

## Clinical Policy: Elinzanetant (Lynkuet)

Reference Number: PA.CP.PMN.304

Effective Date: 02/2026

Last Review Date: 01/2026

### Description

Elinzanetant (Lynkuet<sup>®</sup>) is a neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist.

### FDA Approved Indication(s)

Lynkuet is indicated for the treatment of moderate to severe vasomotor symptoms due to menopause.

### Policy/Criteria

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness<sup>®</sup> that Lynkuet is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. Vasomotor Symptoms (must meet all):

1. Diagnosis of vasomotor symptoms associated with menopause;
2. Age  $\geq$  18 years;
3. Failure of two formulary estrogen products (*not contraceptives, see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 120 mg (2 capsules) per day.

**Approval duration: 12 months**

##### B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

#### II. Continued Therapy

##### A. Vasomotor Symptoms (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy (e.g., vasomotor symptom reduction);
3. If request is for a dose increase, new dose does not exceed 120 mg (2 capsules) per day.

**Approval duration: 12 months**

##### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

- Approval duration: Duration of request or 12 months (whichever is less); or**
- Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

**III. Diagnoses/Indications for which coverage is NOT authorized:**

- Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration

NK1: neurokinin 1

NK3: neurokinin 3

*Appendix B: Therapeutic Alternatives*

*This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
<b>Estrogen Products</b>		
estradiol (Climara <sup>®</sup> , Divigel <sup>®</sup> , Elestrin <sup>®</sup> , Estrace <sup>®</sup> , EstroGel <sup>®</sup> , Evamist <sup>®</sup> , Menostar <sup>®</sup> , Minivelle <sup>®</sup> , Vivelle Dot <sup>®</sup> , Delestrogen <sup>®</sup> )	Varies by formulation	Varies
Menest <sup>®</sup> (esterified estrogens)	0.3 to 1.25 mg PO QD	1.25 mg/day
Premarin <sup>®</sup> (conjugated estrogens)	0.3 mg PO QD; may titrate if needed	1.25 mg/day
Premphase <sup>®</sup> , Prempro <sup>®</sup> (conjugated estrogens/ medroxyprogesterone)	1 tablet PO QD	1 tablet/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) when the drug is available by both brand and generic.*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): pregnancy
- Boxed warning(s): none reported

**V. Dosage and Administration**

Indication	Dosing Regimen	Maximum Dose
Vasomotor symptoms	120 mg PO QD	120 mg/day

**VI. Product Availability**

Capsule: 60 mg

**VII. References**

1. Lynkuet Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2025. Available at <https://www.lynkuet-us.com/>. Accessed November 3, 2025.
2. Stuenkel CA, Davis SR, Gompel A, et al. Treatment of the symptoms of the menopause: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab.* 2015; 100(11): 39754011.
3. Pinkerton JV, Simon JA, Joffe H, et al. Elinzanetant for the treatment of vasomotor symptoms associated with menopause: OASIS 1 and 2 randomized clinical trials. *JAMA* 2024. Aug 22;332(16):1343–1354. doi:10.1001/jama.2024.14618
4. Menegaz de Almeida A, Oliveira P, Lopes L, et al. Fezolinetant and elinzanetant therapy for menopausal women experiencing vasomotor symptoms: A systematic review and meta-analysis. *Obstet Gynecol.* 2025;145(3):253-261. doi:10.1097/AOG.0000000000005812
5. *Clinical Pharmacology* [database online]. Tampa, FL: Elsevier; 2025. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed November 21, 2025.

Reviews, Revisions, and Approvals	Date
Policy created	01/2026