EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		

***********Customer Service/PAC Alert************
(For Internal Use Only)

THIS IS A HIGH-IMPACT MEDICATION. DO NOT OVERRIDE OR APPROVE WITHOUT SUBMITTING FOR PHARMACIST REVIEW.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet **ALL** of the following criteria?
   - The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - The medication is prescribed by or given in consultation with a hematologist

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the request for a patient **WITH** factor VIII inhibitors and the patient meets the following criterion?
   - The patient has a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter

   If yes, **approve for 12 months by HICL.**
   APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline.

   If no, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Is the request for a patient **WITHOUT** factor VIII inhibitors and the patient meets **ONE** of the following criteria?
   - The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal, **OR**
   - The patient has *mild* or *moderate* hemophilia A **AND** a history of 2 or more bleeds per year

   If yes, **approve for 12 months by HICL.**
   APPROVAL TEXT: Renewal requires physician attestation of clinical benefit compared to baseline.

   If no, do not approve.
   INITIAL DENIAL TEXT: The guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires a diagnosis of hemophilia A (congenital factor VIII deficiency). In addition, the following criteria must also be met:
   - The medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   - The medication is prescribed by or given in consultation with a hematologist
   - Patients with Factor VIII inhibitors must have a history of a high titer of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
   - Patients without Factor VIII inhibitors must meet one of the following criteria:
     - The patient has severe hemophilia A defined as less than 1% factor VIII activity compared to normal
     - The patient has *mild* or *moderate* hemophilia A and a history of 2 or more bleeds per year

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) and meet the following criterion?
   - Physician attestation of clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: The guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires a diagnosis of hemophilia A (congenital factor VIII deficiency). In addition, the following criterion must also be met:
   - Physician attestation of clinical benefit compared to baseline

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Hemlibra.

REFERENCES

- Hemlibra [Prescribing Information]. Genentech, Inc.: South San Francisco, CA; October 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 01/01/19
Created: 02/18
Client Approval: 11/18
P&T Approval: 10/18