REQUEST FOR FORMULARY EXCEPTION OR PRIOR AUTHORIZATION FOR ANTIFUNGAL DRUG

Instructions for Healthcare Professionals:

Prescribers may complete this form and send it to their patient's insurer to request coverage of TOLSURA® (itraconazole capsules) when it is not on the insurer's prescription drug formulary or if the plan requires prior authorization.[1]

Please consider the following when completing the form:

- It is important to clearly identify the rationale for the request based on your clinical judgment.
  - The fungal infection should be specified as pulmonary and/or extrapulmonary as documented in the medical record.
  - While the primary reason for prescribing TOLSURA may be to treat a fungal infection, it will assist payers if your request includes a detailed description of why the patient should have access to TOLSURA. For example:
    - Failed trial(s) of other antifungals(s)
    - Contraindication to formulary or preferred agent
    - Currently being treated with TOLSURA
    - Another specified reason
- Consider attaching, if appropriate, documents that provide additional clinical information to support the request, such as:
  - Full prescribing information
  - Patient chart notes
  - Clinical guidelines
  - A front and back copy of the patient's prescription drug card
- Carefully review the form for completeness and accuracy before sending to the payer. Payers are likely to return incomplete forms to request additional documentation, which can delay their review of your request.
- A special word about expedited requests:
  - You can ask the payer to expedite its decision if you believe that waiting the amount of time for a standard decision could harm the patient's life, health, or ability to regain maximum function or if your patient is currently being treated with TOLSURA.

See Important Safety Information on page 3 and full prescribing information for TOLSURA at www.TOLSURA.com.

References: 1. TOLSURA prescribing information. Mayne Pharma; July 2020.

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Patient Information

Patient's Name: Date of Birth: / /

Street Address:

City, State: Zip Code: Patient Phone Number:

Insurance Information

Name of Subscriber (if different than patient):

Patient Relationship to Subscriber: Subscriber Date of Birth: / /

Medical Insurance Plan Information **Plan Type (check one):** ◯ Commercial ◯ Exchange ◯ Medicaid ◯ Medicare ◯ Other

Payer Name: Member ID: Group Number:

Prescription Drug Plan Information Pharmacy Benefit Manager:

Prescription Drug Plan Name: Member ID: Group Number:

Prescriber Information

Prescriber's Name: Title: NPI #:

Clinic Name: Specialty:

Clinic Address:

City, State: Zip Code: Office Contact Name:

Office Contact Email Address: Office Contact Phone Number: Secure Fax Number:

Medication

Antifungal Agent Name: TOLSURA® (itraconazole capsules) 65 mg[1]

☐ One bottle of 60 capsules (NDC 51862-462-60) ☐ Other quantity:

Medical Information

Please specify the fungal infection as pulmonary and/or extrapulmonary as documented in the medical record by checking the applicable ICD-10-CM diagnosis code(s) from the options below:

Blastomycosis, pulmonary or extrapulmonary:

- ☐ B40.0 Acute pulmonary blastomycosis
- ☐ B40.1 Chronic pulmonary blastomycosis
- ☐ B40.2 Pulmonary blastomycosis, unspecified
- ☐ B40.7 Disseminated blastomycosis
- ☐ B40.9 Blastomycosis, unspecified

Includes Brazilian blastomycosis:

- ☐ B41.0 Pulmonary paracoccidioidomycosis
- ☐ B41.7 Disseminated paracoccidioidomycosis

Histoplasmosis, including chronic cavitary pulmonary disease and disseminated, non-meningeal histoplasmosis:

- ☐ B39.0 Acute pulmonary histoplasmosis capsulati
- ☐ B39.1 Chronic pulmonary histoplasmosis capsulati
- ☐ B39.2 Pulmonary histoplasmosis capsulati, unspecified
- ☐ B39.3 Disseminated histoplasmosis capsulati
- ☐ B39.9 Histoplasmosis, unspecified

☐ **Other applicable codes:**

Aspergillosis, pulmonary and extrapulmonary, in patients who are *intolerant of* or who are *refractory to* amphotericin B therapy:

- ☐ B44.0 Invasive pulmonary aspergillosis
- ☐ B44.1 Other pulmonary aspergillosis, including chronic cavitary pulmonary aspergillosis (CCPA)
- ☐ B44.7 Disseminated aspergillosis
- ☐ B44.81 Allergic bronchopulmonary aspergillosis (ABPA)
- ☐ B44.9 Aspergillosis, unspecified

Rationale for Request

1. Is the patient currently treated with the requested medication? ☐ Yes ☐ No
   If yes, when was treatment with the medication started?

