

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



Thank you for requesting to initiate monkeypox (MPX) treatment for your patient.

<u>Tecovirimat</u> (TPOXX) use for MPX treatment is under an Expanded Access Investigational New Drug (EA-IND) protocol, therefore, certain documentation and return of information related to TPOXX treatment are required by the CDC and FDA. More information for healthcare providers on obtaining and using TPOXX for the treatment of MPX can be found <u>here</u>. Additionally, the EA-IND protocol may be found <u>here</u>.

The following documentation is **<u>required</u>** to be completed:

- 1. Informed Consent. Obtain prior to treatment initiation.
- 2. Patient intake form. See below.
- 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.

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

- 1. <u>Clinical Outcome Form</u>. Completed 3-14 days after completion of treatment. <u>HIGHLY</u> <u>ENCOURAGED</u>.
- 2. **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.
- 3. **Samples of lesions for molecular testing.** A sample from at least 1 lesion prior to tecovirimat treatment but only if baseline diagnostic testing wasn't performed. If new lesions develop during treatment with tecovirimat providers have the option to take a sample of the new lesions to assess antiviral resistance. See <u>Optional Pharmacokinetic Samples for Testing</u> information.
- 4. <u>Patient Diary</u>. Give a symptom diary log to patients during baseline assessment. Patient can use this form to record how they feel and document any side effects to TPOXX.

All documentation, upon completion should be uploaded to the HIPPA compliant, <u>Austin Public Health</u> <u>Document Submission Formstack</u>.

After reviewing the EA-IND and the documentation above, if you would like to request Tecovirimat treatment for your patient with monkeypox, complete the <u>Tecovirimat Patient Intake Form</u> <u>Formstack</u>. Required with this submission is the provider's CV. Once a request is received, the request will be reviewed by the Health Authority, and if approved, the medication will be delivered to your facility.