HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES

EMICIZUMAB (HEMLIBRA)

Generic	Brand	HICL	GCN	Exception/Other
EMICIZUMAB	HEMLIBRA	44640		

If the caller wishes to initiate a request then a MRF must be completed. This drug requires a written request for prior authorization. All requests for high-impact medications require review by a pharmacist prior to final approval.

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Is the request for a patient with the diagnosis of Hemophilia A (congenital factor VIII deficiency) with inhibitors and there is history of one of the following conditions?
   - High-inhibitor titer (i.e., ≥ 5 Bethesda units per milliliter [BU/mL]) as confirmed by laboratory testing
   - Inadequate response to Immune Tolerance Therapy (ITT)
   - Utilization of bypassing agents (e.g. Feiba, NovoSeven)

   If yes, **approve by HICL for 6 months**. Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for Hemlibra has been approved for a 6-month period.
   If no, continue to #2.

2. Is the request for a patient with the diagnosis of Hemophilia A (congenital factor VIII deficiency) without inhibitors and the request meets each of the following conditions?
   - The hemophilia is severe, i.e., endogenous factor VIII level less than 1% AND
   - Patient has experienced life-threatening or significant bleeds, such as at least one episode of a central nervous system or large joint (e.g., ankle, knee, elbow, shoulder, hip) bleed, OR there is evidence of arthropathy

   If yes, **approve by HICL for 6 months**. Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for Hemlibra has been approved for a 6-month period.

   If no, do not approve. Please use status code #238 and the provided denial text.
   DENIAL TEXT (Hemophilia A with inhibitors): Per your health plan's Hemlibra (emicizumab) guideline, this medication is only covered for the treatment of Hemophilia A (congenital factor VIII deficiency) with inhibitors if you have a history of one of the following:
   - High-inhibitor titer, which must be greater than or equal to 5 Bethesda units per milliliter
   - Inadequate response to Immune Tolerance Therapy (ITT)
   - Utilization of bypassing agents (e.g. Feiba, NovoSeven)

   Your provider did not submit information that you meet this condition, and therefore your request was not approved.
   (Initial denial text continued on next page)

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EMICIZUMAB (HEMLIBRA)

INITIAL CRITERIA (CONTINUED)

DENIAL TEXT (Hemophilia A without inhibitors): Per your health plan's Hemlibra (emicizumab) guideline, this medication is only covered for the treatment of Hemophilia A (congenital factor VIII deficiency) without inhibitors if you meet each of the following conditions:

- You have severe Hemophilia A, i.e., endogenous factor VIII level less than 1%
- You experienced life-threatening or significant bleeds, such as at least one episode of a central nervous system or large joint (e.g., ankle, knee, elbow, shoulder, hip) bleed, OR you have evidence of arthropathy

Your provider did not submit information that you meet this condition, and therefore your request was not approved.

RENEWAL CRITERIA

1. Has the patient experienced improvement with Hemlibra in terms of achieving or maintaining a reduction in the frequency of bleeding episodes?

   If yes, **approve by HICL for 6 months.** Please use status code #057 and the approval text provided.
   APPROVAL TEXT: Your request for Hemlibra has been approved for a 6-month period.
   If no, do not approve. Please use status code #238 and the provided denial text.
   DENIAL TEXT: Per your health plan's Hemlibra (emicizumab) guideline, authorization for renewal requires evidence of improvement with therapy in terms of achieving or maintaining a reduction in the frequency of bleeding episodes.
   Your provider did not indicate there has been improvement with Hemlibra and therefore your request was not approved.

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EMICIZUMAB (HEMLIBRA)

RATIONALE
To promote the appropriate use of Hemlibra.

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

REFERENCES

- Hemlibra (emicizumab) [prescribing information]. South San Francisco, CA. Genentech, Inc., October 2018.
- Oldenburg J, Mahlangu JN, Kim B, et al. Emicizumab Prophylaxis in Hemophilia A with Inhibitors. N Engl J Med. 2017; 377:809-818.
- A Study of Emicizumab Administered Subcutaneously (SC) in Pediatric Participants With Hemophilia A and Factor VIII (FVIII) Inhibitors (HAVEN 2). ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). June 10, 2016. Identifier: NCT02795767. Available at https://clinicaltrials.gov/ct2/show/NCT02795767. Accessed November 20, 2017.
- Srivastava A, Brewer A, Street A, et al. Guidelines for the management of hemophilia. Haemophilia. January 2013;19(1):e1-e47. Available at https://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed November 20, 2017.
- Kruse-Jarres R, Kempton CL, Baudo F, et al. Acquired hemophilia A: Updated review of evidence and treatment guidance. Am J Hematol. 2017;92:695–705.
- National Hemophilia Foundation. MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders. Revised August 2017. MASAC Document #250. Available at https://www.wfh.org/en/resources/wfh-treatment-guidelines. Accessed November 20, 2017.

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