

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Garadacimab-gxii (Andembry)

Notes:

- Quantity limits - Yes
- ^ Adequate trial is defined as 3 months treatment duration
- * Intolerance excludes adverse drug reactions that are expected, mild in nature, resolve with continued treatment, and do not require medication discontinuation

Initiation (new start) criteria: Non-formulary **garadacimab-gxii (Andembry)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is an Allergist or Immunologist.
- Patient is at least 12 years of age.
- Patient has a diagnosis of hereditary angioedema (HAE) type I or type II confirmed by either:
 - A complement 4 (C4) level below the lower limit of normal AND a C1 inhibitor (C1-INH) protein level or function below the lower limit of normal
 - A mutation known to cause HAE in either the SERPING1 or F12 gene
- Patient has either:
 - History of two or more attacks in a 3 month period that significantly interrupts daily activities despite short-term treatment.
 - History of attacks involving the face, throat, or gastrointestinal tract that interrupt daily activity despite short-term treatment.
- Patient has failed an adequate trial[^] of lanadelumab or patient has an allergy or intolerance^{*} to lanadelumab.
- Garadacimab-gxii is not used in combination with other products indicated for prophylaxis against HAE attacks (lanadelumab-flyo [Takhzyro], donidalorsen [Dawnzera], C1 esterase inhibitor [Cinryze, Haegarda], berotralstat [Orladeyo], danazol).

Criteria for *new members entering Kaiser Permanente already taking the medication who have not been reviewed previously:* Non-formulary **garadacimab-gxii (Andembry)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Prescriber is an Allergist or Immunologist
- Patient is at least 12 years of age
- Diagnosis of hereditary angioedema (HAE) type I or type II
- Patient has failed an adequate trial[^] of lanadelumab or patient has an allergy or intolerance^{*} to lanadelumab

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- Garadacimab-gxii is not used in combination with other products indicated for prophylaxis against HAE attacks (lanadelumab-flyo [Takhzyro], donidalorsen [Dawnzera], C1 esterase inhibitor [Cinryze, Haegarda], berotralstat [Orladeyo], danazol).

Continued use criteria (12 months thereafter): Non-formulary **garadacimab-gxii (Andembry)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Garadacimab-gxii is continued to be prescribed by an Allergist or Immunologist.
- The patient has a documented improvement in HAE attack frequency, or HAE attack severity while on garadacimab-gxii therapy.
- Garadacimab-gxii continues not to be used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Takhzyro, Dawnzera, Cinryze, Haegarda, Orladeyo, danazol).