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Last P&T Approval/Version: 01/28/2026
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Policy Number: C4734-A

Sporanox, Tolsura (itraconazole)

PRODUCTS AFFECTED

Sporanox (itraconazole), Tolsura (itraconazole)

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Onychomycosis, Tinea sp., Candidiasis, Blastomycosis, Histoplasmosis, Aspergillosis

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

A. ONYCHOMYCOSIS TINEA (SPORANOX ONLY):
   1. Documented diagnosis of onychomycosis due to tinea that has been confirmed by a

fungal diagnostic test.
AND
2. Documentation of trial/failure or contraindication to terbinafine
AND
3. Documented trial/failure of itraconazole

B. PITYRIASIS VERSICOLOR OR TINEA VERSICOLOR (SPORANOX ONLY):
1. Documented diagnosis of Pityriasis versicolor or Tinea versicolor
AND
2. Documentation of trial/failure of or contraindication to fluconazole
AND
3. Documented trial/failure of itraconazole

C. ALL OTHER INDICATIONS:
1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported uses
OR
2. (a) Documentation member has infection caused by or strongly suspected to be caused by Tinea corporis, Tinea cruris, Tinea manuum, Tinea pedis, Tinea capitis.
AND
(b) Documentation member experienced an inadequate treatment response, serious side effect, or contraindication to Lamisil (terbinafine) tablets
AND
3. FOR SPORANOX REQUESTS ONLY: Documented trial/failure of itraconazole

CONTINUATION OF THERAPY:
N/A; Each new infection treatment should be a new review

DURATION OF APPROVAL:
Initial authorization: up to 3 months or length of therapy per indication, Continuation of therapy: N/A

PRESCRIBER REQUIREMENTS:
None

AGE RESTRICTIONS:
Sporanox: 18 years of age and older
Tolsura: 18 years of age and older

QUANTITY:
Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:
The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:
Oral

DRUG CLASS:
Triazoles

FDA-APPROVED USES:
TOLSURA (itraconazole) is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis, and
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy

Limitations of Use: Tolsura is not indicated for the treatment of onychomycosis. Tolsura is NOT interchangeable or substitutable with other itraconazole products.

SPORANOX (itraconazole) capsules are indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis,
- Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

AND indicated for the treatment of the following fungal infections in non-immunocompromised patients:

- Onychomycosis of the toenail, with or without fingernail involvement, due to dermatophytes (tinea unguium),
- Onychomycosis of the fingernail due to dermatophytes (tinea unguium).

Prior to initiating treatment, appropriate nail specimens for laboratory testing (KOH preparation, fungal culture, or nail biopsy) should be obtained to confirm the diagnosis of onychomycosis.

SPORANOX (itraconazole) Oral Solution is indicated for the treatment of oropharyngeal and esophageal candidiasis.

COMPENDIAL APPROVED OFF-LABELED USES:
Vulvovaginal candidiasis in patients with HIV; Coccidioidomycosis; Paracoccidioidomycosis; Sporotrichosis; Talaromycosis (formerly penicilliosis); Tinea infections, treatment of CNS infections including Meningitis, Microsporidiosis

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Itraconazole, available as Sporanox capsules and oral solution and Tolsura capsules, is a broad-spectrum triazole antifungal with activity against dermatophytes, yeasts, and dimorphic fungi. For onychomycosis and tinea infections, itraconazole is an established oral option particularly for patients with extensive disease or failure of topical therapy. In candidiasis, itraconazole is generally reserved for mucocutaneous or refractory disease when fluconazole is not appropriate,

consistent with IDSA recommendations. For blastomycosis and histoplasmosis, IDSA and CDC guidance recognize itraconazole as the preferred first-line agent for mild to moderate disease and as step-down therapy following amphotericin B in more severe cases. In aspergillosis, itraconazole is considered an alternative option in select clinical scenarios, such as chronic pulmonary aspergillosis, when first-line agents are unsuitable. Formulation differences are important to be aware of as absorption varies by product as well as administration instructions, drug–drug interactions, and therapeutic monitoring to optimize safety and efficacy across indications.

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of itraconazole are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Contraindications to itraconazole include: Hypersensitivity to itraconazole or any component of the formulation; concurrent administration with CYP3A4 substrates (i.e., avanafil, cisapride, disopyramide, dofetilide, dronedarone, eplerenone, ergot derivatives, felodipine, irinotecan, isavuconazole, ivabradine, lomitapide, lovastatin, lurasidone, methadone, midazolam (oral), naloxegol, nisoldipine, pimozide, quinidine, ranolazine, simvastatin, ticagrelor, or triazolam); concurrent administration with colchicine, fesoterodine, or solifenacin in patients with varying degrees of renal or hepatic impairment; coadministration with eliglustat in patients who are poor or intermediate metabolizers of CYP2D6 and in patients taking strong or moderate CYP2D6 inhibitors; coadministration with venetoclax in patients with CLL/SLL during the dose initiation and ramp-up phase of venetoclax due to the potential for an increased risk of tumor lysis syndrome; treatment of onychomycosis (or other non-life- threatening indications) in patients with evidence of ventricular dysfunction, such as congestive heart failure (CHF) or a history of CHF; treatment of onychomycosis in women who are pregnant or contemplating pregnancy.

OTHER SPECIAL CONSIDERATIONS:

Itraconazole products have a black box warning for congestive heart failure, cardiac effects, and drug interactions.

CODING/BILLING INFORMATION

CODING DISCLAIMER. *Codes listed in this policy are for reference purposes only and may not be all- inclusive or applicable for every state or line of business. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry-standard coding practices for all submissions. Molina has the right to reject/deny the claim and recover claim payment(s) if it is determined it is not billed appropriately or not a covered benefit. Molina reserves the right to revise this policy as needed.*

HCPCS CODE	DESCRIPTION
NA	

AVAILABLE DOSAGE FORMS:

Sporanox CAPS 100MG
Sporanox Pulsepak CAPS 100MG
Sporanox SOLN 10MG/ML

REFERENCES

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2. Sporanox (itraconazole) oral solution [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc; March 2024.
3. Tolsura (itraconazole capsules), for oral use [prescribing information]. Greenville, NC: Mayne Pharma; October 2024.
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SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Diagnosis Continuation of Therapy Background References	Q1 2026
REVISION- Notable revisions: References	Q1 2025
REVISION- Notable revisions: Diagnosis Required Medical Information Age Restrictions FDA-Approved Uses Compendial Approved Off-Labeled Uses Available Dosage Forms References	Q1 2024
REVISION- Notable revisions: Required Medical Information Duration of Approval Age Restrictions Compendial Approved Off-Labeled Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file