Criteria-Based Consultation Prescribing Program
CRITERIA FOR DRUG COVERAGE
lanadelumab-flyo (Takhzyro)

Initiation (new start) criteria: Formulary lanadelumab-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.

-AND-

- Patient is at least 12 years of age.

-AND-

- Diagnosis of hereditary angioedema (HAE) type I or type II confirmed by either:
  1. Mutation known to cause HAE in either the SERPING1 or F12 gene
  -OR-
  2. A C4 level below the lower limit of normal AND a C1 inhibitor (C1-INH) antigenic level or functional level below the lower limit of normal.

-AND-

- Patient has a contraindication, intolerance, therapeutic failure, or is unable to receive treatment with 17 alpha-alkylated androgens (e.g. danazol) for HAE prophylaxis.

-AND-

- Takhzyro is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, danazol).

-AND-

- Either of the following:
  1. Patient has a history of one or more severe attack(s) every 4 weeks (defined as an attack that significantly interrupts daily activities despite short-term treatment)
  -OR-
  2. A history of attacks with swelling of the face, throat, or gastrointestinal tract; that interrupt usual daily activity despite short term symptomatic treatment.
Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Ianelodelumab-flyo (Takhzyro)

Criteria for new Kaiser Permanente members already taking the medication who have not been reviewed previously: Formulary Ianelodelumab-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.
-AND-
- Patient is at least 12 years of age.
-AND-
- Diagnosis of hereditary angioedema (HAE) reported by the patient.
-AND-
- Patient has a contraindication, intolerance, therapeutic failure, or is unable to receive treatment with 17 alpha-alkylated androgens (e.g. danazol) for HAE prophylaxis.
-AND-
- Takhzyro is not used in combination with other products indicated for prophylaxis against HAE attacks (e.g., Cinryze, Haegarda, danazol).
-AND-
- Either of the following:
  1. Prior to treatment with Takhzyro, patient reported history of one or more severe attack(s) every 4 weeks (defined as an attack that significantly interrupts daily activities despite short-term treatment)
  -OR-
  2. Patient reported a history of attacks with swelling of the face, throat, or gastrointestinal tract; that interrupt usual daily activity despite short term symptomatic treatment.
Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

lanadelumab-flyo (Takhzyro)

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

- Takhzyro is continued to be prescribed by an Allergist or Immunologist.
- AND-
- A decrease in the number of HAE attacks while on Takhzyro therapy.
- AND-
- A decrease in the use of therapies used for treatment of HAE attacks (e.g., Berinert, Ruconest, icatibant, Kalbitor) or a decrease in urgent/emergent care visits for treatment of HAE attacks, while on Takhzyro therapy.
- AND-
- Takhzyro continues not to be used in combination with other products indicated for prevention of HAE attacks (e.g., Cinryze, Haegarda, danocrine)
- AND-
- If the number of HAE attacks the patient experienced in the previous 6 months while on Takhzyro therapy is:
  1. Zero (0) HAE attacks: Recommend extending the dosing interval of Takhzyro to 300 mg every 4 weeks for 12 months.
  2. One or more HAE attacks: continuation of Takhzyro 300 mg every 2 weeks for 6 months.