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 that interrupt usual daily activity despite short term symptomatic treatment.

Criteria for *current Kaiser Permanente members* already taking the medication who have not been reviewed previously: Formulary **lanadelumab-flyo (Takhzyro)** will be covered on the prescription drug benefit for 12 months when the following criteria are met:

- Refer to “Initiation (new start) criteria”

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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 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, danazol)

-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.