products as prophylactic therapy, ^ Hemlibra, Qfitlia,

Hypnavorz, Alhemo);*

^On-demand usage of a bypassing agent or FVIII product may be continued

4. If request is for a dose increase, both (a and b):*
 - a. Documentation of member's current body weight in kg (if requesting a higher dose than previously requested);
 - b. New dose does not exceed FDA-labeled maximum dosing.

Approval duration:

Medicaid/HIM/ICHRA – 12 months

Commercial – 6 months or to the member's renewal date, whichever is longer

B. Other diagnoses/indications (must meet 1 or 2):

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
 - a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
 - b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BU: Bethesda unit

FDA: Food and Drug Administration

FVIII: factor VIII

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
FVIII products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples		
Advate [®] , Adynovate [®] , Afstyl [®] , Altuviiiio [®] , Elocate [®] , Esperoct [®] , Jivi [®] , Kogenate FS [®] , Kovaltry [®] , Novoeight [®] , Nuwiq [®] , Xyntha [®]	See individual Prescribing Information for dosing regimen	
Bypassing products for control and prevention of bleeding episodes and/or for routine prophylaxis - examples		
NovoSeven [®] RT, SevenFact [®] , Feiba [®]	See individual Prescribing Information for dosing regimen	

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings [Pending]

- Contraindication(s): **pending**
- Boxed warning(s): **pending**

Appendix D: General Information

- Examples of member responding positively to therapy may include: reduction in number of all bleeds over time, reduction in number of joint bleeds over time, or reduction in number of target joint bleeds over time.
- There are no strict criteria for failing FVIII product or a bypassing agent for routine prophylaxis; however, the following reasons are acceptable to fulfill the criteria:
 - Prescriber has documented clinical criteria which support his or her assessment that the member has failed therapy;
 - Clinically significant bleeding, hemarthroses, life-threatening bleeding episodes, joint swelling, upcoming surgery/procedure not responding to current therapy, or other clinical assessment as determined by prescriber.
- Serious bleeding episodes include bleeds in the following sites: intracranial; neck/throat; gastrointestinal; joints (hemarthrosis); muscles (especially deep compartments such as the iliopsoas, calf, forearm); or mucous membranes of the mouth, nose and genitourinary tract.
- A spontaneous bleed is defined as a bleeding episode that occurs without apparent cause and is not the result of trauma.

V. Dosage and Administration [Pending]

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis of bleeding episodes in hemophilia A*	Weight-based SC loading dose, followed by a weight-based SC maintenance of once weekly or once monthly*	See regimen*

VI. Product Availability [Pending]

Pending

VII. References

1. Mancuso ME, Chan AKC, Shanmukhaiah C, et al. Mim8 Bispecific Antibody Prophylaxis in Hemophilia A with or without Inhibitors. N Engl J Med. 2026;394(17):1696-1709.
2. Medical and Scientific Advisory Council (MASAC) of the National Bleeding Disorders (formerly National Hemophilia Foundation): Database of treatment guidelines. Available at: <https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents>. Accessed April 30, 2026.
3. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia. Haemophilia. 2020;26(suppl 6):1-158.
4. Rezende SM, Neumann I, Angchaisuksiri P, et al. 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. J Thromb Haemost. 2024;22(9):2629-2652.

Coding Implications **[Pending]**

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
Pending	Pending

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created pre-emptively	04.22.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy,

contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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