CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Takhzyro (lanadelumab-flyo)
BILLING CODE	J0593
BENEFIT TYPE	Medical
SITE OF SERVICE ALLOWED	Home/Office
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product: Haegarda QUANTITY LIMIT— 2 vials (300 mg/2 ml per vial) per 28 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
2. Medication must be prescribed by or in consultation with an allergist or immunologist; AND
3. Member has a diagnosis of HAE type I or type II confirmed by both of the following:
   a) Low C4 level;
   b) Low (<50% of normal) C1 inhibitor antigenic and/or functional level; AND
4. Chart notes must document the member's baseline frequency of HAE attacks; AND
5. Member is inadequately controlled with on-demand treatment alone; AND
6. Takhzyro is being prescribed for ongoing prophylaxis and will not be used to treat acute attacks; AND
7. Member has a trial and failure of or contraindication to Haegarda.
8. **Dosage allowed:** 300 mg subQ 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.

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

For **reauthorization**:

1. Chart notes must be provided that show a reduced rate of HAE attacks since starting treatment.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 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.
01/13/2021	Updated criteria to align with the other HAE prophylactic drug revisions. Updated references. Greatly simplified the diagnostic confirmation criteria. Removed minimum required number of attacks, per guidelines; will just ask for baseline measure. Removed the statement about causative medications. Added that they must try on-demand treatment first. Rewrote the renewal criteria and removed log book requirement. Extended initial auth duration to 6 mo and renewal to 12 mo. Corrected the J code for billing.

References:

1. Takhzyro [package insert]. Lexington, MA: Dyax Corp.; November, 2018.
2. 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.
3. 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.
4. Lumry W. Management and Prevention of Hereditary Angioedema Attacks. Am J Manag Care. 2013;19:S111-S118.
5. Busse PJ, Christiansen SC, Riedl MA, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema [published online ahead of print, 2020 Sep 6]. *J Allergy Clin Immunol Pract*. 2020;S2213-2198(20)30878-3. doi:10.1016/j.jaip.2020.08.046.
6. 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;73(8):1575-1596. doi:10.1111/all.13384.
7. Banerji A, Riedl MA, Bernstein JA, et al. Effect of Lanadelumab Compared With Placebo on Prevention of Hereditary Angioedema Attacks: A Randomized Clinical Trial [published correction appears in JAMA. 2019 Apr 23;321(16):1636]. *JAMA*. 2018;320(20):2108-2121. doi:10.1001/jama.2018.16773.

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