POLICY Document for HEMLIBRA (emicizumab-kxwh))

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 1: Preferred Product

Hemophiliaq CAREFIRST: EXCEPTIONS CRITERIA
HEMOPHILIA A

PREFERRED PRODUCTS: ELOCTATE, HEMLIBRA, XYNTHA/SOLOFUSE, NUWIQ

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the Factor VIII products specified in this policy. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members who are requesting treatment with the targeted products

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Factor VIII Products

	Product(s)
Preferred*	• **Eloctate** (antihemophilic factor [recombinant]) • **Hemlibra** (emicizumab-kxwh) • **Nuwiq** (antihemophilic factor [recombinant]) • **Xyntha (including Solofuse)** (antihemophilic factor [recombinant])
Targeted	• **Advate** (antihemophilic factor [recombinant]) • **Adynovate** (antihemophilic factor [recombinant]) • **Afstyla** (antihemophilic factor [recombinant]) • **Altuviiio** (antihemophilic factor [recombinant]) • **Esperoct** (antihemophilic [recombinant]) • **Jivi** (antihemophilic factor [recombinant]) • **Kogenate FS** (antihemophilic factor [recombinant])

	• **Kovaltry** (antihemophilic factor [recombinant]) • **Novoeight** (antihemophilic factor [recombinant]) • **Recombinate** (antihemophilic factor [recombinant]) • **Roctavian** (Valoctogene roxaparvovec-rvox)

*: Medications considered formulary or preferred on your plan may still require a clinical prior authorization review

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred product.

Coverage for the targeted product is provided when the following criteria is met:

A. Member has a documented inadequate response, contraindication, or intolerable adverse event to all preferred products.

Section 2: Clinical Criteria

Specialty Guideline Management Hemlibra

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Hemlibra	emicizumab-kxwh

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ages newborn and older with hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:
For continuation requests: Chart notes documenting benefit from therapy (e.g., reduced frequency or severity of bleeds).

Prescriber Specialties

Must be prescribed by or in consultation with a hematologist.

Coverage Criteria

Hemophilia A (congenital factor VIII deficiency)[1-3]

Authorization of 12 months may be granted for treatment of hemophilia A (congenital factor VIII deficiency) when all of the following criteria is met:

- Member must be using the requested medication for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.
- Member meets one of the following criteria:
  - Member has mild disease (See Appendix A) and has had an insufficient response to desmopressin or a documented clinical reason for not using desmopressin (See Appendix B).
  - Member has moderate or severe disease (See Appendix A).
- Member will not use the requested medication in combination with Alhemo or Hympavzi.
- Member has not previously received treatment with a gene therapy product (e.g., Roctavian) for the treatment of hemophilia A.
- Prophylactic use of factor VIII products (e.g., Advate, Adynovate, Eloctate) will be discontinued after the first week of starting therapy with the requested medication.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in coverage criteria section when the member is experiencing benefit from therapy (e.g., reduced frequency or severity of bleeds) and member is not using the requested medication in combination with factor VIII products (e.g., Advate, Adynovate, Eloctate, etc.) for prophylactic use.

Dosage and Administration

For initial and continuation requests, dosing does not exceed the following:

- Induction: 3 mg/kg subcutaneously once weekly for the first 4 weeks.
- Maintenance: 1.5 mg/kg once weekly, or 3 mg/kg once every 2 weeks, or 6 mg/kg once every 4 weeks.

Appendix

Factor assay levels are required to determine the diagnosis and are of value in monitoring treatment response.

Appendix A: Classification of Hemophilia by Clotting Factor Level (% Activity) and Bleeding Episodes[2,4]

Severity	Clotting Factor Level % activity	Bleeding Episodes
Severe	<1%	Spontaneous bleeding episodes, predominantly into joints and muscles Severe bleeding with trauma, injury or surgery
Moderate	1% to 5%	Occasional spontaneous bleeding episodes Severe bleeding with trauma, injury or surgery
Mild	6% to 40%	Severe bleeding with serious injury, trauma or surgery

Appendix B: Clinical Reasons For Not Utilizing Desmopressin in Patients with Hemophilia A[3,5,6]

Age < 2 years
Pregnancy
Fluid/electrolyte imbalance
High risk for cardiovascular or cerebrovascular disease (especially the elderly)
Predisposition to thrombus formation
Trauma requiring surgery
Life-threatening bleed
Contraindication or intolerance to desmopressin
Stimate Nasal Spray is unavailable due to backorder/shortage issues (where applicable)

REFERENCES:

SECTION 1

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17. Xyntha [package insert]. Philadelphia, PA; Wyeth Pharmaceuticals LLC; July 2022.

SECTION 2

1. Hemlibra [package insert]. South San Francisco, CA: Genentech, Inc.; January 2024.
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