

# Initial Prior Authorization

## Tolsura

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tolsura	itraconazole

### Indications

#### FDA-Approved Indications

Tolsura is indicated for the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

- Blastomycosis, pulmonary and extrapulmonary
- Histoplasmosis, including chronic cavitory 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.

Specimens for fungal cultures and other relevant laboratory studies (wet mount, histopathology, serology) should be obtained before therapy to isolate and identify causative organisms. Therapy may be instituted before the results of the cultures and other laboratory studies are known; however, once these results become available, anti-fungal therapy should be adjusted accordingly.

#### Limitations 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. Therefore, follow the specific dosage recommendations for Tolsura.

## Coverage Criteria

Authorization may be granted for the requested drug when ONE of the following criteria are met:

- The requested drug is being prescribed for the treatment of blastomycosis
- The requested drug is being prescribed for the treatment of histoplasmosis
- The requested drug is being prescribed for the treatment of aspergillosis in a patient intolerant of or refractory to amphotericin B therapy

## Duration of Approval (DOA)

- 2845-A: DOA: 6 months

## References

1. Tolsura capsule [package insert]. Greenville, NC: Mayne Pharma; October 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed January 29, 2025.
3. Micromedex® (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 01/17/2025).

## Document History

Written by: UM Development (ME)

Date written: 01/2019

Revised: 12/2019 (no clinical changes); (NZ) 02/2021 (split out diagnosis questions), (DFW) 03/2022 (no clinical changes), (VLS) 02/2023 (no clinical changes), 02/2024 (no clinical changes), ANB 02/2025 (no clinical changes)

Reviewed: Medical Affairs (AN) 01/2019, (CHART) 01/02/2020, 02/25/2021, 02/24/2022, 02/23/2023, 02/29/2024, 02/27/2025

External Review: 04/2019, 04/2020, 06/2021, 06/2022, 06/2023, 06/2024, 06/2025

### **CRITERIA FOR APPROVAL**

- |   |   |     |    |
|---|---|-----|----|
| 1 | Is the requested drug being prescribed for the treatment of blastomycosis?<br>[If Yes, then no further questions. If No, then go to 2.] | Yes | No |
|---|---|-----|----|

2	Is the requested drug being prescribed for the treatment of histoplasmosis? [If Yes, then no further questions. If No, then go to 3.]	Yes	No
3	Is the requested drug being prescribed for the treatment of aspergillosis in a patient intolerant of or refractory to amphotericin B therapy? [No further questions]	Yes	No

Mapping Instructions			
	Yes	No	DENIAL REASONS
1.	Approve, 6 Months	Go to 2	
2.	Approve, 6 Months	Go to 3	
3.	Approve, 6 Months	Deny	<p>Your plan only covers this drug when it is used for certain health conditions. Covered use is for treatment of specific fungal infections. Your plan does not cover this drug for your health condition that your doctor told us you have. We reviewed the information we had. Your request has been denied. Your doctor can send us any new or missing information for us to review. For this drug, you may have to meet other criteria. You can request the drug policy for more details. You can also request other plan documents for your review.</p> <p>[Short Description: Diagnosis]</p>