

## Commercial/Healthcare PA Criteria

*Effective: May 8<sup>th</sup>, 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 cavitary 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 cavitary 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