Clinical Policy Title:	emicizumab-kxwh
Policy Number:	RxA.159
Drug(s) Applied:	Hemlibra®
Original Policy Date:	2/28/2024
Last Review Date:	2/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Clinical Policy

The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

I. Initial Approval Criteria

A. Congenital Hemophilia A with Inhibitors (Factor VIII deficiency) (must meet all):

1. Prescribed for prophylaxis of bleeding episodes;
2. Patient has developed high-titer factor VIII inhibitors (> 5 Bethesda units [BU]);
3. Prescribed by or in consultation with a hematologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Congenital Hemophilia A Without Inhibitors (Factor VIII deficiency) (must meet all)**:**

1. Prescribed for prophylaxis of bleeding episodes;
2. Patient meets one of the following:
   a. Diagnosis of mild haemophilia A (factor VIII level > 5%);
   b. Diagnosis of moderate hemophilia A (factor VIII level >1% < 5%);
   c. Diagnosis of severe hemophilia A (factor VIII level < 1%);
3. Medical records documenting a failure to meet clinical goals (e.g., continuation of spontaneous bleeds, inability to achieve appropriate trough level, previous history of inhibitors) after a trial of one of the following prophylactic factor VIII replacement products: Advate, Altuviiio, Kogenate FS, Kovaltry, Novoeight, Nuwiq, Xyntha, Koate, Adynovate, Afstyla, Eloctate, Jivi;
4. Prescribed by or in consultation with a hematologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Congenital Hemophilia A With or Without Inhibitors (must meet all):

1. Member is currently receiving medication within the last 90 days;
2. Prescribed for prophylaxis of bleeding episodes.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF): Database of treatment guidelines. Available at: https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents. Accessed July 31, 2023.
2. Mehta P, Reddivari AKR. Hemophilia. In: StatPearls. StatPearls Publishing; 2023. Available at: https://www.ncbi.nlm.nih.gov/books/NBK551607/. Accessed July 31, 2023.
3. Srivastava A, Santagostino E, Dougall A, et al. WFH guidelines for the management of hemophilia, 3rd edition. Haemophilia. 2020;26(S6):1-158. Available at: https://onlinelibrary.wiley.com/doi/10.1111/hae.14046. Accessed July 31, 2023.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 2. In initial therapy and continued therapy: I.B - Added one Criteria- Member meets one of the following (a or b): a. Member has not received treatment with valoctocogene roxaparvovec; b. Request is for prophylaxis post-valoctocogene roxaparvovec gene therapy administration 3. Updated Approval Duration for initial therapy and continued therapy: I.B- Added 1 month approval duration for use post-valoctocogene gene therapy administration in hemophilia A. 4. Reference reviewed and updated.	06/16/2020	09/14/2020
Policy was reviewed: 1. Updated format of Approval Duration for initial therapy and continued therapy. 2. Continued therapy criteria II.A.1 was rephrased to “Member is currently receiving medication that has been authorized by RxAdvance..” 3. Reference reviewed and updated.	02/22/2021	06/10/2021
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Continued Therapy Approval II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Appendix A was updated to include abbreviations for TAM and aPCC.	10/27/21	01/17/2022

4. Appendix D was updated to include warning about thrombotic microangiopathy and thromboembolism. 5. References were reviewed and updated.		
Policy was reviewed: 1. Dosing Information, Maximum Dose, emicizumab-kxwh (Hemlibra®): Updated to maximum dosing information from "3 mg/kg/week for the first 4 weeks, followed by 1.5 mg/kg/week thereafter" to "3 mg/kg/week for the first 4 weeks, followed by up to 6 mg/kg every 4 weeks thereafter" for indication "Routine prophylaxis of bleeding episodes". 2. Initial Approval Criteria, 1.A.3: Updated to include new diagnostic criteria "Member has severe hemophilia A...". 3. References were reviewed and updated.	01/12/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	01/18/2023	04/13/2023
Policy was reviewed: 1. PA Policy reinstated as drug require PA. 2. Lines of Business Policy updated to All lines of business (except Medicare). 3. Dosage form updated. 4. Statement about provider sample was updated. 5. Approval duration was updated to All Lines of Business (except Medicare): 6 months. 6. Continued Therapy Approval Criteria, II.A.1: updated to “Member is currently receiving…” 7. Appendix B: Updated to remove "Appendix B: Therapeutic alternatives". 8. Appendix C: Contraindications/Boxed Warnings was removed. 9. Appendix D: Renamed appendix as Appendix B: General Information. 10. References were reviewed and updated.	07/21/2023	10/19/2023