LOUISIANA BLUE

Noxafil® PowderMix (posaconazole delayed-release oral suspension)

Policy # 00833
Original Effective Date: 04/10/2023
Current Effective Date: 04/01/2025

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 Noxafil®‡ PowderMix (Posaconazole delayed-release oral suspension) to be **eligible for coverage**** when the patient selection criteria are met.

Patient Selection Criteria

Coverage eligibility for Noxafil PowderMix (posaconazole delayed-release oral suspension) will be considered when the following criteria are met:

- Noxafil PowderMix is being used as prophylaxis for invasive *Aspergillus* or *Candida* infection; AND
- Patient is immunocompromised (e.g., hematopoietic stem cell transplant [HSCT] recipient with graft-versus-host disease [GVHD] or presence of hematologic malignancy with prolonged neutropenia from chemotherapy); AND
- Patient is at least 2 years of age and no more than 18 years of age; AND
- Patient weighs 40 kg or less.

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 Noxafil PowderMix (posaconazole delayed-release oral suspension) for any non-FDA approved indications to be **investigational.***

Based on review of available data, the Company considers the use of Noxafil PowderMix (posaconazole delayed-release oral suspension) when the patient selection criteria are not met to be **investigational.***

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Background/Overview

Noxafil contains the active ingredient posaconazole, which is an azole antifungal that is available in several dosage forms each with indications that slightly vary. It is available as an injection, delayed release tablets, immediate release oral suspension, and delayed release oral suspension. Noxafil injection and delayed released tablets are indicated for the treatment of invasive aspergillosis in adults and pediatric patients 13 years of age and older. The dosage form targeted by this medical policy, which is the delayed release oral suspension, is indicated for the prophylaxis of invasive *Aspergillus* and *Candida* infections in pediatric patients 2 years of age and older who weigh 40 kg or less who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy. The injection, delayed release tablets, and oral suspension are also indicated for prophylaxis; however, the approved patient population varies. The injection is approved for use in adults and pediatric patients 2 years of age and older. The delayed release tablets are approved for use in adults and pediatric patients 2 years of age and older who weigh greater than 40 kg. The oral suspension is approved for use in adults and pediatric patients 13 years of age and older. The Noxafil immediate release oral suspension has an additional indication for the treatment of oropharyngeal candidiasis (OPC), including OPC refractory to itraconazole and/or fluconazole, in adult and pediatric patients 13 years of age and older. Dosing for Noxafil PowderMix can be found in the package insert. The package insert also notes that Noxafil PowderMix is not recommended for use in patients who weigh greater than 40 kg because the recommended dosage cannot be achieved with this formulation. Noxafil PowderMix is not to be substituted for the delayed release tablets or the immediate release oral suspension.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Noxafil PowderMix is indicated for the prophylaxis of invasive *Aspergillus* and *Candida* infections in pediatric patients 2 years of age and older who weigh 40 kg or less who are at high risk of developing these infections due to being severely immunocompromised, such as HSCT recipients with GVHD or those with hematologic malignancies with prolonged neutropenia from chemotherapy.

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.

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The intent of this policy is to ensure that Noxafil PowderMix is being utilized appropriately according to its FDA labeled indication. This is also to ensure safe use of the drug as it is indicated in a limited patient population.

References

1. Noxafil [package insert]. Merck and Company, Incorporated. Whitehouse Station, New Jersey. Revised January 2022.

Policy History

Original Effective Date: 04/10/2023
Current Effective Date: 04/01/2025
03/02/2023 Medical Policy Committee review
03/08/2023 Medical Policy Implementation Committee approval. New policy.
03/07/2024 Medical Policy Committee review
03/13/2024 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/06/2025 Medical Policy Committee review
03/12/2025 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 03/2026

*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.

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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.