

## Austin Public Health Tecovirimat (TPOXX) Treatment Information Sheet for Health Care Providers



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

<u>Tecovirimat</u> (TPOXX) use for MPOX treatment is under an Expanded Access Investigational New Drug (EA-IND) <u>protocol</u> 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.

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)
- 2. Patient intake form. Indicate if you need a clinical consultation with the CDC
  - New providers who have not previously requested TPOXX must provide their CV when completing the intake form
- 3. <u>Adverse event form</u>. Life-threatening or serious adverse events associated with TPOXX should be reported to the CDC (<u>regaffairs@cdc.gov</u>) within 24 hours of occurrence, or as soon as possible.
- 4. Clinical Outcome Form. Completed 3-14 days after completion of treatment.
- **New!** 5. **TPOXX shipment information form**. Submit this form with the consent and patient intake forms.

Completed documents should be uploaded to the HIPPA compliant, <u>Austin Public Health Document Submission Formstack</u>.

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

- 1. **Photos of lesions.** Ideally, a photograph of at least 1 lesion prior to tecovirimat treatment and then the same lesion photographed again during treatment between days 7 and 14 (indicated dates on photos). Provide photo(s) of any new lesions that develop during or up to 7 days after completion of TPOXX treatment.
- 2. 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.
- 3. Pharmacokinetic Testing. See Optional Pharmacokinetic Samples for Testing information.
- 4. <u>Patient Diary</u>. Give a symptom diary log to patients during baseline assessment. Patients can use this form to record how they feel and document any side effects of TPOXX.

APH will send your request to the Health Authority for review and send it to the CDC for approval. Please indicate if you need a clinical consultation with the CDC on the Patient Intake Form. The medication will be shipped to your facility, or other designated facility, directly.