Effective date: 11/1/2019
Review date: 7/19, 7/20, 3/21, 2/22, 3/23, 3/24, 6/25, 11/25, 6/26
Scope: Medicaid

TAKHZYRO (lanadelumab-flyo)

POLICY

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 2 years of age and older

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

II. CRITERIA FOR INITIAL APPROVAL

Authorization for 6 months may be granted for prevention of hereditary angioedema attacks in members 2 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 management of HAE
B. Member has documented diagnosis of HAE type I or type II and meets one of the following (1 or 2):
    1. Documentation that the member has C1 inhibitor deficiency or dysfunction as confirmed by laboratory testing and meets one of the following criteria:
        a. C1 inhibitor (C1-INH) antigenic level is below the lower limit of normal as defined by the laboratory performing the test; OR
        b. 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. Documentation that the 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), heparan sulfate-glucosamine 3-O-sulfotransferase 6 (HS3ST6), or myoferlin (MYOF) pathogenic variant as confirmed by genetic testing, OR
        b. Member has a family history of angioedema and the member's angioedema was refractory to a trial of high-dose antihistamine therapy (e.g., cetirizine 40mg per day or the equivalent) for at least one month.
C. Will not be used in combination with Haegarda (C1 esterase inhibitor), Orladeyo(berotralstat), Andembry (garadacimab-gxii), Cinryze (C1 esterase inhibitor) or Dawnzera (donidalorsen),
D. Member requires long-term prophylactic treatment based on the provider's assessment of the patient's disease activity, quality of life, availability of health care resources, and/or failure to achieve adequate control by appropriate on-demand therapy [i.e., Ekterly (sebetralstat), Kalbitor(ecallantide), Icatibant, Ruconest (C1 esterase inhibitor) or Berinert (C1 esterase inhibitor), etc.]
E. Other causes of angioedema have been ruled out (e.g., angiotensin-converting enzyme inhibitor [ACE-I] induced an angioedema, angioedema related to an estrogen containing drug, allergic angioedema).

III. CONTINUATION OF THERAPY

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

A. Documentation that the member meets all criteria for initial approval.
B. Documentation that the member has documentation of experiencing a significant reduction in frequency of attacks (e.g., ≥ 50%) since starting prophylactic treatment.;
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. QUANTITY LIMIT

- Takhzyro 150mg/ml or 300mg/2mL: 2 syringes or vials every 28 days

V. REFERENCES

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; February 2025. Accessed May 2026.
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.