2. Please list all reasons for selecting TOLSURA over alternatives:
   ☐ Contraindications ☐ Drug resistances ☐ Allergies ☐ History of adverse drug reactions to alternative
   ☐ Previously tried and failed treatments – please specify:
   ☐ Other reason(s):

3. **For expedited requests:** As the patient's healthcare provider, I am requesting that you expedite your determination on this request within 24 hours because (check one):
   ◯ Waiting for a standard decision could harm the patient's life, health, or ability to regain maximum function. ◯ The patient is undergoing a current course of treatment with TOLSURA.

I Certify That the Information Provided in This Form Is Accurate to the Best of My Knowledge.

Healthcare Provider's Signature Date

References: 1. TOLSURA prescribing information. Mayne Pharma; July 2020.

INDICATIONS AND IMPORTANT SAFETY INFORMATION

BOXED WARNING:

WARNING: CONGESTIVE HEART FAILURE and DRUG INTERACTIONS

» **CONGESTIVE HEART FAILURE**

TOLSURA can cause or exacerbate congestive heart failure (CHF). When itraconazole was administered intravenously to healthy human volunteers and dogs, negative inotropic effects were seen. If signs or symptoms of congestive heart failure occur or worsen during administration of TOLSURA, reassess the benefit and risk of continuing treatment.

» **DRUG INTERACTIONS**

- Co-administration of certain drugs that are metabolized by human CYP3A4 enzymes are contraindicated with TOLSURA because plasma concentrations of such drugs are increased, which may also increase or prolong both the pharmacologic effects and/or adverse reactions to these drugs.
- Co-administration with colchicine, fesoterodine and solifenacin is contraindicated in subjects with varying degrees of renal or hepatic impairment, and
- Co-administration with eligustat is contraindicated in subjects taking strong or moderate CYP2D6 inhibitors.
- Increased plasma concentrations of some of these drugs caused by co-administration with TOLSURA can lead to QT prolongation and/or ventricular tachyarrhythmias, including occurrences of torsades de pointes, a potentially fatal arrhythmia.

Indications and Usage

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, pulmonary and extrapulmonary, in patients who are intolerant of or who are refractory to amphotericin B therapy

Limitations of Use:

TOLSURA is NOT indicated for the treatment of onychomycosis.
TOLSURA is NOT interchangeable or substitutable with other itraconazole products.

Contraindications

Co-administration with certain drugs that either affect metabolism of itraconazole or those whose metabolism is affected by itraconazole
Hypersensitivity to itraconazole

Warnings and Precautions

- **Hepatotoxicity:** Serious hepatotoxicity, including liver failure and death, were reported with the use of itraconazole. Discontinue treatment if signs of liver dysfunction occur
- **Cardiac Dysrhythmias:** Life-threatening cardiac dysrhythmias and/or sudden death have occurred in patients using certain drugs that are metabolized by human CYP450 enzymes concomitantly with oral itraconazole and/or other CYP3A4 inhibitors.
- **Peripheral Neuropathy:** This has been reported in patients on long-term therapy with itraconazole. Monitor and promptly evaluate neurologic symptoms
- **Hearing loss:** Reversible or permanent hearing loss has been reported in patients. Discontinue treatment if hearing loss occurs

Adverse Reactions

Most common adverse reactions (incidence ≥1%) are nausea, rash, vomiting, edema, headache, diarrhea, fatigue, fever, pruritus, hypertension, abnormal hepatic function, abdominal pain, dizziness, hypokalemia, anorexia, malaise, decreased libido, somnolence, albuminuria, and impotence.

To report SUSPECTED ADVERSE REACTIONS, contact Mayne Pharma at 1-844-825-8500 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information, please see full Prescribing Information and Patient Information Leaflet.