Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: **Veozah (fezolinetant) and Lynkuet (elinzanetant)**

Effective: May 1, 2026

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

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

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

Food and Drug Administration – Approved Indications

Lynkuet (elinzanetant) is a dual neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause.

Veozah (fezolinetant) is a neurokinin 3 receptor (NK3R) antagonist approved for the treatment of moderate to severe vasomotor symptoms due to menopause. Veozah is dosed once daily.

Veozah has been associated with elevations in ALT and AST levels greater than three times the upper limit of normal. Veozah is contraindicated in patients with cirrhosis. Baseline bloodwork should be conducted to evaluate ALT, AST, and serum bilirubin before initiating treatment with Veozah. Follow-up blood work should be conducted monthly for the first 3 months, at 6 months, and 9 months after starting therapy and then when symptoms like nausea, vomiting, and jaundice suggest liver injury.

Per the 2023 North American Menopause Society (NAMS) nonhormone therapy position statement, hormone therapy is the most effective treatment for vasomotor symptoms. For women who are not good candidates for hormone therapy (e.g., contraindications), use of nonhormone treatment such as selective serotonin reuptake inhibitors (SSRIs), selective serotonin-norepinephrine reuptake inhibitors (SNRIs), gabapentin, and fezolinetant can be considered.

Clinical Guideline Coverage Criteria

Initial authorization:

The plan may authorize coverage of **Lynkuet (elinzanetant)** for Members when **ALL** of the following criteria are met and limitations do not apply:

1. Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2. Trial and failure, contraindication, or intolerance to a drug from both of the following classes:
   A. Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.)
   B. Non-hormonal therapy (e.g. paroxetine mesylate, venlafaxine, clonidine, gabapentin, etc.)

Subsequent Reauthorizations:

1. Documentation the Member has been reassessed for this condition within the previous year, has demonstrated a positive response to therapy, and treatment with Lynkuet (elinzanetant) continues to be medically necessary

Initial authorization:

The plan may authorize coverage of **Veozah (fezolinetant)** for Members when **ALL** of the following criteria are met and limitations do not apply:

1. Diagnosis of moderate to severe vasomotor symptoms due to menopause

AND

2. Trial and failure, contraindication, or intolerance to a drug from both of the following classes:
    A. Menopausal hormone therapy (e.g., Premarin, Bijuva, Estrogel, etc.)
    B. Non-hormonal therapy (e.g. paroxetine mesylate, venlafaxine, clonidine, gabapentin, etc.)

Reauthorizations:

First Reauthorization:

1. Documentation the Member had follow-up laboratories to assess hepatic function

AND

2. Documentation Member has been reassessed for this condition within the previous six months, has demonstrated a positive response to therapy, and treatment with Veozah continues to be medically necessary

Subsequent Reauthorizations:

1. Documentation the Member has been reassessed for this condition within the previous year, has demonstrated a positive response to therapy, and treatment with Veozah continues to be medically necessary

Limitations

1. Veozah is limited to 30 capsules per 30 days and Lynkuet (elinzanetant) is limited to 60 tablets per 30 days.
2. Initial request will be approved 6 months. Reauthorization requests will be approved for 12 months.
3. Samples, free goods, or similar offerings of the requested medication do not qualify for an established clinical response or exception but will be considered on an individual basis for prior authorization.

Codes

None

References

1. "The 2023 Nonhormone Therapy Position Statement of the North American Menopause Society" Advisory Panel. The 2023 nonhormone therapy position statement of the North American Menopause Society. *Menopause*. 2023;30:573-590.
2. Lynkuet® (elinzanetant) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025.
3. Makary M, et al. Updated labeling for menopausal hormone therapy. JAMA. doi:10.1001/jama.2025.22259
4. Nappi RE, et al. Global cross-sectional survey of women with vasomotor symptoms associated with menopause: prevalence and quality of life burden [published correction appears in Menopause. 2022 Jun 01;29(6):759]. Menopause. 2021;28(8):875–882. doi:10.1097/GME.0000000000001793
5. Panay N, et al. Elinzanetant for the treatment of vasomotor symptoms associated with menopause: a phase 3 randomized clinical trial. JAMA Intern Med. 2025;185(11):13191327. doi:10.1001/jamainternmed.2025.4421
6. Pinkerton JV, et al. Elinzanetant for the treatment of vasomotor symptoms associated with menopause: OASIS 1 and 2 randomized clinical trials. JAMA. 2024;332(16):1343–1354. doi:10.1001/jama.2024.14618
7. The American College of Obstetricians & Gynecologists. ACOG president says label change on estrogen will increase access to hormone therapy. Accessed November 25, 2025. https://www.acog.org/news/news-releases/2025/11/acog-president-says-label-change-on-estrogen-will-increase-access-to-hormone-therapy
8. The Menopause Society. The Menopause Society comments on the FDA announcement on hormone therapy. Accessed November 25, 2025. https://menopause.org/press-releases/the-menopause-society-comments-on-the-fda-announcement-on-hormone-therapy
9. U.S. Department of Health and Human Services. Fact Sheet: FDA initiates removal of "Black Box" warnings from menopausal hormone replacement therapy products. Accessed November 25, 2025. https://www.hhs.gov/press-room/fact-sheet-fda-initiates-removal-
10. Veozah (fezolinetant) [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; December 2024.

Approval And Revision History

October 10, 2023: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- October 8, 2024: No Changes.
- October 14, 2025: No changes.
- April 14, 2026: Effective May 1, 2026, added Lynkuet (elinzanetant) to the MNG. Removed CareLink as a covered line of business.

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.