Effective date: 11/1/2019
Review date: 7/19, 7/20, 3/21, 2/22 Scope: Medicaid

SPECIALTY GUIDELINE MANAGEMENT

POLICY

TAKHZYRO (lanadelumab-flyo)

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
Prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years of age and older

All other indications are considered experimental/investigational and are not a covered benefit.

III. CRITERIA FOR INITIAL APPROVAL

Authorization for 6 months may be granted for prevention of hereditary angioedema attacks in members 12 years of age or older when the following criteria is met:

A. Medication is prescribed by, or in consultation with allergist/immunologist or a physician who specializes in the treatment of HAE or related disorders.
B. Patient has documented diagnosis of HAE type I or type II and meets one of the following (1 or 2):
    1. Member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets both of the following criteria:
        a. Member has a C4 level below the lower limit of normal as defined by the laboratory performing the test, and
        b. Member meets one of the following criteria:
            i. C1 inhibitor (C1-INH) antigenic level is below the lower limit of normal as defined by the laboratory performing the test; OR
            ii. Normal C1-INH antigenic level and a low C1-INH functional level (functional C1-INH less than 50% or C1-INH functional level below the lower limit of normal as defined by the laboratory performing the test); OR
    2. Member has normal C1 inhibitor as confirmed by laboratory testing and meets one of the following criteria:
        a) Member has an F12, angiopoietin-1, plasminogen or kininogen-1 (KNG1) gene mutation as confirmed by genetic testing, OR
        b) Member has a family history of angioedema and the angioedema was refractory to a trial of high-dose antihistamine (e.g., cetirizine) for at least one month.
C. Dose does not exceed FDA approved labeling.
D. Will not be used in combination with Cinryze, Orladeyo or Haegarda

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continuation of therapy when all of the following criteria are met:

A. Member meets all criteria for initial approval.

B. Member has had a favorable clinical response (i.e., decrease in HAE acute attack frequency, decrease in HAE attack severity, or decrease in duration of HAE attacks) since initiating Takhzyro prophylactic therapy compared with baseline (i.e., prior to initiating prophylactic therapy).
C. Documentation of the number of acute HAE attacks experienced in the previous 6 months while on Takhzyro therapy is provided and dosing regimen being requested is provided:
    1. If member experienced no (zero) acute HAE attacks in the previous 6 months the member is eligible for approval of Takhzyro 300mg given every 4 weeks for 6 months; OR
    2. If member experienced one or more acute HAE attacks in the previous 6 months the member is eligible for approval of Takhzyro 300mg given every 2 weeks for 6 months.

IV. REFERENCES

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; November 2021.
2. Maurer M, Magerl M, Ansotegui I, et al. The international WAO/EAACI guideline for the management of
hereditary angioedema – the 2017 revision and update. *Allergy*. 2018;00:1-22.