MEDICATION POLICY:
Veozah (fezolinetant)

Generic Name: fezolinetant

Applicable Drugs: Veozah

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/26/2024

Date Last Reviewed / Revised: 02/26/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of moderate to severe vasomotor symptoms due to menopause.

II. Documentation that member has met A or B.

A. If age is < 60 years old and the last menstrual period was within the last 10 years, there must be documentation of i and ii:

i. Therapeutic failure or contraindication to menopausal hormonal therapy (HT).

ii. Therapeutic failure of at least 2 non-HT medications (e.g., citalopram, escitalopram, paroxetine, desvenlafaxine, and gabapentin) at suggested dosing range or contraindications to all non-HT medications (See Table 1 in Appendix).

B. If age is ≥ 60 years and the last menstrual period was over 10 years ago, there must be documentation of i:

i. Therapeutic failure of at least 2 non-HT medications (e.g., citalopram, escitalopram, paroxetine, desvenlafaxine, and gabapentin) at suggested dosing range or contraindications to all non-HT medications (See Table 1 in Appendix).

III. Documentation of baseline serum alanine aminotransferase (ALT), serum aspartate aminotransferase (AST), and total bilirubin.

IV. Prescribed according to FDA labeling.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Known cirrhosis.
- Severe renal impairment or end-stage renal disease (eGFR < 30 ml/min/1.73m^2).
- AST, ALT, or total bilirubin ≥ 2 times the upper limit of normal.
- Concomitant use of CYP1A2 inhibitors (e.g., cimetidine, fluvoxamine mexiletine).

OTHER CRITERIA

- N/A

Quantity / Days Supply Restrictions

- Thirty 45 mg tablets per 30 days.

Approval Length

- **Authorization:** 1 year.
- **Re-Authorization:** 1 year.

Appendix

Table 1. Suggested dosage ranges for non-HT for VMS per 2023 North American Menopause Society Advisory Panel Statement [4]

Medication	Dosage range	Suggested titration
SSRIs		
• Citalopram[a]	10 to 20 mg daily	Start with 10mg daily
• Escitalopram[a]	10 to 20 mg daily	Start with 10mg daily. May initiate at 5 mg daily but this dose has not been evaluated for efficacy.
• Paroxetine mesylate[b]	7.5mg daily	No titration needed
• Paroxetine HCl[a]	10 to 25 mg daily	Start with 10 mg daily
SNRIs		
• Desvenlafaxine[b]	100 to 150 mg daily	Start with 25 to 50 mg daily and titrate up by that dose each day
• Venlafaxine[b]	37.5 to 150 mg daily	Start with 37.5mg daily
Gabapentinoids		
• Gabapentin[b]	900 to 2400 mg daily	Start with 100 to 300 mg at bedtime, then add 300 mg at night, then a separate dose of 300 mg in the morning). Titrate to effective dose.

[a]Off-label indication, [b]FDA-label indication.

Abbreviations: SNRIs, serotonin-norepinephrine reuptake inhibitors; SSRIs, selective serotonin reuptake inhibitors.

References

1. Veozah. Prescribing information. Astellas Pharma US, Inc; 2023. Accessed December 10, 2023. https://www.astellas.com/us/system/files/veozah_uspi.pdf

2. 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 A;401(10382):1091-1102. doi: 10.1016/S0140-6736(23)00085-5
3. 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;108(8):1981-1997. doi: 10.1210/clinem/dgad058
4. The 2023 nonhormone therapy position statement of the North American Menopause Society Advisory Panel. The 2023 nonhormone therapy position statement of The North American Menopause Society. *Menopause.* 2023;30(6):573-590. doi: 10.1097/GME.0000000000002200
5. 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. doi: 10.1097/GME.0000000000002028
6. Morga A, Ajmera M, Gao E, et al. Systematic review and network meta-analysis comparing the efficacy of fezolinetant with hormone and nonhormone therapies for treatment of vasomotor symptoms due to menopause. *Menopause.* 2023. doi: 10.1097/GME.0000000000002281

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.