CareSource Rxinnovations

PHARMACY POLICY STATEMENT
Georgia Medicaid

DRUG NAME	Takhzyro (lanadelumab-flyo)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Takhzyro, approved by the FDA in 2018, is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older.
HAE is a rare autosomal dominant disease characterized by episodic unpredictable swelling, which can occur in a variety of anatomic locations. The swelling results from excess production of the vasodilator bradykinin. Attacks may be painful and cause functional impairment but are not associated with pruritis. The most common types of HAE are caused by deficiency (type 1) or dysfunction (type 2) of C1 inhibitor (C1-INH). Type 1 is the most prevalent.

Takhzyro (lanadelumab-flyo) will be considered for coverage when the following criteria are met:

Hereditary Angioedema (HAE)

For **initial** authorization:
1. Member must be 2 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. Members 6 years of age and older must have a trial and failure of or contraindication to Haegarda.
8. **Dosage allowed/Quantity limit:**
   12 years of age and older: 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.
   6 to less than 12 years of age: 150 mg subQ every 2 weeks. A dosing interval of 150 mg every 4 weeks may be considered if the patient is well-controlled (e.g., attack free) for more than 6 months.
   2 to less than 6 years of age: 150 mg subQ every 4 weeks.
   QL: 2 vials or syringes per 28 days

If all the above requirements are met, 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 all the above requirements are met, the medication will be approved for an additional 12 months.

CareSource considers Takhzyro (lanadelumab-flyo) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
07/05/2022	Transferred to new template. Updated references. Switched to pharmacy benefit.
02/20/2023	Updated to at least 2 years of age and added dosing per label update; only have to complete Haegarda trial if >6 years of age.
06/11/2025	Annual review; no updates.

References:

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4. 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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7. Maurer M, Magerl M, Betschel S, et al. The international WAO/EAACI guideline for the management of hereditary angioedema - The 2021 revision and update. *World Allergy Organ J*. 2022;15(3):100627. Published 2022 Apr 7. doi:10.1016/j.waojou.2022.100627
8. Mendivil J, Malmenäs M, Haeussler K, Hunger M, Jain G, Devercelli G. Indirect Comparison of Lanadelumab and Intravenous C1-INH Using Data from the HELP and CHANGE Studies: Bayesian and Frequentist Analyses. *Drugs R D*. 2021;21(1):113-121. doi:10.1007/s40268-021-00337-4

Effective date: 06/01/2026
Revised date: 06/11/2025