Clinical Policy Title:	icatibant
Policy Number:	RxA.136
Drug(s) Applied:	Firazyr®
Original Policy Date:	02/07/2020
Last Review Date:	4/15/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Hereditary Angioedema (must meet all)**:**

1. Documented diagnosis of type I or II HAE confirmed by one of the following (a or b):
   a. Low C4 level, low C1-INH antigenic or functional levels, and history of recurrent angioedema;
   b. Normal C4 level, normal C1-INH antigenic and functional levels, and both of the following (i and ii):
      i. History of recurrent angioedema;
      ii. Family history of angioedema OR demonstration of mutation associated with disease;
2. Prescribed by or in consultation with a hematologist, allergist, pulmonologist or immunologist;
3. Prescribed for treatment of acute HAE attacks;
4. Request does not exceed 6 doses per month;
5. Member is not using icatibant in combination with another FDA-approved product for treatment of acute HAE attacks (e.g., Berinert®, Ruconest®, Kalbitor®).

Initial Approval duration:

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Hereditary Angioedema (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Request does not exceed 6 doses per month;
3. Member is not using icatibant in combination with another FDA-approved product for treatment of acute HAE attacks (e.g., Berinert®, Ruconest®, Kalbitor®).

Approval duration:

All Lines of Business (except Medicare): 12 months

References

1. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema—The 2021 revision and update. *Allergy*. 2022;77(7):1961-1990. Available at: https://pubmed.ncbi.nlm.nih.gov/35006617/. Accessed April 10, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	02/07/2020

Policy reviewed & updated.	04/28/2020	05/20/2020
Policy was reviewed. 1. Policy title table was updated. 2. Initial approval criteria I.A.1 was updated based on updated guidelines. 3. Approval duration for commercial plans was updated for initial and continued approval criteria. 4. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. References reviewed and updated.	01/25/2021	03/09/2021
Policy was reviewed. 1. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	11/25/2021	01/17/2022
Policy was reviewed. 1. Initial Approval Criteria I.A.5 and Continued Therapy Criteria II.A.3: Updated to add request does no exceed 6 doses per month. 2. Initial Approval Criteria and Continued Therapy Criteria: Approval Duration updated to add Up to 6 doses per month. 3. Initial Approval Criteria: Approval duration for Medicaid and Commercial plan updated from 12 months to 6 months 4. References reviewed and updated.	10/14/2022	01/17/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed. 1. Initial approval duration increased to 12 months. 2. Removed age requirement. 3. Removed daily dosing requirement. 4. Removed reathorization requirement for positive response to threapy. 5. References reviewed and updated.	4/15/2024	