Austin Public Health

Tecovirimat (TPOXX) Treatment Information Sheet

for Health Care Providers

Note: **All providers are encouraged to discuss the** Study of Tecovirimat for Human MPOX Virus (STOMP) **clinical trial with their patients. Providers whose patients refuse to enroll should follow the directions below.**

Tecovirimat (TPOXX) use for MPOX treatment is under an Expanded Access Investigational New Drug (EA-IND) protocol for patients who have severe disease or involvement of anatomic areas that might result in serious sequelae, or are at high risk for severe disease.

NEW! Provide the patient case description and shipment information for your facility with the new **TPOXX Request** Form attached to this email! Email the filled out form to dshsmpxconsult@dshs.texas.gov and CC the Austin Public Health POC at APH.Preparedness@austintexas.gov.

Providers must complete and return the following documentation to have TPOXX for their patients. Completion of the following documents is required:

1. **Informed Consent.** Obtain prior to treatment initiation. (Spanish, English)
   - Alternative Consent Forms
     - Short Form (Spanish, English)
     - Written Summary (Spanish, English)
2. **FDA 1572 Form.** Requires a clinician's curriculum vitae. Access the electronic form through the Tecovirimat IND Online Registry.
3. **Patient intake form.** Baseline assessment. Access the electronic form through the Tecovirimat IND Online Registry.
4. **Clinical Outcome Form.** Completed 3-14 days after completion of treatment. Access the electronic form through the Tecovirimat IND Online Registry.
5. **Serious Adverse Events.** Life-threatening or serious adverse events associated with TPOXX should be reported to the CDC (regaffairs@cdc.gov) within 24 hours of occurrence, or as soon as possible.

New! Visit the **Tecovirimat (TPOXX) IND Registry for Providers/Facilities** to fill out digital copies of these required documents! Learn more about the registry process, here.

The following documentation is **optional** to complete:

1. **Samples of lesions for resistance testing.** Lesion specimens may be sent to CDC for tecovirimat-treated patients with persistent lesions and/or any new lesions that develop during and/or after tecovirimat treatment to assess for the development of antiviral resistance mutations. See Optional Lesion Specimens to CDC for Resistance Testing for instructions on the collection, storage, and submission of samples.
2. **Pharmacokinetic Testing.** See Optional Pharmacokinetic Samples for Testing information.

The Texas Department of State Health Services will forward the **TPOXX Request Form** information to CDC for approval. The medication will be shipped to your facility directly. Continue to the Tecovirimat IND Online Registry to complete and submit all other required documents.

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