MEDICAL MUTUAL®

Drug Policy

Policy:	**250701**	**Initial Effective Date:** **07/17/2025**
Code(s):	**HCPCS J3490, J3590 or J9999**	**Annual Review Date:** **07/17/2025**
SUBJECT:	Andembry® (garadacimab subcutaneous injection – CSL Behring)	**Last Revised Date:** **07/17/2025**

☐Subject to Site of Care

Prior approval is required for some or all procedure codes listed in this Corporate Drug Policy.

OVERVIEW

Andembry, an activated Factor XII (FXIIa) inhibitor (monoclonal antibody), is indicated for **prophylaxis to prevent attacks of hereditary angioedema (HAE)** in adult and pediatric patients ≥ 12 years of age.[1]

POLICY STATEMENT

This policy involves the use of Andembry. Prior authorization is recommended for pharmacy and medical benefit coverage of Andembry. Approval is recommended for those who meet the conditions of coverage in the **Criteria, Dosing, Initial/Extended Approval, Duration of Therapy**, and **Labs/Diagnostics** for the diagnosis provided. **Waste Management** applies for all covered conditions that are administered by a healthcare professional. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria and Waste Management section. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Andembry as well as the monitoring required for AEs and long-term efficacy, initial approval requires Andembry be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Andembry is recommended in those who meet the following criteria:

1. **Hereditary Angioedema (HAE) Due to C1 Inhibitor (C1-INH) Deficiency – Prophylaxis.** Approve Andembry for 1 year if the patient meets ONE of the following (A or B):

A) Initial therapy. Approve if the patient meets BOTH of the following (i, ii and iii):
- **i.** Patient is ≥ 12 years of age; AND
- **ii.** Patient has HAE type I or type II as confirmed by the following diagnostic criteria (a and b):
  Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement.
  - **a)** Patient has low levels of functional C1-INH protein (≤ 50% of normal) at baseline, as defined by the laboratory reference values*; AND
  - **b)** Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values*; AND
- **iii.** The medication is prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders; OR

B) Patient is currently receiving Andembry. Approve if the patient meets ALL of the following (i, ii, and iii):
Note: If the patient is currently receiving the requested therapy, but has not previously received approval of Andembry for this indication through the Coverage Review Department, review under criteria for Initial Therapy.
- **i.** Patient has a diagnosis of HAE type I or type II*; AND
  Note: A diagnosis of HAE with normal C1-INH (also known as HAE type III) does NOT satisfy this requirement.
- **ii.** According to the prescriber, the patient has had a favorable clinical response since initiating Andembry prophylactic therapy compared with baseline (i.e., prior to initiating prophylactic therapy); AND
  Note: Examples of a favorable clinical response include decrease in HAE acute attack frequency, decrease in HAE attack severity, or decrease in duration of HAE attacks.
- **iii.** The medication is prescribed by or in consultation with an allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.

Dosing in Andembry *(medical benefit only)*. *Dosing must meet the following:*
The recommended dosage of ANDEMBRY is an initial loading dose of 400 mg (two injections of 200 mg) administered subcutaneously on the first day of treatment followed by a maintenance dosage of 200 mg administered subcutaneously every month.

Missed Dose(s): If a dose of ANDEMBRY is missed, administer the dose as soon as possible.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Andembry has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant Use with Other Hereditary Angioedema (HAE) Prophylactic Therapies.** Andembry has not been studied in combination with other prophylactic therapies for HAE, and combination therapy for long-term prophylactic use is not recommended. Patients may use other medications, including Cinryze® (C1 esterase inhibitor [human] intravenous infusion), for on-demand treatment of acute HAE attacks, and for short-term (procedural) prophylaxis.
   Note: Examples of other HAE prophylactic therapies include Cinryze (C1 esterase inhibitor [human] intravenous infusion), Haegarda (C1 esterase inhibitor [human] subcutaneous injection), Orladeyo (berotralstat capsules), and Takhzyro (lanadelumab-flyo subcutaneous injection).

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Andembry® subcutaneous injection [prescribing information]. King of Prussia, PA: CSL Behring; June 2025.
2. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 guidelines for the management of hereditary angioedema. *J Allergy Clin Immunol Pract*. 2021;9(1):132-150.e3.
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.

FOR MEDICAL BENEFIT COVERAGE REQUESTS:

Prior approval is required for HCPCS Codes J3490 and J3590 or J9999

†When *unclassified drugs* (J3490) or *unclassified biologics* (J3590) or *unclassified antineoplastics* (J9999) is determined to be Andembry

Edits and Denials:

MEDICAL MUTUAL®

Drug Policy

Prior approval: Prior approval is required for Andembry **(HCPCS Codes J3490 , J3590, J9999)**. Requests for prior approval will be authorized by a nurse reviewer if submitted documentation meets criteria outlined within the Corporate Medical Policy.

Requests for prior approval will be forwarded to a qualified physician reviewer if submitted documentation does not meet criteria outlined within Corporate Medical Policy.

TOPPS: Claims received with **HCPCS Codes J3490, J3590, J9999** will pend with **Remark Code M3M or M4M** and will be adjudicated in accordance with the Corporate Medical Policy.

Liability: A participating provider will be required to write off charges denied as not medically necessary.

HCPCS Code(s):	
J3490	Unclassified drugs
J3590	Unclassified biologics
J9999	Unclassified antineoplastics