Drug Coverage Policy

Effective Date 11/1/2024
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 and have discretion in making individual coverage determinations. 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 Healthcare Coverage Policy

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. 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
The use of Tolsura in the prevention/treatment of systemic fungal infections is not addressed in guidelines.

Medical Necessity Criteria

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 3 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 3 months if the patient meets the following:
   A) Patient 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 3 months if the patient meets the following:
   A) Patient 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	**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.

Individual and Family Plans:

Product	Criteria
Tolsura (itraconazole) 65 mg capsule	**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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, 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; April 2022.
2. Tolsura – Advanced antifungal delivery technology. Available at: https://tolsura.com/about-tolsura/. Accessed on July 25, 2024.
3. Sporanox® capsule [prescribing information]. Titusville, NJ: Janssen; February 2024.
4. Sporanox® oral solution [prescribing information]. Titusville, NJ: Janssen; March 2024.

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.** **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.**	11/1/2024

	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.	

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