ALASKA MEDICAID
Prior Authorization Criteria

# Andembry
# (garadacimab-gxii)

## FDA INDICATIONS AND USAGE[1]

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.

## APPROVAL CRITERIA[1,2,3]

- Patient meets FDA labeled age **AND**;
- Prescribed by or in consultation with an allergist or immunologist **AND**;
- Patient has the diagnosis of hereditary angioedema due to C1-esterase inhibitor deficiency (HAE-C1-INH) [type 1 or type 2] **AND**;
- Andembry will be used for HAE prophylaxis **AND**;
- Andembry will not be used in combination with another agent indicated for HAE prophylaxis **AND;**
- Patient has a documented history of 3 or more moderate to severe HAE attacks per month **AND**;
- Medications with an established link to angioedema (e.g. angiotensin converting enzyme inhibitors, estrogen replacement therapy, etc,) have been evaluated and discontinued where appropriate. **AND;**
- Patient has tried and failed or has a documented clinical contraindication to at least one preferred agent approved for HAE prophylaxis from one of the following classes
    a. C1 Esterase Inhibitor
    b. Plasma kallikrein inhibitor

## DENIAL CRITERIA [1]

1. Failure to meet approval criteria **OR**;
2. Andembry prescribed to be used in combination with another agent indicated for HAE prophylaxis

## CAUTIONS[1]

- The safety of Andembry in pregnancy or breastfeeding has not been determined.
- The most common adverse reactions include nasopharyngitis and abdominal pain.

## DURATION OF APPROVAL

- Initial Approval: up to 3 months
- Reauthorization Approval: up to one year

## QUANTITY LIMIT

- Initial loading dose of 400mg (two 200mg autoinjectors/syringes) on day 1 of treatment, followed by 200mg (1 autoinjector/syringe) once monthly

**REFERENCES / FOOTNOTES:**

1. Andembry (garadacimab-gxii) [prescribing information]. King of Prussia, PA: CSL Behring; June 2025
2. 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.
3. Craig TJ, Reshef A, Li HH, et al. Efficacy and safety of garadacimab, a factor XIIa inhibitor for hereditary angioedema prevention (VANGUARD): a global, multicentre, randomised, double-blind, placebo-controlled phase 3 trial. Lancet. 2023;401(10382):1079-1090.