

Commercial/Healthcare PA Criteria

Effective: May 8th, 2019

Prior Authorization: Tolsura

Products Affected: Tolsura (itraconazole oral) oral capsules

Medication Description: Tolsura is an azole antifungal 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

Covered Uses: the treatment of the following fungal infections in immunocompromised and non-immunocompromised adult patients:

1. Blastomycosis, pulmonary and extrapulmonary
2. Histoplasmosis, including chronic cavitory pulmonary disease and disseminated, non-meningeal histoplasmosis
3. Aspergillosis, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy.

*Note: Tolsura is not indicated for the treatment of onychomycosis.

Exclusion Criteria:

1. Diagnosis of onychomycosis
2. Patients with known hypersensitivity to itraconazole

Required Medical Information:

1. Diagnosis
2. Previous therapies tried/failed [documentation required]

Age Restrictions: N/A

Prescriber Restrictions: N/A

Coverage Duration: 12 months

Other Criteria:

- A. Patient has one of the following diagnoses:
 - a. Histoplasmosis; OR
 - b. Pulmonary or Extrapulmonary Blastomycosis; OR
 - c. Pulmonary or Extrapulmonary Aspergillosis; AND
- B. Patient must have had a trial and failure with generic itraconazole 100 mg tablets; AND
- C. If the diagnosis is aspergillosis, must also have had an intolerance to or treatment failure with amphotericin B.

References:

1. Product Information: TOLSURA(TM) oral capsules, itraconazole oral capsules. Mayne Pharma (per FDA), Greenville, NC, 2018.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	4/24/2019