STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

EMICIZUMAB-KXWH

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
EMICIZUMAB-KXWH	HEMLIBRA	44640		GPI-10 (8510503020)	

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?
   - Therapy is prescribed by or in consultation with a hematologist
   - The requested medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes

   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 or GPI-10.**
   If no, continue to #3.

3. Is the request for a patient **WITHOUT** factor VIII inhibitors?

   If yes, continue to #4.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

4. Does the patient have moderate to severe hemophilia A, defined as less than 5% factor VIII activity compared to normal?

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, continue to #5.

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EMICIZUMAB-KXWH

INITIAL CRITERIA (CONTINUED)

5. Does the patient have mild hemophilia A, defined as 5%-40% factor VIII activity compared to normal, and meet **ONE** of the following criteria?
   - The patient has experienced severe, traumatic, or spontaneous bleeding episode(s) (may occur in joint or muscle)
   - The patient has experienced a life-threatening bleed (e.g., intracranial hemorrhage [ICH])
   - The patient has venous access difficulties impeding regular clotting factor infusions

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for approval:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. Therapy is prescribed by or in consultation with a hematologist (a type of blood doctor)
   C. The requested medication will be used for routine prophylaxis to prevent or reduce the frequency of bleeding episodes
   D. **If you have hemophilia A with factor VIII inhibitors (a type of protein), approval also requires:**
      1. You have a history of a high titer (concentration) of factor VIII inhibitor defined as at least 5 or more Bethesda units per milliliter
   E. **If you have hemophilia A without factor VIII inhibitors (a type of protein), approval also requires ONE of the following criteria:**
      1. You have moderate to severe hemophilia A, defined as less than 5% factor VIII activity compared to normal
      2. You have mild hemophilia A, defined as 5%-40% factor VIII activity compared to normal, and meet ONE of the following:
         a. You have experienced severe, traumatic, or spontaneous (sudden) bleeding episode(s) (may occur in joint or muscle)
         b. You have experienced a life-threatening bleed (for example intracranial hemorrhage [ICH: a type of bleeding in your head])
         c. It is difficult to access your veins which prevents or delays you in receiving regular clotting factor infusions

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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EMICIZUMAB-KXWH

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of hemophilia A (congenital factor VIII deficiency) **AND** meet the following criterion?
   - The patient has had clinical benefit compared to baseline

   If yes, **approve for 12 months by HICL or GPI-10.**
   If no, do not approve.
   RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

   Our guideline named **EMICIZUMAB-KXWH (Hemlibra)** requires the following rule(s) be met for renewal:
   A. You have hemophilia A (congenital factor VIII deficiency: a type of bleeding disorder)
   B. You had a clinical benefit after using the medication compared to baseline

   Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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; June 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/23
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P&T Approval: 01/23