Oravig® (miconazole buccal tablets)

Policy # 00521
Original Effective Date: 01/01/2017
Current Effective Date: 09/09/2024

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 Oravig®‡ (miconazole buccal tablets) to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criterion

Coverage eligibility for Oravig (miconazole buccal tablets) will be considered when the following criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) at least TWO of the following generic prescription antifungal products (nystatin suspension, fluconazole, clotrimazole troches), unless there is clinical evidence or patient history that suggests the use of TWO of the following generic prescription antifungal products (nystatin suspension, fluconazole, clotrimazole troches) will be/was ineffective or will/did cause an adverse reaction to the patient.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of Oravig (miconazole buccal tablets) WITHOUT evidence that the patient has tried and failed at least TWO of the following generic prescription antifungal products (nystatin suspension, fluconazole, clotrimazole troches) to be **not medically necessary.****

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Background/Overview

Oravig is an azole antifungal indicated for the local treatment of oropharyngeal candidiasis in adults. The dose of Oravig is one 50 mg buccal tablet applied to the gum region once daily for 14 days. These tablets should not be crushed, chewed, or swallowed. There are various other treatment options for oropharyngeal candidiasis that are available as low cost, generic formulations. These include nystatin suspension, fluconazole, and clotrimazole troches. In fact, Oravig was compared to clotrimazole troches in clinical trials and the results were similar. The generic alternatives provided give a clinically and economically viable option for treatment versus the branded product, Oravig.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Oravig was approved in 2010 for the local treatment of oropharyngeal candidiasis in adults. Various generic alternatives are on the market for the treatment of this condition.

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 patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests TWO of the following generic prescription antifungal products (nystatin suspension, fluconazole, clotrimazole troches) will be/was ineffective or will/did cause an adverse reaction to the patient. Based on a review of the data, in the absence of the above mentioned caveat, there is no advantage of using Oravig (miconazole buccal tablets) over TWO of the following generic prescription antifungal products (nystatin suspension, fluconazole, clotrimazole troches).

References

1. Oravig [package insert]. Dara Biosciences, Inc. Raleigh, North Carolina. Updated April 2015.

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Policy History

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08/04/2016	Medical Policy Committee review
08/17/2016	Medical Policy Implementation Committee approval. New policy.
08/03/2017	Medical Policy Committee review
08/23/2017	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/09/2018	Medical Policy Committee review
08/15/2018	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2019	Medical Policy Committee review
08/14/2019	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/06/2020	Medical Policy Committee review
08/12/2020	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/05/2021	Medical Policy Committee review
08/11/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/04/2022	Medical Policy Committee review
08/10/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2023	Medical Policy Committee review
08/09/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/01/2024	Medical Policy Committee review
08/14/2024	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 08/2025

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**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.

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.