Medical Policy

Takhzyro® (lanadelumab-flyo)	
MEDICAL POLICY NUMBER	Med_Clin_Ops-060
CURRENT VERSION EFFECTIVE DATE	January 1, 2024
APPLICABLE PRODUCT AND MARKET	*Individual Family Plan:* All Plans *Small Group*: All Plans *Medicare Advantage:* All Plans

Brand New Day/Central Health Medicare Plan develops policies and makes coverage determinations using credible scientific evidence including but not limited to MCG™ Health Guidelines, the ASAM Criteria™, and other third party sources, such as peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations, and expert opinion as relevant to supplement those sources. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice. Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/Central Health Medicare Plan Medical Policy may contact the Health Plan. Brand New Day/Central Health Medicare Plan policies and practices are compliant with federal and state requirements, including mental health parity laws.

If there is a difference between this policy and the member specific plan document, the member benefit plan document will govern. For Medicare Advantage members, Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), govern. Refer to the CMS website at http://www.cms.gov for additional information.

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PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of Takhzyro® (lanadelumab-flyo) therapy.

POLICY/CRITERIA

Prior Authorization and Medical Review is required.

Initial coverage for Takhzyro will be provided for 6 months and may be renewed.

Initial Therapy

1. Patient must be at least 12 years of age or older; **AND**
2. Takhzyro is prescribed by, or in consultation with a specialist in: allergy, immunology, hematology, pulmonology, or medical genetics; **AND**

3. Patient has a diagnosis of Hereditary Angioedema (HAE) type I or type II as confirmed by the following:
    a. Patient has low levels of functional C1-INH protein (< 50% of normal) at baseline, as defined by the laboratory reference values; **AND**
    b. Patient has lower than normal serum C4 levels at baseline, as defined by the laboratory reference values; **AND**
4. Patient has a history of one of the following criteria for long-term HAE prophylaxis:
    a. History of two (2) or more severe HAE attacks (i.e. airway swelling, debilitating cutaneous or gastrointestinal episodes) per month; **OR**
    b. Patient is disabled more than 5 days per month by HAE; OR
    c. History of at least one laryngeal attack caused by HAE; **AND**
5. Patient has a documented contraindication, severe intolerance, or therapeutic failure to 17 alpha-alkylated androgens (e.g., danazol) for HAE prophylaxis; **AND**
6. Patient has tried and failed treatment with acute therapy (i.e., Kalbitor, Firazyr, Ruconest, or Berinert) and it did not result in meaningful outcomes, such as decreased severity of attacks, avoidance of hospitalization, etc; **AND**
7. Medications known to cause angioedema (i.e. ACE-Inhibitors, estrogens, angiotensin II receptor blockers) have been evaluated and discontinued when appropriate, regardless of HAE type.

Continuation Therapy

1. Significant improvement in severity, duration, and/or frequency of attacks have been achieved and sustained.
2. Documentation including frequency of administration will also be required at time of recertification to monitor for appropriate use.
3. If 0 attacks have occurred during the prior 6 months while on the medication, a trial with an extended dosing interval of 300mg every four weeks will be required based on package labeling which states that a dose of 300 mg every four weeks is also effective.
4. If documentation is provided that the patient is not attack free (has experienced at least 1 attack), but has had a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline, a dosing frequency of 300mg every 2 weeks can be continued.
5. If documentation is provided that the patient has not experienced a decrease in severity, duration, and/or frequency of attacks while on the medication compared to baseline (no benefit from the medication), further treatment will not be authorized.

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic
2. Acute treatment of HAE.

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BACKGROUND

Takhzyro (lanadelumab-flyo) is non-plasma derived, recombinant, fully human, monoclonal antibody indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in patients 12 years and older.

DEFINITIONS

1. TAKHZYRO™ (lanadelumab-flyo) injection, for subcutaneous use. Initial U.S. Approval: 2018.
    a. TAKHZYRO (lanadelumab-flyo) injection is a ready-to-use, clear to slightly opalescent, colorless to slightly yellow solution supplied in a carton containing one single-dose glass vial

CODING

Applicable NDC Codes	
47783-0644-01	Takhzyro solution single-dose vial 150 MG/1 ML

Applicable Procedure Code	
J0593	Injection, lanadelumab-flyo, (Takhzyro), 1 mg.

Applicable ICD-10 Codes	
D84.1	Defects in the complement system

EVIDENCE BASED REFERENCES

1. Bowen T, Cicardi M, Farkas H, et al. 2010 international consensus algorithm for the diagnosis, therapy and management of hereditary angioedema. Ann Allergy Asthma Immunol. 2010;6:24.
2. Craig T, Pursun EA, Bork K, et al. WAO guideline for the management of hereditary angioedema. WAO Journal. 2012;5:182-199.
3. 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: In Practice. 2013;1:458-467. Available at: https://haei.org/wp-content/uploads/2015/04/Zuraw-B-L-US-HAEA-MAB-2013-Recommendations.pdf.
4. Wagenaar-Bos IGA, Drouet C, Aygoren-Pursun E, et al. Functional C1-inhibitor diagnostics in hereditary angioedema: assay evaluation and recommendations. J Immunol. Methods. 2008;338:14-20.
5. Zuraw BL, Bork K, Binkley KE, et al. Hereditary angioedema with normal C1 inhibitor function: consensus of an international expert panel. Allergy Asthma Proc. 2012;33:S145-S156.
6. Magerl M, Germenis AE, Maas C, et al. Hereditary angioedema with normal C1 inhibitor. Update on evaluation and treatment. Immunol Allergy Clin N Am. 2017;37:571-584.
7. Takhzyro (lanadelumab-flyo) [prescribing information]. Lexington, MA: Dyax Corp; January 2018.

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POLICY HISTORY

Original Effective Date	May 24, 2021
Revised Date	November 1, 2021: Annual review – no changes made. November 8, 2022: Annual review – no changes made. March 1, 2023: Adopted by MA UM Committee – no changes made. January 1, 2024 - Updated to Brand New Day/Central Health Medicare Plan (no policy revisions made)

Approved by Pharmacy and Therapeutics Committee on 11/8/2022