

Criteria-Based Consultation Prescribing Program CRITERIA FOR DRUG COVERAGE

Ianadelumab-flyo (Takhzyro)

Initiation (new start) criteria: Formulary **Ianadelumab-flyo (Takhzyro)** will be covered on the prescription drug benefit for 6 months when the following criteria are met:

- Prescriber is an Allergist or Immunologist.
- Patient is at least 2 years of age.
- 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 below the lower limit of normal
 - A mutation known to cause HAE in either the SERPING1 or F12 gene
- Patient has either:
 - History of one or more attack(s) every 4 weeks 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.
- Takhzyro is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, danazol).

Criteria for *new members entering Kaiser Permanente already taking the medication who have not been reviewed previously*: Formulary **Ianadelumab-flyo (Takhzyro)** 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 2 years of age
- Diagnosis of hereditary angioedema (HAE) type I or type II.
- Takhzyro is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, danazol).

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lanadelumab-flyo (Takhzyro)

Continued use criteria (6 months after initiation, and 12 months thereafter): Formulary **lanadelumab-flyo (Takhzyro)** will continue to be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Takhzyro 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 Takhzyro therapy.
- Takhzyro continues not to be used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, Orladeyo, danazol)
- If the patient is 6+ years of age, and the number of acute HAE attacks the patient experienced in the previous 6 months, while on Takhzyro therapy is:

Ages 12+ years of age:

1. Zero (0) acute HAE attacks: Recommend extended dosing interval of Takhzyro to 300 mg every 4 weeks for 12 months.
2. One or more acute HAE attacks: continuation of Takhzyro 300 mg every 2 weeks for 6 months.

Ages 6 to 11 years of age:

1. Zero (0) acute HAE attacks: Recommend extended dosing interval of Takhzyro to 150 mg every 4 weeks for 12 months.
2. One or more acute HAE attacks: continuation of Takhzyro 150 mg every 2 weeks for 6 months.