Fezolinetant (Veozah®)

Goal(s):

- To ensure appropriate and safe use of fezolinetant in specified patient populations.

Length of Authorization:

- 6 to 12 months

Requires PA:

- Fezolinetant 45 mg tablets.

Step Therapy Required Prior to Coverage:

- Prevention of vasomotor symptoms: conventional hormone therapy (see preferred drug list options at (www.orpdl.org)
- Current PMPDP preferred drug list per OAR 410-121-0030 at www.orpdl.org
- Searchable site for Oregon FFS Drug Class listed at www.orpdl.org/drugs/

Approval Criteria		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this a request for continuation of therapy previously approved by the FFS program?	**Yes:** Go to **Renewal Criteria**	**No:** Go to #3
3. Is the request to treat moderate to severe vasomotor symptoms due to menopause?	**Yes**: Go to #4	**No:** Pass to RPh. Deny; medical appropriateness
4. Does the patient, have inadequate effect, intolerance or contraindication to a 30-day trial of menopausal hormone therapy (e.g., estrogen/progestin)? *Contraindications to estrogen include history of breast cancer, hepatic disease, cardiovascular disease, or a venous thromboembolism event. Intolerance to progestin include breast tenderness and vaginal bleeding.	**Yes:** Go to #5	**No:** Pass to RPh. Deny; medical appropriateness Refer provider to preferred drug list option for conventional hormone therapy at www.orpdl.org
5. If patient has an intolerance or contraindication to hormonal therapy, do they have an inadequate effect, intolerance or contraindication to a 30-day trial of paroxetine, escitalopram, citalopram, venlafaxine, desvenlafaxine, or gabapentin?	**Yes**: Go to #6	**No:** Pass to RPh. Deny; medical appropriateness

Approval Criteria		
6. Is the patient currently taking a CYP1A2 inhibitor (i.e., cimetidine, amiodarone, mexiletine, ciprofloxacin, or fluvoxamine)?	**Yes:** Pass to RPh. Deny; medical appropriateness. Note: CYP1A2 inhibitors are contraindicated with fezolinetant therapy.	**No:** Go to #7
7. Have baseline renal function tests been obtained?	**Yes:** Go to #8 and document baseline labs_____	**No:** Pass to RPh. Deny; medical appropriateness.
8. Is the estimated glomerular filtration rate (eGFR) < 30 mL/min?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Go to #9
9. Have baseline liver function tests (AST, ALT, Alk Phos, and bilirubin) been obtained?	**Yes:** Go to #10 and document baseline labs_____	**No:** Pass to RPh. Deny; medical appropriateness.
10. Do liver function tests (LFTs) indicate presence of severe cirrhosis (i.e., serum transaminase concentrations or total bilirubin greater than 2 times the upper limit of normal)?	**Yes:** Pass to RPh. Deny; medical appropriateness.	**No:** Approve for 3 months.

Renewal Criteria		
1. Have frequency and severity of vasomotor symptoms been reduced from baseline with fezolinetant treatment?	**Yes:** Go to #2	**No:** Pass to RPh. Deny; medical appropriateness.
2. Have LFTs been requested at months 1-, 2-, and 3 after starting treatment with fezolinetant?	**Yes:** Go to #3 and document LFT results_____	**No:** Pass to RPh. Deny; medical appropriateness.
3. Do LFTs indicate severe cirrhosis (i.e., serum transaminase concentrations or total bilirubin greater than 2 times the upper limit of normal)?	**Yes**: Pass to RPh. Deny; medical appropriateness.	**No:** Approve for 12 months**.**