

## 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](http://www.orpdl.org)))
- Current PMPDP preferred drug list per OAR 410-121-0030 at [www.orpdl.org](http://www.orpdl.org)
- Searchable site for Oregon FFS Drug Class listed at [www.orpdl.org/drugs/](http://www.orpdl.org/drugs/)

<b>Approval Criteria</b>		
1. What diagnosis is being treated?	Record ICD10 code.	
2. Is this a request for continuation of therapy previously approved by the FFS program?	<b>Yes:</b> Go to <b>Renewal Criteria</b>	<b>No:</b> Go to #3
3. Is the request to treat vasomotor symptoms in a post-menopausal person?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness
4. Does the patient have intolerance or contraindications to hormone replacement 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.	<b>Yes:</b> Go to #5	<b>No:</b> Pass to RPh. Deny; medical appropriateness  Refer provider to preferred drug list option for conventional hormone therapy at <a href="http://www.orpdl.org">www.orpdl.org</a>
5. Is the patient currently taking a CYP1A2 inhibitor (i.e., cimetidine, amiodarone, mexiletine, ciprofloxacin, or fluvoxamine)?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness.  Note: CYP1A2 inhibitors are contraindicated with fezolinetant therapy.	<b>No:</b> Go to #6

Approval Criteria		
6. Have baseline renal function tests been obtained?	<b>Yes:</b> Go to #7 and document baseline labs_____	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
7. Is the estimated glomerular filtration rate (eGFR) < 30 mL/min?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness.	<b>No:</b> Go to #8
8. Have baseline liver function tests (LFTs) been obtained?	<b>Yes:</b> Go to #9 and document baseline labs_____	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
9. Do LFTs indicate presence of severe cirrhosis (i.e., serum transaminase concentrations greater than 2 times the upper limit of normal)?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness.	<b>No:</b> Approve for 6 months.

Renewal Criteria		
1. Have frequency and severity of vasomotor symptoms been reduced with fezolinetant treatment?	<b>Yes:</b> Go to #2	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
2. Have liver function tests (LFTs) been requested at 3-, 6-, and 9-month intervals after starting treatment with fezolinetant?  *Note LFTs should be obtained during fezolinetant treatment if symptoms (such as nausea, vomiting, or yellowing of the skin and eyes) suggest liver injury.	<b>Yes:</b> Go to #3 and document LFT results_____	<b>No:</b> Pass to RPh. Deny; medical appropriateness.
3. Do LFTs indicate severe cirrhosis (i.e., serum transaminase concentrations greater than 2 times the upper limit of normal)?	<b>Yes:</b> Pass to RPh. Deny; medical appropriateness.	<b>No:</b> Approve for 12 months.