itraconazole (Onmel®)

Policy # 00440
Original Effective Date: 01/01/2015
Current Effective Date: 11/09/2020

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 the branded itraconazole product, Onmel®‡, to be **eligible for coverage**** for up to 12 consecutive weeks of therapy when patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for the branded itraconazole product, Onmel, for up to 12 consecutive weeks of therapy will be considered when the following criterion is met:

- There is clinical evidence or patient history that suggests the use of generically available oral itraconazole 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 the branded itraconazole product, Onmel, WITHOUT clinical evidence or patient history that suggests the use of generically available oral itraconazole will be/was ineffective or will/did cause an adverse reaction to the patient to be **not medically necessary.****

When Services Are Considered Investigational

Based on review of available data, the Company considers the use of the branded itraconazole product, Onmel, for more than 12 consecutive weeks of therapy to be **investigational.***

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Background/Overview

Onmel is indicated for the treatment of onychomycosis for 12 consecutive weeks of therapy. Each tablet of Onmel contains 200mg of itraconazole. There are currently generic versions of oral itraconazole on the market that are also indicated for onychomycosis. The studies used for the approval of Onmel showed that two 100mg capsules of itraconazole had similar outcomes as compared to 200mg of Onmel.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Onmel is FDA approved for the treatment of onychomycosis.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the use of generically available oral itraconazole 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 the brand name itraconazole product, Onmel, over the available generic oral itraconazole products.

References

1. Onmel [package insert]. Merz Pharmaceuticals, LLC. Greensboro, NC 27410.
2. Drugs@FDA.

Policy History

Original Effective Date: 01/01/2015
Current Effective Date: 11/09/2020

10/02/2014	Medical Policy Committee review
10/15/2014	Medical Policy Implementation Committee approval. New policy.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. No change to coverage.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. No change to coverage.

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10/05/2017 Medical Policy Committee review
10/18/2017 Medical Policy Implementation Committee approval. No change to coverage.
10/04/2018 Medical Policy Committee review
10/17/2018 Medical Policy Implementation Committee approval. No change to coverage.
10/03/2019 Medical Policy Committee review
10/09/2019 Medical Policy Implementation Committee approval. No change to coverage.
10/01/2020 Medical Policy Committee review
10/07/2020 Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date: 10/2021

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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.

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.