Drug Coverage Policy

Effective Date 11/15/2025
Coverage Policy Number.....IP0275
Policy Title.....Antifungals - Tolsura

Antifungals – Tolsura

- Tolsura® (itraconazole capsules – Mayne Pharma)

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.

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. Other practice guidelines recommend itraconazole for the treatment of various infections, but none cite Tolsura specifically.

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POLICY STATEMENT
Prior Authorization is required for benefit coverage of Tolsura. 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 is considered medically necessary when ONE of the following is met (1, 2, or 3):

FDA-Approved Indications

1. **Aspergillosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 6 months if the patient meets the following:
   A) Preferred product criteria is met for the product(s) as listed in the below table(s)

2. **Blastomycosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 12 months if the patient meets the following:
   A) Preferred product criteria is met for the product(s) as listed in the below table(s)

3. **Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal – Treatment.** Approve for 6 months if the patient meets the following:
   A) Preferred product criteria is met for the product(s) as listed in the below table(s)

Employer Plans:

Product	Criteria
Tolsura (itraconazole) 65 mg capsule	Patient meets **ONE** of the following: **1.** Approve if the patient has tried one of itraconazole capsules (generics) or itraconazole oral solution (generics). **NOTE:** A trial of either the conventional intraconazole capsules or intraconazole solution would count toward meeting criteria regardless of the formulary status of the product.

Product	Criteria
	2. Patient has been started on a current course of therapy with Tolsura (for a non-oncychomycosis diagnosis): approve to complete the current course.

Individual and Family Plans:

Product	Criteria
Tolsura (itraconazole) 65 mg capsule	Patient meets **ONE** of the following: **1.** Approve if the patient has tried one of itraconazole capsules (generics) or itraconazole oral solution (generics). **NOTE:** A trial of either the conventional intraconazole capsules or intraconazole solution would count toward meeting criteria regardless of the formulary status of the product. **2.** Patient has been started on a current course of therapy with Tolsura (for a non-oncychomycosis diagnosis): approve to complete the current course.

Conditions Not Covered

Tolsura for any other use is considered not medically necessary, 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 a. 2025 clinical practice guideline by the Infectious Disease Society of America on histoplasmosis: treatment of asymptomatic *hispoplasma* pulmonary nodules (histoplasmomas) and mild or moderate acute pulmonary histoplasmosis in adults, children, and pregnant people.*Clin Infect Dis.* 2025 March 17. [Online ahead of print]

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Updated** policy name from "Itraconazole (Tolsura)" to "Antifungals – Tolsura" **Aspergillosis – Pulmonary or Extrapulmonary – Treatment.**	11/1/2024

	Updated indication from "Aspergillosis" to "Aspergillosis – Pulmonary or Extrapulmonary – Treatment" **Removed** "18 years of age or older" **Removed** "Intolerant or refractory to amphotericin B therapy" **Updated** authorization duration from "12 months" to "3 months" **Blastomycosis – Pulmonary or Extrapulmonary – Treatment.** **Updated** indication from "Blastomycosis" to "Blastomycosis – Pulmonary or Extrapulmonary – Treatment" **Removed** "18 years of age or older" **Updated** authorization duration from "12 months" to "3 months" **Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal – Treatment.** **Updated** indication from "Histoplasmosis" to "Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal – Treatment." **Removed** "18 years of age or older" **Updated** authorization duration from "12 months" to "3 months" **Preferred Product Table.** **Updated** "There is documentation of EITHER of the following (A or B): A. Individual has had an inadequate response, contraindication, or is intolerant to Itraconazole capsule or solution (generic Sporanox), B. Individual is currently receiving Tolsura" to "**ONE** of the following: 1.Approve if the patient has tried one of itraconazole capsules (Sporanox, generics) or itraconazole oral solution (Sporanox liquid, generics). **NOTE:** A trial of either the conventional intraconazole capsules or intraconazole solution would count toward meeting criteria regardless of the formulary status of the product. 2.Patient has been started on a current course of therapy with Tolsura (for a non-oncychomycosis diagnosis): approve to complete the current course. **Added** Individual and Family Plan Preferred Product table.	
Annual Revision	**Aspergillosis – Pulmonary or Extrapulmonary – Treatment:** The duration of approval for this	9/15/2025

	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 6 months.	
Selected Revision	**Updated** policy template **Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal Treatment**: The duration of approval for this condition was changed to 6 months. Previously, it was 3 months.	11/15/2025

The policy effective date is in force until updated or retired.