



Effective Date10/15/2023
Next Review Date... 10/15/2024
Coverage Policy Number IP0275

Itraconazole (Tolsura)

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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. 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

This policy supports medical necessity review for itraconazole (Tolsura®).

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

Medical Necessity Criteria

Itraconazole (Tolsura) is considered medically necessary when ONE of the following is met (1, 2, or 3):

- 1. Aspergillosis. Individual meets ALL the following criteria (A, B, and C):
A. 18 years of age or older
B. Intolerant or refractory to amphotericin B therapy
C. Meets the preferred covered alternative(s) criteria as indicated in the table below
2. Blastomycosis. Individual meets BOTH of the following criteria (A and B):

- A. 18 years of age or older
 - B. Meets the preferred covered alternative(s) criteria as indicated in the table below
3. **Histoplasmosis.** Individual meets **BOTH** of the following criteria (A and B):
- A. 18 years of age or older
 - B. Meets the preferred covered alternative(s) criteria as indicated in the table below

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

Employer Group Non-Covered Products and Preferred Covered Alternatives by Drug List:

Non-Covered Product	Standard / Performance	Value / Advantage	Cigna Total Savings	Legacy
Tolsura (itraconazole) 65 mg capsule	There is documentation of EITHER of the following (A <u>or</u> 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			

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.

Reauthorization Criteria

Itraconazole (Tolsura) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

Authorization Duration

Initial approval duration is up to 12 months.

Reauthorization approval duration is up to 12 months.

Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

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

Background

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. 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; itraconazole capsules are also indicated 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.

References

1. Tolsura[®] capsule [prescribing information]. Greenville, SC: Mayne Pharma; December 2018.
2. Tolsura – Advanced antifungal delivery technology. Available at: <https://tolsura.com/about-tolsura/>. Accessed on July 14, 2023.
3. Sporanox[®] capsule [prescribing information]. Titusville, NJ: Janssen; December 2019.
4. Sporanox[®] oral solution [prescribing information]. Titusville, NJ: Janssen; April 2019.

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