Clinical Policy: Fezolinetant (Veozah)

Reference Number: PA.CP.PMN.289
Effective Date: 08/2023
Last Review Date: 07/2025

Description
Fezolinetant (Veozah®) is a neurokinin 3 (NK3) receptor antagonist.

FDA Approved Indication(s)
Veozah 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® that Veozah 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 ≥ 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 45 mg (1 tablet) 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 as evidenced (e.g., vasomotor symptom reduction);
3. If request is for a dose increase, new dose does not exceed 45 mg (1 tablet) 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

2. Refer to the off-label use policy for the relevant line of business 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:

A. 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 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
Estrogen Products		
estradiol (Climara®, Divigel®, Elestrin®, Estrace®, EstroGel®, Evamist®, Menostar®, Minivelle®, Vivelle Dot®, Delestrogen®)	Varies by formulation	Varies
Menest® (esterified estrogens)	0.3 to 1.25 mg PO QD	1.25 mg/day
Premarin® (conjugated estrogens)	0.3 mg PO QD; may titrate if needed	1.25 mg/day
Premphase®, Prempro® (conjugated estrogens/ medroxyprogesterone)	1 tablet PO QD	1 tablet/day

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

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known cirrhosis; severe renal impairment or end-stage renal disease; concomitant use with CYP1A2 inhibitors
- Boxed warning(s): risk of hepatotoxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Vasomotor symptoms	1 tablet PO daily	1 tablet/day

VI. Product Availability

Tablet: 45 mg

VII. References

1. Veozah Prescribing Information. Northbrook, IL: Astellas Pharma US, Inc; December 2024. Available at: https://www.veozah.com. Accessed May 1, 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. Schaudig K, Wang X, Bouchard C, et al. Efficacy and safety of fezolinetant for moderate-severe vasomotor symptoms associated with menopause in individuals unsuitable for hormone therapy: phase 3b randomised controlled trial. *BMJ*. 2024 Nov 18;387:e079525. doi: 10.1136/bmj-2024-079525. Lederman S, Ottery FD, Cano A, et al. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT 1): a phase 3 randomised controlled study. *Lancet*. 2023 Apr 1;401(10382):1091-1102. doi: 10.1016/S0140-6736(23)00085-5.
4. Johnson KA, Martin N, Nappi RE, et al. Efficacy and safety of fezolinetant in moderate to severe vasomotor symptoms associated with menopause: A phase 3 RCT. *J Clin Endocrinol* Metab. 2023 Jul 14;108(8):1981-1997. doi: 10.1210/clinem/dgad058.
5. Clinical Pharmacology [database online]. Tampa, FL: Elsevier; 2025. Available at: https://www.clinicalkey.com/pharmacology/. Accessed May 1, 2025.

Reviews, Revisions, and Approvals	Date
Policy created	07/2023
3Q 2024 annual review: no significant changes; in Appendix B, removed commercially unavailable brand alternatives; references reviewed and updated.	07/2024
3Q 2025 annual review: For initial approval criteria, clarified number of failed agents from hormonal therapy products to two formulary estrogen products; updated black box warning for risks of hepatotoxicity per PI; for Appendix B, removed estropiate due to product unavailability; references reviewed and updated.	07/2025