BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.85.070

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Hematological Agents	**Original Policy Date:**	July 4, 2025
Subject:	Andembry	**Page:**	1 of 4

Last Review Date: March 6, 2026

Andembry

Description

Andembry (garadacimab-gxii)

Background
Andembry (garadacimab-gxii) is an inhibitor of activated Factor XII (FXIIa) that binds to the catalytic domain of activated Factor XII (FXIIa and βFXIIa) and inhibits its catalytic activity. FXII is the first factor activated in the contact activation pathway and initiates the inflammatory bradykinin-producing kallikrein-kinin system. The inhibition of FXIIa decreases the activation of prekallikrein to kallikrein and the generation of bradykinin, which is associated with inflammation and swelling in hereditary angioedema (HAE) attacks, thus reducing the cascade of events leading to an HAE attack (1).

Regulatory Status
FDA-approved indication: Andembry is an activated Factor XII (FXIIa) inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients aged 12 years and older (1).

The safety and effectiveness of Andembry in pediatric patients less than 12 years of age have not been established (1).

Related policies
Berinert, Cinryze, Dawnzera, Ekterly, Haegarda, Icatibant, Kalbitor, Orladeyo, Ruconest, Takhzyro

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Andembry may be considered **medically necessary** if the conditions indicated below are met.

Andembry may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

1. Hereditary Angioedema (HAE) with **ONE** of the following:
    a. Patient has a C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing **AND ALL** of the following:
        i. C4 level below the lower limit of normal as defined by the laboratory performing the test
        ii. C1 inhibitor (C1-INH) antigenic level below the lower limit of normal as defined by the laboratory performing the test **OR** normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test)
    b. Patient has normal C1 inhibitor as confirmed by laboratory testing **AND ONE** of the following:
        i. F12, angiopoietin-1, plasminogen, or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing
        ii. Documented family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month

AND ALL of the following:

1. Routine prevention of hereditary angioedema attacks
2. **NO** dual therapy with other agents for the prevention of hereditary angioedema attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro)

Prior – Approval *Renewal* Requirements

Age 12 years of age and older

Diagnosis

Patient must have the following:

Hereditary Angioedema (HAE)

AND ALL of the following:

1. Routine prevention of hereditary angioedema attacks
2. Patient has experienced a significant reduction in frequency of hereditary angioedema attacks since starting treatment
3. **NO** dual therapy with other agents for the prevention of hereditary angioedema attacks (e.g., Cinryze, Haegarda, Orladeyo, Takhzyro)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Andembry (garadacimab-gxii) is an activated Factor XII inhibitor indicated for prophylaxis to prevent attacks of HAE. The safety and effectiveness of Andembry in pediatric patients less than 12 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Andembry while maintaining optimal therapeutic outcomes.

References

1. Andembry [package insert]. Kankakee, IL: CSL Behring LLC; June 2025.

Policy History

Date	Action
July 2025	Addition to PA
December 2025	Annual review. Per SME, removed initiation requirement to t/f a short term course of an androgen
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.