



STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES

ITRACONAZOLE - TOLSURA

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ITRACONAZOLE	TOLSURA		45848	GPI-14 (11407035000113)	

**GUIDELINES FOR USE**

1. Does the patient have a diagnosis of **ONE** of the following types of fungal infections?
  - Blastomycosis, pulmonary and extrapulmonary
  - Histoplasmosis, including chronic cavitory pulmonary disease and disseminated, nonmeningeal histoplasmosis
  - Aspergillosis, pulmonary and extrapulmonary, **AND** the patient is intolerant to or refractory to amphotericin B therapy

If yes, continue to #2.

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

2. Does the patient meet **ALL** of the following criteria?
  - The patient is 18 years of age or older
  - Therapy is prescribed by or given in consultation with an infectious disease specialist
  - The patient had a previous trial of a generic itraconazole formulation
  - 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 or GPI-14 as follows:**

**INITIAL REQUESTS**

- **FIRST APPROVAL:** approve for 1 fill with a quantity limit of #126 per 30 days.
- **SECOND APPROVAL:** approve for 11 months with a quantity limit of #120 per 30 days.

**SUBSEQUENT REQUESTS**

- **Approve for 12 months with a quantity limit of #120 per 30 days.**

If no, do not approve.

**DENIAL TEXT:** See the denial text at the end of the guideline.

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GUIDELINES FOR USE (CONTINUED)

**DENIAL TEXT: \*Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **ITRACONAZOLE (Tolsura)** requires the following rule(s) be met for approval:

- A. You have **ONE** of the following fungal infections:
  1. Blastomycosis, pulmonary and extrapulmonary (type of fungal infection affecting in and outside of the lungs)
  2. Histoplasmosis (type of fungal infection), including chronic cavitary pulmonary (affecting the lungs) disease and disseminated, nonmeningeal (not affecting spinal cord and brain membranes) histoplasmosis
  3. Aspergillosis, pulmonary and extrapulmonary (type of fungal infection in and outside of the lungs), **AND** you are intolerant to or refractory to (not responsive to) amphotericin B therapy
- B. You are 18 years of age or older
- C. Therapy is prescribed by or given in consultation with an infectious disease specialist
- D. You had a previous trial of a generic itraconazole formulation
- E. Tolsura is prescribed because you had a poor clinical response to other formulations of itraconazole due to poor bioavailability (amount of drug in the body that has an effect)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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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; September 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/21

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P&T Approval: 04/21