| Pharmacy Policy Bulletin: J-1293 Veozah (fezolinetant) – Commercial and Healthcare Reform | |
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| **Number:** J-1293 | **Category:** Prior Authorization |
| **Line(s) of Business:**<br>☒ Commercial<br>☒ Healthcare Reform<br>☐ Medicare | **Benefit(s):**<br>**Commercial:**<br>**Prior Authorization (1.):**<br>**1.** Other Managed Prior Authorization = Yes w/ Prior Authorization<br><br>**Healthcare Reform:** Not Applicable |
| **Region(s):**<br>☒ All<br>☐ Delaware<br>☐ New York<br>☐ Pennsylvania<br>☐ West Virginia | **Additional Restriction(s):**<br>None |
| **Version:** J-1293-002 | **Original Date:** 06/07/2023 |
| **Effective Date: 06/24/2024** | **Review Date:** 06/05/2024 |

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| **Drugs Product(s):** | • Veozah (fezolinetant) |
| **FDA-Approved Indication(s):** | • Treatment of moderate to severe vasomotor symptoms due to menopause |

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| **Background:** | • Veozah is a self-administered, oral neurokinin 3 (NK3) receptor antagonist.<br>• Veozah blocks neurokinin B binding to the kisspeptin/neurokinin B/dynorphin neuron to control activity in the thermoregulatory center.<br>• Examples of vasomotor symptoms (VMS) due to menopause include hot flashes and night sweats. Mild symptoms involve a sensation of heat without sweating; moderate symptoms involve a sensation of heat with sweating and the patient is able to continue an activity; while severe symptoms are a sensation of heat with sweating and the inability to continue an activity.<br>• The 2015 Endocrine Society Guideline recommends menopausal hormone therapy first-line for most symptomatic postmenopausal women under 60 years of age or under 10 years since the onset of menopause for treatment of VMS. Women should be screened for cardiovascular and breast cancer risks before treatment and recommended an appropriate therapy based on individual risks and benefits. Women who do not have contraindications to hormone therapy or excessive cardiovascular or breast cancer risks and are willing to take hormone therapy should receive estrogen monotherapy if they do not have a uterus, or an estrogen with a progestin if they have a uterus.<br>• The 2022 North American Menopause Society Position Statement states that hormone therapy is the most effective treatment for VMS while also preventing bone loss and fracture. The benefits of hormone therapy appear to outweigh the risks in women younger than 60 years or are within 10 years of the onset of menopause and have no contraindications. The benefit-risk ratio is less favorable in women who are older than 60 years or more than 10 years from the onset of menopause. Transdermal and vaginal routes of administration may |

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| | decrease risk of stroke and VTE, but there is currently insufficient comparative randomized clinical trial data.<br>• Oral hormone therapy products available as generics include Estrace (estradiol), Activella (estradiol-norethindrone acetate), estradiol-norethindrone acetate, and norethindrone acetate-ethinyl estradiol.<br>• The efficacy of Veozah for the treatment of moderate to severe VMS in postmenopausal women was evaluated in two phase 3, randomized, placebo-controlled, double-blind, clinical trials in 1,022 women for a duration of 12 weeks. Patients were postmenopausal women with one or more of the following: prior hysterectomy, prior oophorectomy, or prior hormone therapy. Patients who were on prior hormone therapy underwent a washout period before starting on Veozah.<br>• Prescribing Considerations:<br>○ Veozah is contraindicated with hepatic cirrhosis and requires monitoring hepatic function at baseline and at 3 months, 6 months, and 9 months after initiation of therapy or when symptoms suggest liver injury.<br>○ Veozah is contraindicated in patients with severe renal impairment (eGFR 15 to less than 30 mL/min/1.73 $m^2$) or end-stage renal disease (eGFR less than 15 mL/min/1.73 $m^2$).<br>○ Veozah is contraindicated in patients using CYP1A2 inhibitors. |

## Approval Criteria

**I. Initial Authorization**

When a benefit, coverage of Veozah may be approved when all of the following criteria are met **(A., B., and C.)**:

**A.** The member is 18 years of age or older.

**B.** The member is using Veozah for moderate to severe vasomotor symptoms due to menopause. (ICD-10: N95.1).

**C.** The member meets one (1) of the following criteria **(1. or 2.)**:

**1.** The member has experienced therapeutic failure, contraindication, or intolerance to a generic hormone therapy product.

**2.** The prescriber attests that hormone therapy is not clinically appropriate for the member.

**II. Reauthorization**

When a benefit, reauthorization of Veozah may be approved when the following criterion is met **(A.)**:

**A.** The prescriber attests that the member has experienced positive clinical response to therapy.

**III.** An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

## Limitations of Coverage

**I.** Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

**II.** For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

## Authorization Duration

- Commercial and HCR Plans: If approved, up to a 12 month authorization may be granted.

## Automatic Approval Criteria

None

**References:**


1. Veozah [package insert]. Northbrook, IL: Astellas Pharma US Inc; May 2023.
2. Avis NE, et al. Vasomotor Symptoms Across the Menopause Transition: Differences Among Women. *Obstet Gynecol Clin North Am*. 2018 Dec;45(4):629-640.
3. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2023.
4. U.S Department of Health and Human Services. National Institute of Health. National Heart, Lung, and Blood Institute. Available at: https://www.nhlbi.nih.gov/files/docs/pht_facts.pdf. Accessed May 24, 2023.
5. Reuters. US FDA approves Astellas Pharma pill for menopause hot flashes. Available at: https://www.reuters.com/business/healthcare-pharmaceuticals/us-fda-approves-astellas-pharmas-therapy-menopause-related-symptoms-2023-05-12/. Accessed May 19, 2023.
6. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From the Women's Health Initiative randomized controlled trial. *JAMA*. 2002;288(3):321-333.
7. Stuenkel CA, Davis SR, Gompel A, et al. Treatment of symptoms of the menopause: an endocrine society clinical practice guideline. *J Clin Endocrinol Metab*. 2015;100(11):3975-4011.
8. The 2022 Hormone Therapy Position Statement of the North American Menopause Society Advisory Panel. The 2022 hormone therapy position statement of The North American Menopause Society. *Menopause*. 2022;29(7):767-794.