Clinical Policy Title:	icatibant
Policy Number:	RxA.136
Drug(s) Applied:	Firazyr®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
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. Age ≥ 18 years;
4. Prescribed for treatment of acute HAE attacks;
5. Request does not exceed 6 doses per month;
6. Member is not using icatibant in combination with another FDA-approved product for treatment of acute HAE attacks (e.g., Berinert®, Ruconest®, Kalbitor®); and
7. Dose does not exceed 30 mg (1 syringe) per dose, with up to 3 doses administered within a 24-hour period.

Approval duration: Up to 6 doses per month
Commercial: 6 months
Medicaid: 6 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. Member is experiencing improvement in symptoms of acute HAE attacks;
3. Request does not exceed 6 doses per month;
4. Member is not using icatibant in combination with another FDA-approved product for treatment of acute HAE attacks (e.g., Berinert®, Ruconest®, Kalbitor®);
5. If request is for a dose increase, new dose does not exceed 30 mg (1 syringe) per dose, with up to 3 doses administered within a 24-hour period.

Approval duration: Up to 6 doses per month
Commercial: 12 months
Medicaid: 12 months

References

1. Cicardi M, Bork K, Caballero T, et al. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. Allergy. 2012; 67(2): 147-157. Available at: https://pubmed.ncbi.nlm.nih.gov/22126399/. Accessed October 14, 2022.
2. Cicardi M, Aberer W, Banerji A, et al. Classification, diagnosis, and approach to treatment for angioedema: consensus report from the Hereditary Angioedema International Working Group. Allergy. 2014; 69(5): 602-616. Available at: https://pubmed.ncbi.nlm.nih.gov/24673465/. Accessed October 14, 2022.
3. 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 October 14, 2022.
4. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. Allergy. 2018; 73(8):1575-1596. Available at: https://pubmed.ncbi.nlm.nih.gov/29318628/. Accessed October 14, 2022.

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.	10/14/2022	01/17/2023

3. Initial Approval Criteria: Approval duration for Medicaid and Commercial plan updated from 12 months to 6 months 4. References reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023