MEDICAL MUTUAL®

Drug Policy

Policy:	Veozah (fezolinetant)	Annual Review Date: 12/19/2024 Last Revised Date: 12/19/2024

OVERVIEW

Veozah is indicated for the treatment of moderate to severe vasomotor symptoms (VMS) due to menopause. Veozah is a NK3 receptor antagonist that blocks neurokinin B (NKB) binding on the kisspeptin/neurokinin B/dynorphin (KNDy) neuron to modulate neuronal activity in the thermoregulatory center.

POLICY STATEMENT

This policy involves the use of Veozah. Prior authorization is recommended for pharmacy benefit coverage of Veozah. 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 Veozah as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Veozah 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 Veozah is recommended in those who meet the following criteria:

1. <u>Vasomotor Symptoms due to Menopause; Initial Therapy</u>
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 <u>or</u> b):
  - **a.** The patient meets one of the following (i <u>or</u> 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
      <u>Note:</u> Examples of menopausal hormone therapy include estradiol, Premarin, Prempro, etc.
  - **b.** The patient meets one of the following (i or ii):
    - **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)

C. The total bilirubin is *not* elevated for the evaluating laboratory*; AND
D. Baseline liver function tests have been done to determine that transaminases are not greater than or equal to 2 times the upper limit of normal*.

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, B, and C; 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

Veozah 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.** Veozah has not been evaluated for use in patients 66 years of age or older.

2. **Concurrent use with hormone therapy.** Veozah has not been evaluated for use in combination with hormonal therapy.

3. **Concurrent use with CYP1A2 inhibitors (including estradiol).** Veozah is contraindicated in individuals using CYP1A2 inhibitors.

4. **Patients with severe renal impairment or end-stage renal disease.** Veozah is contraindicated in individuals with severe renal impairment or end-stage renal disease.

5. **Patients with cirrhosis.** Veozah is contraindicated in individuals with cirrhosis.

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

***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. Veozah™ [prescribing information]. Northbrook, IL: Astellas; May 2023.