Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Takhzyro® (lanadelumab-flyo)

Effective: January 1, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Public Plans Products

☒ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual-eligible product); Fax 617-673-0956
*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☒ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956
☒ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956
☒ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Four principles guide the approach to pharmacologic treatment of hereditary angioedema (HAE) and include: availability of effective on-demand acute therapy for all patients, early treatment to prevent attack progression, treatment of attacks irrespective of the site of swelling, and incorporation of long-term prophylaxis based on highly individualized decision-making reflecting a physician-patient partnership.

Approval of Takhzyro was based on results from a trial in which treatment with Haegarda resulted in a significantly reduced number of HAE attacks compared to placebo.

Food and Drug Administration - Approved Indications

Takhzyro (lanadelumab-flyo) 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.

Clinical Guideline Coverage Criteria

The plan may authorize Takhzyro when **ALL** the following criteria are met:

1. Documented diagnosis of hereditary angioedema

AND

2. Documentation the requested medication is being prescribed for routine prophylaxis of hereditary angioedema attacks

AND

3. The Member is at least 2 years of age or older

AND

4. Prescribed by or in consultation with an allergist, immunologist, or hematologist

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0593	Injection, lanadelumab-flyo, 1 mg (code may be used for Medicare when drug administered under direct supervision of a physician, not for use when drug is self-administered)

References

1. Takhzyro (lanadelumab-flyo) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals; February 2023.

2. Maur er M, et al. The international WAO/EAACI guideline for the management of hereditary angioedema – the 2017 revision and update. World Allergy Organization Journal. 2018:11(5):2-20.
3. Busse PJ, et al. US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. J Allergy Clin Immunol Pract 2021;9:132-50.

Approval And Revision History

September 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

September 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent endorsement date(s) and changes made:

- November 14, 2023: Removed the Limitations The Plan may authorize coverage of Takhzyro (lanadelumab-flyo) for up to 12 months if coverage criteria are met and Any indications other than FDA-approved indications are considered experimental or investigational and will not be approved by the health plan. Minor wording changes. Added age requirements and provider requirements (eff 2/1/24).
- November 2023: Administrative Updates: Rebranded from Tufts Health Unify to Tufts Health One Care for 2024 and administrative update in support of calendar year 2024 Medicare Advantage and PDP Final Rule.
- November 12, 2024: No changes (eff 1/1/25).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- July 2025: Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template.
- December 9, 2025: No changes (eff 1/1/26)
- December 2025: Joint Medical Policy and Health Care Services UM Committee review (effective 1/1/26)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guidelines not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.