LOUISIANA BLUE

Vivjoa™ (oteseconazole)

Policy # 00814
Original Effective Date: 12/12/2022
Current Effective Date: 12/09/2024

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 Vivjoa™‡ (oteseconazole) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Vivjoa (oteseconazole) will be considered when the following criteria are met:

- Patient has a diagnosis of recurrent vulvovaginal candidiasis (RVVC); AND
- Patient has a documented history of greater than or equal to 3 episodes of vulvovaginal candidiasis in a 12-month period; AND
- Patient does not have reproductive potential; AND
- Patient is postmenopausal OR patient has permanent infertility due to any reason such as tubal ligation, hysterectomy, or salpingo-oophorectomy; AND
- Patient has received an initial short course of oral therapy with generic fluconazole (100 mg, 150 mg, or 200 mg) dosed every third day for three doses to attempt mycologic remission unless there is clinical evidence or patient history that suggests the use of generic oral fluconazole will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Patient has tried and failed (e.g., intolerance or inadequate response) a maintenance antifungal regimen of generic oral fluconazole (100 mg, 150 mg, or 200 mg) once weekly for at least 6 months of therapy unless there is clinical evidence or patient history that suggests the use of generic oral fluconazole will be ineffective or cause an adverse reaction to the patient; AND
  *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met)*
- Maintenance therapy with the requested drug will not exceed 11 weeks.

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When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Vivjoa (oteseconazole) when the patient has not received a short course of oral therapy with generic fluconazole to attempt mycologic remission to be **not medically necessary.****

Based on review of available data, the Company considers the use of Vivjoa (oteseconazole) when the patient has not tried and failed a maintenance antifungal regimen of generic oral fluconazole for at least 6 months 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 Vivjoa (otesaconazole) for any indication other than RVVC to be **investigational.***

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

Based on review of available data, the Company considers the use of Vivjoa (otesaconazole) when the length of therapy exceeds 11 weeks of maintenance treatment to be **investigational.***

Background/Overview

Vivjoa is an antifungal that is indicated to reduce the incidence of RVVC in females with a history of RVVC who are not of reproductive potential. It is available as 150 mg capsules. Two different dosing regimens, found in the package insert, can be utilized for administration. The first regimen consists of a Vivjoa only regimen, while the second consist of a fluconazole and Vivjoa regimen. Vivjoa is contraindicated in females who are of reproductive potential.

RVVC is defined as three or more episodes of vulvovaginal candidiasis in a 12-month period. Symptoms that may occur include pruritus, vaginal soreness, dyspareunia, external dysuria, and abnormal discharge. The recommended therapy for RVVC is treatment with azole antifungals. More specifically, a topical azole antifungal or oral fluconazole recommended for induction therapy and oral fluconazole recommended for maintenance therapy. Although Vivjoa is the first of its class to have the specific indication for RVVC, fluconazole remains the standard of care in guidelines.

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FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Vivjoa is approved to reduce the incidence of RVVC in females who have a history of RVVC who are not of reproductive potential.

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.

A total of 656 adults and post-menarchal pediatric females with RVVC (defined as ≥3 episodes of VVC in a 12-month period) were randomized in two multicenter, multinational, double-blind, placebo-controlled trials: Trial 1 and Trial 2. A total of 219 adults and post-menarchal pediatric females with RVVC were randomized in a multicenter, double-blind trial, Trial 3.

Trial 1 and Trial 2 were both randomized, placebo-controlled trials evaluating the efficacy and safety of Vivjoa in the reduction of RVVC. Both trials consisted of two phases: an open-label induction phase and an 11-week maintenance phase. Patients received three sequential doses of 150 mg of fluconazole (every 72 hours) on Days, 1, 4 and 7 during the induction phase. Patients returned 14 days after the first dose of fluconazole and if the acute VVC episode was resolved, they were randomized (2:1) to receive either 150 mg of Vivjoa or placebo for 7 days followed by 11 weekly doses in the maintenance phase.

For both Trial 1 and Trial 2, efficacy was assessed by the proportion of patients with ≥1 culture verified acute VVC episode (positive fungal culture for Candida species associated with a clinical signs and symptoms score of ≥3) during the maintenance phase through week 48. Evaluation of clinical signs and symptoms included erythema (redness), edema (swelling), excoriation (skin picking), itching, burning and irritation.

Vivjoa was superior to placebo with reference to the proportion of patients with ≥1 culture-verified acute VVC episode through week 48 or the proportion of patients with ≥1 culture verified acute VVC episode or who took medication known to treat VVC during the maintenance phase through week 48. The proportion of patients with one or more culture verified acute VVC episodes in Trial 1 was 6.7% in the Vivjoa group vs. 42.8% in the placebo group ($P < 0.001$). The proportion of patients with one or more culture verified acute VVC episodes in Trial 2 was 3.9% in the Vivjoa group vs. 39.4% in the placebo group ($P < 0.001$).

Trial 3 was a randomized, double-blind trial evaluating the efficacy and safety of Vivjoa versus fluconazole and placebo in adults and post-menarchal pediatric females with RVVC. The trial consisted of two phases: induction and maintenance.

During the induction phase, patients received 1050 mg of Vivjoa over two days (600 mg [4x150mg] on Day 1 and 450 mg [3x150mg] on Day 2) or three sequential doses of 150 mg of fluconazole (every 72 hours) on Days, 1, 4 and 7. Patients returned 14 days after the first dose and moved to the maintenance phase if the acute VVC episode was resolved. During the maintenance phase, patients received 150 mg Vivjoa weekly or placebo weekly for 11 weeks.

Efficacy was assessed by the proportion of patients with ≥1 culture verified acute VVC episode during the maintenance phase (post-randomization through week 50) or who failed clearing their infection during the induction phase.

Vivjoa was superior to fluconazole/placebo in the proportion of patients meeting the primary endpoint. The proportion of patients with ≥ one culture verified acute VVC episode through week 50 or unresolved VVC episode during the induction phase was 10.3% in the Vivjoa group vs. 42.9% in the fluconazole/placebo group.

References

1. Vivjoa [package insert]. Mycovia Pharmaceuticals, Inc. Durham, North Carolina. Updated April 2022.
2. Vivjoa Drug Evaluation. Express Scripts. May 2022.

Policy History

Original Effective Date: 12/12/2022
Current Effective Date: 12/09/2024

11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. New policy.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
11/07/2024	Medical Policy Committee review
11/13/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 11/2025

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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.

‡ Indicated trademarks are the registered trademarks of their respective owners.

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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.