PRIOR AUTHORIZATION WITH STEP THERAPY POLICY

POLICY: Antifungals – Tolsura Prior Authorization with Step Therapy Policy
- Tolsura® (itraconazole capsules – Mayne Pharma)

REVIEW DATE: 07/31/2024

OVERVIEW

Tolsura, an azole antifungal, is indicated in immunocompromised and non-immunocompromised adults for the following uses:[1]

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

Limitation 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.

Tolsura contains itraconazole dispersed in a polymer matrix and encapsulated in a hard gelatin capsule.[1] Compared with conventional itraconazole, Tolsura has improved overall absorption.[2] Itraconazole capsules (Sporanox®, generic) are also indicated for these uses and for the treatment of onychomycosis in non-immunocompromised patients.[3] Itraconazole oral solution (Sporanox®, generic) is indicated for the treatment of oropharyngeal and esophageal candidiasis.[4] The drug exposure with itraconazole oral solution is greater than that of the capsules when the same dose of drug is given.

Guidelines

The use of Tolsura in the prevention/treatment of systemic fungal infections is not addressed in guidelines.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Tolsura. This Prior Authorization Policy also contains a Step Therapy component. When clinically appropriate, patients are directed to try one Step 1 Product (itraconazole capsules or oral solution) prior to Tolsura (Step 2). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tolsura is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Aspergillosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 3 months if the patient meets ONE of the following (A or B):
   A) Patient has tried one of itraconazole capsules or oral solution; OR
   B) Patient is currently receiving Tolsura for this condition.

2. **Blastomycosis – Pulmonary or Extrapulmonary – Treatment.** Approve for 3 months if the patient meets ONE of the following (A or B):
   A) Patient has tried one of itraconazole capsules or oral solution; OR
   B) Patient is currently receiving Tolsura for this condition.

3. **Histoplasmosis – Including Chronic Cavitary Pulmonary Disease and Disseminated, Non-Meningeal – Treatment.** Approve for 3 months if the patient meets ONE of the following (A or B):
   A) Patient has tried one of itraconazole capsules or oral solution; OR
   B) Patient is currently receiving Tolsura for this condition.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tolsura is not recommended in the following situations:

1. **Onychomycosis.** Tolsura is not indicated for the treatment of onychomycosis (noted as a Limitation of Use in the Tolsura prescribing information).[1]

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Tolsura® capsule [prescribing information]. Greenville, SC: Mayne Pharma; April 2022.
2. Tolsura – Advanced antifungal delivery technology. Available at: https://tolsura.com/about-tolsura/. Accessed on July 25, 2024.
3. Sporanox® capsule [prescribing information]. Titusville, NJ: Janssen; February 2024.
4. Sporanox® oral solution [prescribing information]. Titusville, NJ: Janssen; March 2024.