SmartHealth Ascension

Emicizumab-kxwh

(Hemlibra®) J7170

Covered with prior authorization

Emicizumab-kxwh (Hemlibra®) may be authorized when the following criteria are met:

- Documentation that administration is required by a professional in an office, clinic, or infusion center to verify the medical necessity of ongoing professional administration; **AND**
- Individual has a diagnosis of severe hemophilia A (defined as less than 1 International Unit per deciliter [1IU/dL] endogenous Factor VIII); **AND**
- Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- One of the following:
    - Switching from factor VIII agents for routine prophylaxis: discontinue factor VIII agents after the first week of Hemlibra®; **OR**
    - Switching from bypassing agents (i.e., NovoSeven RT, SevenFact, FEIBA) for routine prophylaxis: discontinue bypassing agents 24 hours after Hemlibra initiation;

OR

- Individual has a diagnosis of mild to moderate hemophilia A (defined as endogenous Factor VIII less than 40 IU/dL [less than 40%], but greater than or equal to 1 IU); **AND**
- Individual is using for routine prophylaxis to prevent or reduce the frequency of bleeding episodes; **AND**
- One of the following:
    - One or more episodes of spontaneous bleeding into joint; **OR**
    - One or more episodes of spontaneous bleeding into the central nervous system; **OR**
    - Four or more episodes of soft tissue bleeding in an 8 week period; **OR**
    - Severe phenotype hemophilia as noted by the individual's risk factors that increase the risk of a clinically significant bleed, including but not limited to, participation in activities likely to cause injury/trauma, procoagulant and anticoagulant protein levels, comorbid conditions affecting functional ability and physical coordination, or history of a clinically significant bleed; **AND**
- One of the following:
    - Switching from factor VIII agents for routine prophylaxis: discontinue factor VIII agents after the first week of Hemlibra®; **OR**
    - Switching from bypassing agents (i.e., NovoSeven RT, SevenFact, FEIBA) for routine prophylaxis: discontinue bypassing agents 24 hours after Hemlibra initiation; **AND**

- Prescribed by or in consultation with a hematologist, pediatric hematologist, or a prescriber who specializes in hemophilia; **AND**
- Subcutaneous injection dosing follows approved regimen:
    - Loading dose: 3 mg/kg once weekly for the first 4 weeks; **AND**
    - Maintenance dose:
        - 1.5 mg/kg once every week; **OR**
        - 3 mg/kg once every two weeks; **OR**
        - 6 mg/kg once every four weeks

Exclusion criteria:

Requests may not be approved for the following:

- Product self-administration or administration by parent;
- Product use for non-FDA approved indications or indications not supported by industry-accepted guidelines;
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use;
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk;

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy. Individual has a positive therapeutic response to treatment (for example, reduction in frequency and/or severity of bleeding episodes).

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:

This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

HEMLIBRA® (emicizumab-kxwh) is a bispecific factor IXa- and factor X-directed antibody 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.

References:

Comprehensive Medical Care. (updated periodically). National Hemophilia Foundation. Retrieved June 21, 2022, from https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/comprehensive-medical-care
Emicizumab (Lexi-Drugs). (2022, April 19). Lexicomp. Retrieved June 21, 2022, from https://online.lexi.com/lco/action/doc/retrieve/docid/patch_f/6568098?cesid=2Y0866I7855&searchUrl=%2Flco%2Faction%2Fsearch%3Fq%3DHemlibra%26t%3Dname%26acs%3Dfalse%26acq%3DHemlibra
Hemlibra Prescribing Information. (2022, June). Genentech. Retrieved June 21, 2022, from https://www.gene.com/download/pdf/hemlibra_prescribing.pdf

Waldron, J. (2022, June 1). *Sanofi's Hemlibra rival gets FDA breakthrough tag*. Fierce Biotech. Retrieved June 21, 2022, from https://www.fiercebiotech.com/biotech/sanofis-hemlibra-rival-gets-step-closer-approval-fda-breakthrough-tag

Criteria History/ Revision Information:

Date	Summary of Changes
June 2022	Criteria for use summary developed by Ascension Medical Specialty Prior Authorization Team
July 2022	Criteria for use summary approved by Ascension Therapeutic Affinity Group

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team or email your questions to smarthealthspecialty@ascension.org.