San Francisco
Department of Public Health

Tecovirimat (TPOXX): San Francisco Department of Public Health New Treatment Provider Process

Updated November 15th, 2022

STOMP Trial:

Please inform your patients about an ongoing clinical trial, the Study of Tecovirimat for Human Monkeypox Virus (STOMP). This trial is actively enrolling participants, and the goal of the trial is to learn more about TPOXX safety and effectiveness. If your patient is interested, please call 415-535-9495 or email ID-Research.ZSFG@ucsf.edu.

To become a TPOXX prescriber:

A. Review the following:

   1. Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children
   2. Tecovirimat IND_Form FDA 1572.pdf
   3. CDC Information for New Prescribers regarding how to become a prescriber and describing required documentation (also see Appendix A, below)

B. New providers must register with the CDC tecovirimat IND online registry to establish themselves as a tecovirimat prescriber.

C. CDC IRB serves as the central IRB for review and approval of the TPOXX EA-IND protocol and determined that its use does not constitute research involving human subjects as defined by 45 CFR 46.102. Since this EA-IND protocol for TPOXX is solely for treatment use and not considered human subjects research, federal-wide assurance requirements do not apply. *However*, some health care systems or institutions may require local IRB review or a formal reliance agreement with the CDC IRB.

   1. Provider seeks guidance from their institution about whether local IRB review or reliance with CDC IRB is needed.

   2. If required by institution, submit to local IRB for review and approval. Local IRB review does not necessarily have to occur before step D.

D. Provider sees patient who has indication for tecovirimat treatment, obtains written informed consent using consent form, and completes online patient intake form (CDC will send online link to provider once provider is registered). Informed Consent Form and Patient Intake Form should be submitted to CDC within 7 days of treatment initiation. See below for how to submit the consent form to CDC.

E. For first time orders, please contact the Medical Health Operating Area Coordinator (MHOAC) program, which facilitates tecovirimat ordering. The requesting provider emails sf-mhoac@sfdph.org:

   1. Requesting entity does not need to be pre-approved by CDC to provide treatment - approval process can be in progress. Requesting entity needs to have the signed Informed Consent Form from patient.

2. Requesting entity should include the following information in their response:
    - Points of Contact- Name, Email, Phone #
        - Requestor- usually clinician, program manager
        - Logistics- staff who will be receiving shipment
    - Ship-To Address- usually loading dock or shipment receiving, not necessarily facility address
    - Any times the location is/is not available to receive a shipment
    - Desired delivery date/time of therapeutics
    - Medication Type
        - TPOXX (Tecovirimat Monohydrate 200 mg): See CDC protocol for dosing and administration information
            - Cold transport not required; product will be shipped in temperature controlled, disposable container
        - IV TPOXX (Tecovirimat Inj., 200 mg/20 mL): Please request in increments of 7 doses (Boxes of 7)
            - Cold chain transport required; will be delivered in Credo Cube; return of cube to CDPH required
    - Quantity of doses
3. SFDPH recommends using the NYC treatment eligibility guidance.
    a. CDC Guidance: Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC
4. Pediatric patients may be treated under CDC-sponsored tecovirimat EA-IN. Please refer to the Protocol for pediatric dosing and special considerations.

Immediate need – Patient urgently needs Tecovirimat

If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment ***once informed consent has been obtained. Paperwork does not need to be completed to initiate treatment.***

The use of tecovirimat for monkeypox is under the EA-IND which has been CDC IRB-approved and authorized by FDA to proceed. Patient-level approval is not required from FDA in order to initiate treatment.

Appendix A. Minimal Required Information to Complete and Return to CDC

Required

- Informed consent – The CDC provides Informed Consent forms in multiple languages, please scroll down on CDC website to find available consent forms. The English version can be found here. Consent must be obtained ***prior to treatment initiation***. The signed informed consent form can be kept on file at the clinic or hospital that consented the patient.
- FDA Form 1572 – This form is accessed via the IND online registry. This is to be completed by the responsible clinician/healthcare facility overseeing the patient's treatment. One signed 1572 per

facility suffices for all TPOXX treatments administered under the EA-IND at the same facility. Please fill out this form in the online registry **within 7 calendar days**.

- Patient Intake Form - to provide patient's baseline condition at the time of tecovirimat treatment decision. This form will be emailed to the provider once the provider has completed the IND online registry. Please return within **7 calendar days** of tecovirimat treatment to the extent possible.
- Serious Adverse Events: Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [226KB, 3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible.

Optional

- Clinical Outcome Form to provide progress of the patient during **and** post treatment. This form is optional and available on the IND online registry. If clinical labs (e.g., CBC with differential, UA, metabolic panel) can be performed during and at the conclusion of treatment, please include the results.
- Lesion samples for resistance testing: Ideally, a sample from at least 1 lesion prior to TPOXX treatment but only if baseline diagnostic testing wasn't performed, as well as samples from any new lesions that develop during and after TPOXX treatment to assess for development of antiviral resistance mutations. See Optional Lesion Samples for Resistance Testing [117KB, 1 page] for instructions on collection, storage, and submission of samples.
- Pharmacokinetic samples for testing: During TPOXX treatment, plasma samples may be collected to monitor TPOXX levels for adequate drug exposure in patients. See Optional Pharmacokinetic Samples for Testing [253KB, 5 pages] for instructions on collection, storage, and submission of samples.