

## **Clinical Policy: Fezolinetant (Veozah)**

Reference Number: CP.PMN.289

Effective Date: 09.01.23

Last Review Date: 08.24

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

### **Description**

Fezolinetant (Veozah<sup>®</sup>) 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 health plans affiliated with Centene Corporation<sup>®</sup> 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  $\geq$  18 years;
3. Failure of hormonal therapy products (*not contraceptives, see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 45 mg per day (1 tablet per day).

**Approval duration: 12 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## **II. Continued Therapy**

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

1. Member meets one of the following (a or b):
  - a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
  - b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B*);
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 per day (1 tablet per day).

**Approval duration: 12 months**

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

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
  - a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
  - b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

## **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 – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents.

## **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 for all relevant lines of business and may require prior authorization.*

<b>Drug Name</b>	<b>Dosing Regimen</b>	<b>Dose Limit/ Maximum Dose</b>
<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
estropipate	0.75 mg PO QD; may titrate if needed (range: 0.75 to 6 mg/day)	6 mg/day
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): known cirrhosis; severe renal impairment or end-stage renal disease; concomitant use with CYP1A2 inhibitors
- Boxed warning(s): none reported

**V. Dosage and Administration**

<b>Indication</b>	<b>Dosing Regimen</b>	<b>Maximum Dose</b>
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; May 2023. Available at: <https://www.veozah.com>. Accessed May 29, 2024.

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. ClinicalTrials.gov. A study of fezolinetant to treat hot flashes in women going through menopause (Daylight). Available at: <https://clinicaltrials.gov/ct2/show/NCT05033886>. Accessed May 26, 2023.
4. 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.
5. 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.
6. Clinical Pharmacology [database online]. Elsevier; 2024. Available at: <https://www.clinicalkey.com/pharmacology/>. Accessed May 29, 2024.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	06.01.23	08.23
3Q 2024 annual review: no significant changes; in Appendix B, removed commercially unavailable brand alternatives; references reviewed and updated.	05.29.24	08.24

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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