UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2383-1
Program	Prior Authorization/Medical Necessity
Medication	Andembry® (garadacimab-gxii)
P&T Approval Date	11/2025
Effective Date	1/1/2026

1. Background:

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.

2. Coverage Criteria [a]:

A. Initial Authorization

1. **Andembry** will be approved based on **all** of the following criteria:

   a. Diagnosis of hereditary angioedema (HAE) as confirmed by **one** of the following:

      (1) C1 inhibitor (C1-INH) deficiency or dysfunction (Type I or II HAE) as documented by **one** of the following (per laboratory standard):

         (a) C1-INH antigenic level below the lower limit of normal

         (b) C1-INH functional level below the lower limit of normal

-OR-

      (2) HAE with normal C1 inhibitor levels and **one** of the following:

         (a) Confirmed presence of variant(s) in the gene(s) for factor XII, angiopoietin-1, plasminogen-1, kininogen-1, myoferlin, and heparan sulfate-glucosamine 3-O-sulfotransferase 6

         (b) Recurring angioedema attacks that are refractory to high-dose antihistamines with confirmed family history of angioedema

         (c) Recurring angioedema attacks that are refractory to high-dose antihistamines with unknown background de-novo mutation(s) (i.e., no family history) (HAE-unknown)

-AND-

   b. Prescribed for the prophylaxis of HAE attacks

-AND-

c. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Dawnzera, Haegarda, Orladeyo, Takhzyro)

-AND-

d. Prescriber attests that patient has experienced attacks of a severity and/or frequency such that they would clinically benefit from prophylactic therapy with Andembry

-AND-

e. Prescribed by **one** of the following:

(1) Immunologist

(2) Allergist

Authorization will be issued for 12 months.

B. Reauthorization

1. **Andembry** will be approved based on **all** of the following criteria:

a. Documentation of positive clinical response to Andembry therapy

-AND-

b. Reduction in the utilization of on-demand therapies used for acute attacks (e.g., Berinert, Firazyr, Ruconest) as determined by claims information, while on Andembry therapy

-AND-

c. Prescribed for the prophylaxis of HAE attacks

-AND-

d. Not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Dawnzera, Haegarda, Orladeyo, Takhzyro)

-AND-

e. Prescribed by **one** of the following:

(1) Immunologist
(2) Allergist

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Andembry [package insert]. King of Prussia, PA: CSL Behring LLC.; June 2025.
2. Wu, E. Hereditary angioedema with normal C1 inhibitor. In: UpToDate, Saini, S (Ed), UpToDate, Waltham, MA, 2025.
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. doi:10.1111/all.15214

Program	Prior Authorization/Medical Necessity - Andembry® (garadacimab-gxii)
Change Control	
11/2025	New program.