Veozah™ (fezolinetant)

Policy # 00855
Original Effective Date: 11/13/2023
Current Effective Date: 11/11/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider Veozah™‡ (fezolinetant) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility will be considered for Veozah (fezolinetant) when the following patient selection criteria are met:

- Patient has a diagnosis of moderate to severe vasomotor symptoms due to menopause; AND
- Patient meets ONE of the following:
    - Patient has tried and failed (e.g., intolerance or inadequate response) at least one generic estrogen or estrogen-progestin combination product: OR
    - Patient is not a candidate for hormonal therapy AND has tried and failed at least one generic non-hormonal alternative. Examples of generic non-hormonal alternatives include (but are not limited to) paroxetine, venlafaxine, and gabapentin; OR
    - There is clinical evidence or patient history that suggests generic estrogen or estrogen-progestin products AND all available non-hormonal alternative products will be ineffective or cause an adverse reaction to the patient.

*(Note: These specific patient selection criteria are additional Company requirements for coverage eligibility and will be denied as not medically necessary** if not met).*

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Veozah (fezolinetant) when the patient has not tried and failed at least one generic estrogen or estrogen-progestin product or at least one non-hormonal alternative to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of Veozah (fezolinetant) when the patient selection criteria are not met (except those denoted above as **not medically necessary****) to be **investigational.***

Background/Overview

Veozah is a neurokinin-3 (NK3)-receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. Drugs with this mechanism of action are thought to restore thermoregulatory balance by modulating the brain circuits triggered by the decrease of estrogen levels at menopause. Veozah is an oral tablet (45 mg) given once daily with or without food. Prior to starting Veozah, the patient should have baseline bloodwork performed to evaluate hepatic function. While using Veozah, follow-up blood work should be done at 3 months, 6 months, and 9 months after initiation of therapy and anytime symptoms suggest liver injury.

Vasomotor symptoms are symptoms such as hot flashes and night sweats which can be prevalent during peri-menopause and menopause. As many as 74% of women experience vasomotor symptoms during menopause and it can be present in up to 88% of women during peri-menopause. Declining estrogen levels, by way of the thermoregulatory zone, lead to vasomotor symptoms. Vasomotor symptoms are associated with decreased sleep quality, difficulty with concentration, irritability, and reduced quality of life. Symptoms generally persist for around 7 years, with some women experiencing vasomotor symptoms for up to 12 years or longer. Other agents that are FDA-approved for the treatment of vasomotor symptoms associated with menopause include hormone therapy with various estrogen products and paroxetine 7.5 mg capsules. Guidelines from the North American Menopause Society note that hormone therapy is the most effective treatment for

vasomotor symptoms and should be considered in menopausal women under 60 years of age and within 10 years of their final menstrual periods. These guidelines also recommend cognitive-behavior therapy, clinical hypnosis, SSRIs/SNRIs, gabapentin, oxybutynin, weight loss, and stellate ganglion block as alternative therapies in patients who cannot tolerate hormone therapy. Veozah is addressed in these guidelines as a level 1 recommended therapy with good and consistent scientific evidence.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Veozah was approved in May 2023 for the treatment of moderate to severe vasomotor symptoms due to menopause.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The efficacy of Veozah for the treatment of moderate to severe vasomotor symptoms due to menopause was evaluated in the first 12-week, randomized, placebo-controlled, double-blind portion of each of two phase 3 clinical trials. In each of these two trials, after the first 12 weeks, women on placebo were then re-randomized to Veozah for a 40-week extension to evaluate safety for up to 52 weeks total exposure.

In Trials 1 and 2, 1022 women (522 in Trial 1 and 500 in Trial 2) who had a minimum average of 7 moderate to severe vasomotor symptoms per day were randomized to one of two doses of fezolinetant (including the 45 mg dosage strength) or placebo. Randomization was stratified by smoking status. The mean age of the postmenopausal women was 52 years. The study population included menopausal women with one or more of the following: prior hysterectomy (32.1%), prior oophorectomy (21.6%), or prior hormone therapy use (19.9%). Those who were on prior hormone therapy underwent a wash-out period prior to trial participation.

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The coprimary efficacy endpoints for both trials were the mean change from baseline in moderate to severe vasomotor symptoms frequency and severity to Weeks 4 and 12. Data from each trial demonstrated statistically significant and clinically meaningful (≥2 hot flashes over 24 hours) reduction from baseline in the frequency of moderate to severe vasomotor symptoms for Veozah 45 mg compared to placebo at Weeks 4 and 12. Data from each trial also demonstrated a statistically significant reduction from baseline in the severity of moderate to severe vasomotor symptoms (over 24 hours) at Weeks 4 and 12 for Veozah 45 mg compared to placebo.

References

1. Veozah [package insert]. Astellas Pharma US, Inc. Northbrook, IL. Updated May 2023

Policy History

Original Effective Date: 11/13/2023
Current Effective Date: 11/11/2024
10/05/2023 Medical Policy Committee review
10/11/2023 Medical Policy Implementation Committee approval. New policy.
10/03/2024 Medical Policy Committee review
10/08/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 10/2025

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*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.