



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Exception/Other
ITRACONAZOLE	TOLSURA		45848	

**GUIDELINES FOR USE**

1. Is the patient 18 years of age or older and meets **ALL** of the following criteria?
  - The patient is diagnosed with **ONE** of the following types of fungal infections:
    - Blastomycosis, pulmonary and extrapulmonary
    - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
    - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy
  - Tolsura is prescribed by or in consultation with an Infectious Disease Specialist
  - The patient has had a previous trial of a generic itraconazole formulation
  - Physician attestation that Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

If yes, **approve for a total of 12 months by GPID (45848) as follows:**

- **For requests that require a loading dose, enter both of the following approvals:**
  - **FIRST APPROVAL:** approve for 1 month with a quantity limit of #126 capsules per 30 days for 1 fill.
  - **SECOND APPROVAL:** approve for 11 months with a quantity limit of #120 capsules per 30 days (Please enter a start date of one day after the END date of the first approval).
- **For requests that do NOT require a loading dose: approve for 12 months with a quantity limit of #120 capsules per 30 days.**

If no, do not approve.

**DENIAL TEXT:** The guideline named **ITRACONAZOLE (Tolsura)** requires that the patient is 18 years of age or older. In addition, the following criteria must be met:

- The patient is diagnosed with **ONE** of the following fungal infections:
  - Blastomycosis, pulmonary and extrapulmonary
  - Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, nonmeningeal histoplasmosis
  - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy
- Tolsura is prescribed by or in consultation with an Infectious Disease Specialist
- The patient has had a previous trial of a generic itraconazole formulation
- Physician attestation that Tolsura is prescribed due to subclinical response to other formulations of itraconazole suspected to be due to poor bioavailability

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**RATIONALE**

For further information, please refer to the Prescribing Information and/or Drug Monograph for Tolsura.

**REFERENCES**

- Tolsura [Prescribing Information]. Greenville, NC: Mayne Pharma; December 2018.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/19

Created: 03/19

Client Approval: 03/19

P&T Approval: 01/19