Centers for Disease Control and Prevention

Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox

Updated August 18, 2022

Summary of Recent Changes

Updates as of August 18, 2022

- Tecovirimat (TPOXX) expanded access Investigational New Drug (EA-IND) Protocol (version 6.1 dated August 10, 2022) was amended to:
  - Shorten the Patient Intake form with required vs. optional data fields delineated
  - Make the Clinical Outcome form optional for one time follow-up within 3-14 days after treatment completion. Eliminate during treatment follow-up.
  - Extend the time for returning the requested forms (e.g., within 7 calendar days of treatment initiation)
  - Add drug interactions information on tecovirimat and certain antiretroviral drugs
  - Further clarify IV tecovirimat infusion via syringe pumps. Avoid use of pre-filled IV bags and glass IV bottles
  - Update opening the capsule and mixing with food instructions (replaced water with liquids)
  - Include an alternative option for obtaining informed consent (short form with a written summary)

CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under EA-IND. The streamlined process reduces the number of required forms and gives patients the option to see their doctor virtually.

How to obtain TPOXX

- TPOXX is available through the Strategic National Stockpile, and multiple state health and territorial departments are pre-positioning supplies of TPOXX within their jurisdictions. Clinicians and care facility pharmacists requesting TPOXX should contact their state/territorial health department. Pre-positioned supply may be the fastest route to obtain TPOXX.
- For urgent clinical situations after hours, providers may contact the CDC Emergency Operations Center (770-488-7100) for clinical consultation on patient cases.
- Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent.
- Forms requested under the EA-IND can be returned to CDC **after** treatment begins. Please return completed forms to CDC via encrypted email (regaffairs@cdc.gov) or uploading to secure ShareFile (please zip multiple files and use filenames with patient initials, patient age, hospital/facility name, state, tecovirimat start date, and file contents [e.g., 1572, CV, Patient Intake Form]). Personally identifiable information should not be emailed without encryption.

Protocol

- Because TPOXX is FDA-approved only for treatment of smallpox, CDC holds an protocol (version 6.1 dated August 10, 2022) [495 KB, 22 pages] to allow access to and use of TPOXX for treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children.
    - The protocol includes Instructions for mixing TPOXX capsules with food [287 KB, 1 page]: This patient instruction sheet explains how to open TPOXX capsules and mix with breastmilk, infant formula, milk or food for infants and children who cannot swallow pills.
- The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. The EA-IND also provides liability coverage under the PREP Act for compensation to patients if seriously injured via the Countermeasures Injury Compensation Program (CICP).
- On August 12, 2022, CDC IRB approved [134 KB, 1 page] a protocol amendment; continuation was approved on July 20 [111 KB, 1 page].
- Clinicians, care facilities, and hospitals providing TPOXX can immediately transition to the revised protocol and forms (version 6.1 dated August 10, 2022) [495 KB, 22 pages]. Healthcare providers should complete the following forms:

Required

1. **Informed Consent Form** English [268 KB, 6 pages] | Spanish [335 KB, 6 pages]: Obtain prior to treatment.
    - Alternative Short Form Consent [134 KB, 3 pages] and Written Summary [317 KB, 5 pages] that can be used to obtain informed consent
2. Patient Intake Form [338 KB, 2 pages]: Baseline assessment.
3. FDA Form 1572 [1 MB, 2 pages]: One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
4. **Serious Adverse Events:** Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [956 KB, 5 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website . (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Optional

- Patient diary [296 KB, 2 pages]: Ideally, give the diary to the patients during baseline assessment. Patient can use this form to record how they feel and any side effects to TPOXX.
- Clinical Outcome Form [369 KB, 2 pages]: Progress information during and post treatment.
- **Photos of lesions:** If feasible, take lesion photos at baseline prior to TPOXX treatment, and post-treatment to follow lesion progression and healing during treatment.
- **Lesions 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. Optional Lesion Samples for Resistance Testing [106 KB, 1 page] has 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. Optional Pharmacokinetic Samples for Testing [375 KB, 4 pages] has instructions on collection, storage, and submission of samples.

Institutional Review Board (IRB) Approval

- CDC IRB serves as the central IRB for review and approval. Facilities may elect to rely on the CDC IRB for centralized review and approval by submitting a request to the CDC's Human Research Protection Office within 7 calendar days of tecovirimat treatment at your facility. CDC will promptly document an agreement in writing using the CDC IRB Authorization Agreement (Sample Template) [4 MB, 2 pages] which must be signed by both parties.
- Facilities that elect to obtain their own IRB review must ensure compliance with applicable FDA regulations related to the TPOXX EA-IND protocol. Note that the posted TPOXX EA-IND protocol and the attachments must be used without any changes being made by the IRB.

- Since this TPOXX EA-IND protocol is solely for treatment use, CDC determined that its use does not constitute research involving human subjects as defined by 45 CFR 46.102, therefore, the federal-wide assurance requirements do not apply.

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