

PHARMACY POLICY STATEMENT Kentucky Medicaid

DRUG NAME	Takhzyro (lanadelumab-flyo)
BILLING CODE	J3590
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Haegarda QUANTITY LIMIT— 2 vials (300 mg/2 ml per vial) per 30 days
LIST OF DIAGNOSES CONSIDERED NOT MEDICALLY NECESSARY	Click Here

Takhzyro (lanadelumab-flyo) is a **non-preferred** product and will only be considered for coverage under the **medical** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEREDITARY ANGIOEDEMA (HAE)

For **initial** authorization:

1. Member must be 12 years of age or older, and medication is being used **for routine prophylaxis to prevent HAE attacks** (NOT for treatment of acquired angioedema); AND
2. Medication prescribed by or in consultation with a provider specializing in allergy, immunology, or hematology; AND
3. Member has documented trial and failure of or contraindication to Heagarda (Chart notes required); AND
4. Member must have a confirmed diagnosis of HAE as **one** of the following:
 - a) Type 1 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
 - i) Low levels (below the limits of the laboratory's normal reference range) of C4, C1-INH antigenic protein and C1-INH functional level; AND
 - ii) Positive family history of angioedema OR earlier age of onset (before age 30) with normal C1q antigenic protein level;
 - b) Type 2 HAE documented in chart notes with ALL of the following (Note: tests listed below must be repeated for confirmation of diagnosis):
 - i) Normal or elevated level of C1-INH antigenic protein (as defined by performing lab); AND
 - ii) Low level (below the limits of the laboratory's normal reference range) C4 and C1-INH functional; AND
5. Documentation in medical chart of at least **two** attacks per month before treatment initiation; AND
6. Medication is **not** being used in combination with Haegarda; AND
7. Medications known to cause angioedema (i.e., ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate.
8. **Dosage allowed:** 300 mg every 2 weeks. A dosing interval of 300 mg every 4 weeks is also effective and may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.

Note: Personal documentation (log book, journal, etc.) of medication use will be necessary for reauthorization. Prescribers should be aware and make their patients aware of this requirement for reauthorization.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Chart notes have been provided that show the member's signs and symptoms of disease have improved and the number of acute attacks per month has decreased; AND
3. Log of medication use supported by medical chart or by claims data has been provided.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 6 months.

CareSource considers Takhzyro (lanadelumab-flyo) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Acquired angioedema (AAE)
- Treatment of acute HAE attacks

DATE	ACTION/DESCRIPTION
08/06/2019	New policy Takhzyro created.

References:

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; November, 2018.
2. Bowen T, Cicardi M, Farkas H, et al. 2010 International consensus algorithm for the diagnosis, therapy, and management of hereditary angioedema. Allergy Asthma Clin Immunol. 2010;6(1):24.
3. ClinicalTrials.gov Identifier: NCT02586805. Efficacy and Safety Study of DX-2930 to Prevent Acute Angioedema Attacks in Patients With Type I and Type II HAE. Available at: <https://clinicaltrials.gov/ct2/show/NCT02586805?term=NCT02586805&rank=1>.
4. ClinicalTrials.gov Identifier: NCT02741596. Long-term Safety and Efficacy Study of DX-2930 (SHP643) to Prevent Acute Angioedema Attacks in Patients With Type I and Type II HAE. Available at: <https://www.clinicaltrials.gov/ct2/show/NCT02741596?term=NCT02741596&rank=1>.
5. Craig T, Pursun EA, Bork K, Bowen T, et al. World Allergy Organization Guideline for the Management of Hereditary Angioedema. WAO J. 2012; 5:182-199.
6. Lang DM, Aberer W, Bernstein JA, et al. International consensus on hereditary and acquired angioedema. Ann Allergy Asthma Immunol. 2012;109:395-402.
7. Lumry W. Management and Prevention of Hereditary Angioedema Attacks. Am J Manag Care. 2013;19:S111-S118.

Effective date: 09/26/2019

Revised date: 08/06/2019