



MASSACHUSETTS

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Pharmacy Medical Policy Veozah Step Policy

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Policy Number: 014

BCBSA Reference Number: N/A

Related Policies

- Quality Care Dosing guidelines may apply and can be found in Medical Policy #[621B](#)

Prior Authorization Information

Policy	<input type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Step Therapy <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Administrative	Reviewing Department Policy Effective Date	Pharmacy Operations: Tel: 1-800-366-7778 Fax: 1-800-583-6289 11/1/2023
Pharmacy (Rx) or Medical (MED) benefit coverage	<input checked="" type="checkbox"/> Rx <input type="checkbox"/> MED	To request for coverage: Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) to the address below.	
Policy applies to Commercial Members: <ul style="list-style-type: none"> • Managed Care (HMO and POS), • PPO and Indemnity • MEDEX with Rx plan • Managed Major Medical with Custom BCBSMA Formulary • Comprehensive Managed Major Medical with Custom BCBSMA Formulary • Managed Blue for Seniors with Custom BCBSMA Formulary Policy does NOT apply to: <ul style="list-style-type: none"> • Medicare Advantage 		Blue Cross Blue Shield of Massachusetts Pharmacy Operations Department 25 Technology Place Hingham, MA 02043 Tel: 1-800-366-7778 Fax: 1-800-583-6289 Individual Consideration for the atypical patient: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	

Summary

This is a comprehensive policy covering step therapy and quantity limit requirements for medications used for the treatment of vasomotor symptoms associated with menopause.

Hormone therapy remains the most effective treatment for vasomotor symptoms (VMS) has been shown to prevent bone loss and fracture. For women younger than 60 years and within 10 years of menopause onset and have no contraindications (e.g., unexplained vaginal bleeding, liver disease, prior estrogen sensitive cancer - including breast cancer, prior coronary heart disease (CHD), stroke, MI, or VTE, or

personal history or inherited high risk of thromboembolic disease), the benefit-risk ratio is favorable for treatment of VMS and prevention of bone loss. For women who initiate hormone therapy more than 10 or 20 years from menopause onset or when aged 60 years or older, the benefit-risk ratio appears less favorable because of greater absolute risks of CHD, stroke, VTE, and dementia.

Declining estrogen in menopause leads to uninhibited NKB-mediated stimulation of KNDy neurons which leads to temperature dysregulation and VMS. Veozah (Fezolinetant) is a non-hormonal neurokinin receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. It is a first-in-class neurokinin 3 (NK3) receptor antagonist approved to treat VMS in women who either cannot take or are averse to taking hormone therapy. The product label requires baseline liver function tests as well as follow-up tests at 3 months, 6 months, and 9 months after initiation of therapy and when symptoms suggest liver injury.

Policy

Length of Approval	24 months
Formulary Status	All requests must meet the Step Therapy requirement. For all non-covered medications, the member must also have had a previous treatment failure with, or contraindication to, at least two covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Formulary status/requirements of medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Step Requirement
Step 1		
Paroxetine 7.5mg	Covered, QCD	Covered with no requirements
Any Hormone Replacement Therapy (HRT) - [e.g., Premarin [®] , estradiol, medroxyprogesterone, Prempro [®] , Climara [®] , and Estring [®]]	Covered, QCD	
Step 2		
Veozah [™] (fezolinetant)	ST, QCD	Requires prior use of ONE step 1 medication OR history of prior use of Veozah within the previous 130 days. See below for prior use criteria

QCD - Quality Care Dosing (quantity limits [policy #621B](#)); ST – Step Therapy

Prior Use Criteria

The plan uses prescription claim records to support criteria for prior use within previous 130 days or the trial and failure of formulary alternatives when available. Additional documentation will be required from the provider when historic prescription claim data is either not available or the medication fill history fails to establish criteria for prior use or trial and failure of formulary alternatives. Documentation will also be required to support any clinical reasons preventing the trial and failure of formulary alternatives. Please see the section on documentation requirements for more information.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Phone: 1-800-366-7778
Fax: 1-800-583-6289

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
11/2023	Reformatted policy.
10/2023	Reformatted policy. Policy updated to align with 118E MGL § 51A
9/2023	Implement new policy for Veozah™.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

<https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf>

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests [#434](#)

References

1. Veozah TM [Product Information]. Northbrook, IL. Astellas Pharma US, Inc.; May 2023.
2. Fezolinetant for treatment of moderate-to-severe vasomotor symptoms associated with menopause (SKYLIGHT1): a phase 3 randomized controlled study. Lancet 2023; Vol 401:10382, p1091-1102