MEDICAL MUTUAL®

Drug Policy

Policy:	Lynkuet (elinzanetant)	Annual Review Date: 06/18/2026 Last Revised Date: 06/18/2026

OVERVIEW

Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. Lynkuet is a neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist. Inhibition of Substance P and Neurokinin B through antagonism of NK1 and NK3 receptor signaling on kisspeptin/neurokinin B/dynorphin (KNDy) neurons can modulate neuronal activity in thermoregulation associated with hot flashes.

POLICY STATEMENT

This policy involves the use of Lynkuet. Prior authorization is recommended for pharmacy benefit coverage of Lynkuet. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Lynkuet as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Lynkuet be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lynkuet is recommended in those who meet the following criteria:

1. **Vasomotor Symptoms due to Menopause; Initial Therapy**
   Criteria. *Patient must meet all the following criteria*
   - **A.** Symptoms of disease are moderate to severe; AND
   - B. The patient meets one of the following (a or b):
     - **a.** The patient meets one of the following (i or ii):
       - **i.** The patient has tried a 30-day trial of at least one menopausal hormone therapy*; OR
       - **ii.** The provider and patient have determined that menopausal hormone therapy is contraindicated or does not have a favorable risk/benefit profile*; OR
         Note: Examples of menopausal hormone therapy include estradiol, Premarin, Prempro, etc.
     - **b.** The patient meets one of the following (i or ii):

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2026 Medical Mutual of Ohio

i. The patient has tried a 30 day trial of at least two guideline recommended non-hormonal therapies from two different classes*; OR
ii. The provider and patient have determined that other non-hormonal therapies for the treatment of vasomotor symptoms due to menopause are contraindicated or do not have a favorable risk/benefit profile*; AND
Note: Examples of non-hormonal therapy for vasomotor symptoms due to menopause include clonidine, gabapentin, selective serotonin inhibitors (e.g., paroxetine), serotonin and norepinephrine inhibitors (e.g., desvenlafaxine, venlafaxine), and oxybutynin.

2. **Vasomotor Symptoms due to Menopause; Continuing Therapy**
Criteria. *Patient must meet all the following criteria*

A. The patient continues to meet initial therapy criteria A and B; AND
B. The patient has experienced at least 50% reduction in frequency or severity of vasomotor symptoms associated with menopause*; AND
C. Liver function tests (LFTs) have been done or are planned every 3 months for the first year of therapy and transaminases have not exceeded 2 times the upper limit of normal*.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 3 months
B) *Extended Approval:* 6 months

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lynkuet has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Patients greater than 65 years of age.** There have not been sufficient numbers of geriatric women involved in clinical trials utilizing Lynkuet to determine whether those over 65 years of age differ from younger women in their response to Lynkuet.

2. **Concurrent use with hormone therapy.** Lynkuet has not been evaluated for use in combination with hormonal therapy.
Note: Concurrent use with low-dose vaginal hormone therapy is allowed due to limited systemic absorption.

3. **Patients who are currently pregnant.** Lynkuet is contraindicated in patients who are pregnant; discontinue as soon as possible if pregnancy occurs during treatment.

4. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2026 Medical Mutual of Ohio

***Documentation Requirements:**
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Lynkuet (elinzanetant) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; October 2025.

This document is subject to the disclaimer found at https://www.medmutual.com/For-Providers/Policies-and-Standards/CorporateMedicalDisclaimer.aspx and is subject to change. https://www.medmutual.com/For-Providers/Policies-and-Standards/Prescription-Drug-Resources.aspx

© 2026 Medical Mutual of Ohio