CareSource Rx Innovations

PHARMACY POLICY STATEMENT
Marketplace

DRUG NAME	Andembry (garadacimab-gxii)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Andembry, approved by the FDA in 2025, 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.
HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Andembry (garadacimab-gxii) will be considered for coverage when the following criteria are met:

Hereditary Angioedema (HAE)

For **initial** authorization:
1. Member is at least 12 years of age; AND
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Chart notes must document the member's baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Andembry is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks.
7. **Dosage allowed/Quantity limit:** Initial loading dose of 400 mg (two 200 mg injections) administered subcutaneously followed by maintenance dosage of 200 mg once monthly.
   QL: 1 autoinjector or syringe per 28 days (maintenance)

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must be provided that show a reduced frequency or number of acute attacks since starting treatment.

If all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Andembry (garadacimab-gxii) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
06/19/2025	New policy for Andembry created.

References:

1. Andembry [prescribing information]. CSL Behring LLC; 2025.
2. Reshef A, Hsu C, Katelaris CH, et al. Long-term safety and efficacy of garadacimab for preventing hereditary angioedema attacks: Phase 3 open-label extension study. *Allergy*. 2025;80(2):545-556. doi:10.1111/all.16351
3. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046
4. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *World Allergy Organ J*. 2022;15(3):100627. Published 2022 Apr 7. doi:10.1016/j.waojou.2022.100627

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