



PRIOR AUTHORIZATION WITH STEP THERAPY POLICY

POLICY: Antifungals – Tolsura Prior Authorization with Step Therapy Policy

- Tolsura® (itraconazole capsules – Mayne Pharma)

REVIEW DATE: 07/16/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Tolsura, an azole antifungal, is indicated in immunocompromised and non-immunocompromised adults for the following uses:¹

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

Limitation of use: Tolsura is not indicated for the treatment of onychomycosis.¹ Tolsura is not interchangeable or substitutable with other itraconazole products due to the differences in the dosing between Tolsura and other itraconazole products.

Tolsura contains itraconazole dispersed in a polymer matrix and encapsulated in a hard gelatin capsule.¹ Compared with conventional itraconazole, Tolsura has

improved overall absorption.² Itraconazole capsules (Sporanox®, generic) are also indicated for these uses and for the treatment of onychomycosis in non-immunocompromised patients.³ Itraconazole oral solution (Sporanox®, generic) is indicated for the treatment of oropharyngeal and esophageal candidiasis.⁴ The drug exposure with itraconazole oral solution is greater than that of the capsules when the same dose of drug is given.

Guidelines

Tolsura is referred to as Super-Bioavailable (SUBA) itraconazole in the Infectious Disease Society of America (IDSA) clinical practice guidelines for histoplasmosis (2025).⁵ Tolsura is recommended as a treatment option.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tolsura. This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, patients are directed to try one Step 1 Product (itraconazole capsules or oral solution) prior to Tolsura (Step 2). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

- **Tolsura® (itraconazole capsules – Mayne Pharma)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

- 1. Aspergillosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 6 months if the patient meets ONE of the following (A or B):
A) Patient has tried one of itraconazole capsules or oral solution; OR
B) Patient is currently receiving Tolsura for this condition.
- 2. Blastomycosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 12 months if the patient meets ONE of the following (A or B):
A) Patient has tried one of itraconazole capsules or oral solution; OR
B) Patient is currently receiving Tolsura for this condition.
- 3. Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal – Treatment.** Approve for 3 months if the patient meets ONE of the following (A or B):
A) Patient has tried one of itraconazole capsules or oral solution; OR
B) Patient is currently receiving Tolsura for this condition.

CONDITIONS NOT COVERED

- Tolsura® (itraconazole capsules – Mayne Pharma)

is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Onychomycosis.** Tolsura is not indicated for the treatment of onychomycosis (noted as a Limitation of Use in the Tolsura prescribing information).¹

REFERENCES

1. Tolsura® capsule [prescribing information]. Greenville, SC: Mayne Pharma; October 2024.
2. Tolsura – Advanced antifungal delivery technology. Available at: <https://tolsura.com/about-tolsura/>. Accessed on July 8, 2025.
3. Sporanox® capsule [prescribing information]. Titusville, NJ: Janssen; February 2024.
4. Sporanox® oral solution [prescribing information]. Titusville, NJ: Janssen; March 2024.
5. Arnold S, Spec A, Baddley JW, et al. 2025 clinical practice guideline by the Infectious Disease Society of America on histoplasmosis: treatment of asymptomatic *hispoplasma* pulmonary nodules (histoplasmosis) and mild or moderate acute pulmonary histoplasmosis in adults, children, and pregnant people. *Clin Infect Dis*. 2025 March 17. [Online ahead of print]

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	07/26/2023
Annual Revision	No criteria changes.	07/31/2024
Annual Revision	Aspergillosis – Pulmonary or Extrapulmonary – Treatment: The duration of approval for this condition was changed to 6 months. Previously it was 3 months. Blastomycosis – Pulmonary or Extrapulmonary – Treatment: The duration of approval for this condition was changed to 12 months. Previously it was 3 months.	07/16/2025

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