Pharmacy Medical Necessity Guidelines: Takhzyro™ (lanadelumab-flyo)

Effective: July 1, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

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 patients 12 years and older.

Hereditary angioedema is a rare, episodic, autosomal dominant, swelling disorder that is characterized by C1 esterase inhibitor (C1-INH) deficiency. C1-INH coordinates the activation of the complement, contact, and fibrinolytic systems. A reduction in the activity of C1-INH may result in an elevated level of bradykinin, which is a key mediator in HAE symptoms. Patients with HAE may experience attacks of swelling and inflammation in the extremities, abdomen, face, urogenital tract, and/or the larynx that are random, recurrent, and potentially life-threatening. The age of onset is variable, ranging from early childhood to adult, with a worsening in frequency occurring around puberty. The age of onset can help to differentiate between HAE and acquired angioedema (AAE), which normally does not present until the fourth decade of life.

Treatment of HAE is divided into acute treatment, short-term/procedural prophylaxis to prevent an attack, and long-term/routine prophylaxis to minimize the frequency and severity of attacks. Long-term prophylaxis is recommended for patients who experience more than one attack per month, or for those who feel the condition is significantly impacting their lives. Short-term prophylaxis is recommended before dental procedures, minor surgery, endoscopy, or any situation where trauma may precipitate an attack; however, there are no FDA-approved agents currently available for procedural prophylaxis. A multifaceted approach that uses both pharmacologic and supportive therapies is required for optimal prevention and treatment of HAE.

COVERAGE GUIDELINES

The plan may authorize coverage of Takhzyro (lanadelumab-flyo) for Members when all of the following criteria are met:

Initial Criteria

1. Documented diagnosis of hereditary angioedema by an immunologist or allergist

AND

2. The Member is 12 years of age or older

AND

3. Documentation that "on-demand" therapy (e.g., icatibant, Kalbitor, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand" therapy is limited

AND

4. Documentation the Member has had an insufficient response or contraindication to BOTH of the following classes of medications:
    a. 17α–alkylated androgens (e.g., danazol, stanozolol, oxandrolone, methyltestosterone)
    b. Antifibrinolytic agents (e.g., aminocaproic acid, tranexamic acid)

Reauthorization Criteria

1. The prescribing physician is an immunologist or allergist

AND

2. The Member is 12 years of age or older

AND

3. Documentation of improvement in severity and duration of attacks has been achieved and sustained

LIMITATIONS

- Takhyzro (lanadelumab-flyo) will be authorized for 12 months.
- Members new to the plan stable on Takhyzro (lanadelumab-flyo) should be reviewed against Initial criteria.

CODES

None

REFERENCES

1. Banerji A, Riedl M, Bernstein J et al. Lanadelumab for prevention of attacks in hereditary angioedema: results from the phase 3 HELP study. *Ann Allergy Asthma Immunol*. 2017; 119(5): S5. Abstract OR034.
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. Cicardi M, Bork K, Caballero T, et al. Evidence-based recommendations for the therapeutic management of angioedema owing to hereditary C1 inhibitor deficiency: consensus report of an International Working Group. Allergy. 2012; 67:147-57.
4. Craig T, Riedl M, Dykewicz MS et al. When is prophylaxis for hereditary angioedema necessary? *Ann Allergy Asthma Immunol*. 2009; 102:366-72.
5. Epstein TG, Bernstein JA. Current and emerging management options for hereditary angioedema in the US. *Drugs*. 2008; 68(18):2561-73.
6. Frank, MM. Hereditary angioedema: the clinical syndrome and its management in the United States. *Immunol Allergy Clin North Am*. 2006; 26(4):653-68.
7. Frank, MM. Hereditary angioedema. *J Allergy Clin Immunol*. 2008; 121(2 Suppl):S398-401.
8. Lin G, Agboola F, Chapman R et al. Prophylaxis for hereditary angioedema with lanadelumab and C1 inhibitors: effectiveness and value. Draft evidence report. 2018 August 23. URL: https://icer-review.org/wp-content/uploads/2018/03/ICER_HAE_Draft_Evidence_Report_082318.pdf. Available from Internet. Accessed 2018 August 31.
9. Maurer M, Magerl M, Ansotegui I, 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):1-20.
10. National Institute of Health and Care Excellence (NICE). Lanadelumab-flyo for the long-term prevention of angioedema attacks in hereditary angioedema types I and II. May 2018. URL: https://www.nice.org.uk/guidance/proposed/gid-ta10333. Available from Internet. Accessed 2018 August 30.
11. Takhzyro (lanadelumab-flyo) [prescribing information]. Lexington, MA: Dyax Corp.; 2018 November.
12. Weis M. Clinical review of hereditary angioedema: diagnosis and management*. Postgrad Med J* 2009; 121(6):113-20.
13. Zuraw BL, Banerji A, Bernstein JA et al. US Hereditary Angioedema Association Medical Advisory Board 2013 recommendations for the management of hereditary angioedema due to C1 inhibitor deficiency. *J Allergy Clin Immunol Pract.* 2013a; 1(5):458-67.
14. Zuraw B, Bernstein J, Lang D et al. A focused parameter update: hereditary angioedema, acquired C1 inhibitor deficiency, and angiotensin-converting enzyme inhibitor-associated angioedema. *J Allergy Clin Immunol*. 2013b; 131(6): 1491-3.

APPROVAL HISTORY

March 12, 2019: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 11, 2020: Effective April 1, 2020, updated approval duration to 12 months and added Reauthorization criteria. Updated initial therapy criteria to remove documentation of a specific frequency and type of history of attacks. Documentation that "on-demand" therapy (e.g., icatibant, Kalbitor, Ruconest, or Berinert) did not provide satisfactory control or access to "on-demand" therapy is limited is required.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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