Process to Provide Tecovirimat (TPOXX) for Treatment of Monkeypox

(Updated as of 05/25/2023)

Tecovirimat (TPOXX) is an antiviral medication that is approved by the United States Food and Drug Administration (FDA) [PDF – 24 pages for the treatment of smallpox in adults and children. It is the first-line medication to treat monkeypox in adults and children weighing 13kg or more.

Clinical trials in people showed the drug was safe and had only minor side effects. Based on limited available data, it is felt that tecovirimat may shorten the duration of patients' illness and viral shedding.

CDC holds an expanded access protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat monkeypox during an outbreak.

To obtain TPOXX for Mpox treatment, click here to complete the form. Email completed form to EMSDutyOfficer@ochca.com.

If a provider has a patient in urgent need of treatment, the provider may proceed with TPOXX treatment once informed consent has been obtained. Required CDC IND protocol forms may be submitted to CDC after the patient has initiated treatment. For after office hours, please call 714-834-8180 and ask for the on-call public health nurse.

Required Documentation for Tecovirimat (TPOXX) – New Potential Treatment Provider

- You must obtain informed consent prior to treatment.
  - Retain in patient medical record. It does not need to be submitted to CDC.
- Complete the Patient Intake Form.
  - Must be submitted to CDC per instructions on the form. Retain a copy in patient medical record.
- Your organization must complete and sign the FDA Form 1572. One signed 1572 form per facility suffices for all (including future) TPOXX treatments administered under the EA-IND at the same facility. Send completed 1572 form to regaffairs@cdc.gov or by fax 404-902-5921.
- Required safety reporting by clinicians and healthcare facilities will focus on serious adverse events only and should be reported by filling out 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.
  - Safety reporting is only required if a serious adverse event should occur.
  - Instructions on how to complete MedWatch form here.

Oral Tecovirimat (TPOXX) Treatment

One bottle comes with 42 capsules 200mg oral.

- Pediatric and Adult Patients weighing 40 kg or more (Oral Dosing):
  - For children who weigh less than 28.6 pounds (<13 kg), the capsule can be opened, and medicine mixed with semi-solid food.
  - >40 kg to less than <120 kg

- 600 mg (3 caps) of TPOXX every 12 hours w/meal for 14 days (2 bottles)
  - 120 kg or more: 600 mg of TPOXX every 8 hours for 14 days
    - 600mg (3 caps TID x 14 days w/meal (3 bottles)
- Provider should order a 3 week supply based on estimated patient volume
  - Typical orders are 5-20 oral treatment courses (treatment course is defined as 2 bottles or 84 pills)

IV Tecovirimat

The preferred formulation for treatment MPX is the oral formulation. The IV formulation is available for patients unable to tolerate the oral formulation or disease severity/co-morbidities or absorption issues that warrant use. Patient should be switched to the oral formulation as soon as clinically able.

IV tecovirimat is pre-positioned in limited quantities with facilities throughout the state and county. If a patient needs IV treatment, the MHOAC should be contacted to identify product in the County or Region.

IV TPOXX requests should include a brief clinical description of the patient in need of IV treatment (e.g., MPX case with pharyngitis, unable to take oral medications.) Federal supply of IV tecovirimat is now based on individual patient need. CDPH will use the clinical description to meet immediate needs using the small state cache of IV tecovirimat and to request a re-supply from CDC/SNS.

Reimbursement

Organizations are prohibited from selling or seeking reimbursement for TPOXX (tecovirimat) and must provide TPOXX (tecovirimat) regardless of the recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers any TPOXX (tecovirimat) administration fees for the recipient.

Tracking Inventory

Providers and their facility are expected to track number of new patient starts and inventory of tecovirimat. These data will be collected at the time of tecovirimat requests or monthly if no request has been received.

Resources

- CDPH DCDC (California Department of Public Health Division of Communicable Disease Control): Mpox Information for Health Care Providers
- CDC Information for Healthcare Providers: Tecovirimat (TPOXX) for Treatment of Mpox
  - Informed Consent/Parental Permission FORM for Tecovirimat Treatment
- CDC Guidance for Tecovirimat Use
  - Health Alert Network (HAN) | Potential Risk for New Mpox Cases (cdc.gov) (05/15/2023)
  - HAN Update on Managing Mpox in Patients Receiving Therapeutics (11/17/2022)

- HHS/ASPR (Human & Health Services/Administration for Strategic Preparedness & Response): Response to the Mpox Outbreak
- SNS (Strategic National Stockpile): HHS TPOXX Operational Planning Guide

STOMP: Study of Tecovirimat for Human Monkeypox Virus

Recent Questions & Answers

1. **Can our clinic order additional TPOXX to pre-position supplies for possible summer mpox cases?**
    a. The Department of Health and Human Services (HHS) and Administration for Strategic Preparedness and Response (ASPR) are not currently supporting stockpiling efforts by states and locals; this includes TPOXX (oral or IV) and JYNNEOS vaccine. In turn, CDPH will not be able to pre-position additional large quantities of TPOXX within LHJs at this time. That said, many jurisdictions have ample supplies of TPOXX on hand, and may be able to arrange intra-jurisdictional transfers when necessary. In addition, as of the end of May 2023, CDPH will still have 230 courses of unexpired oral TPOXX (as well as 32 vials of IV TPOXX) available at our warehouse for distribution if/when needed. HHS/ASPR may also become more liberal with their allocations if mpox case rates increase.
    b. Currently, CDPH can still support resource requests of up to 20 bottles of oral TPOXX if/when needed (even if these requests are not tied to specific individual patients).
2. **If my clinic exhausts its current supply of TPOXX, how should they go about acquiring more?**
    a. **The standard resource request process will remain**:
        i. Speak with your LHJ directly to order through your Medical Health Operational Area Coordinator (MHOAC) contact. MHOAC Contact List
    b. **Providers and patients should be encouraged to access TPOXX through an ongoing clinical trial called STOMP (Study of Tecovirimat for Human Mpox Virus) whenever possible.** Further information regarding the STOMP trial is available at: Guidance for Tecovirimat Use | Mpox | Poxvirus | CDC.
3. **How long from ordering to fulfillment?**
    a. Currently, CDPH anticipates that we will be able to fulfill resource requests from the state warehouse promptly, usually within 24 hours.
    b. Should we need to request additional therapeutics from the federal government's Strategic National Stockpile (SNS), please anticipate a **48-to-72-hour timeline** from request to fulfillment.
4. **Information Regarding TPOXX Expiration:**
    a. The majority of previously distributed TPOXX in the state will expire after May 31, 2023. To identify the expiration date of your TPOXX lot, please review the HHS ASPR page on TPOXX expiration (see table 2).
    b. Although the shelf-life of IV TPOXX has been extended, there has been no shelf-life extensions for oral TPOXX. Based on our discussions with the federal

government, CDPH does not anticipate any such shelf-life extension in the near future.

c. **The CDPH warehouse will continue to have oral and IV TPOXX available to providers throughout the state when needed, as discussed above. Requests for such therapeutics can continue to be made through the MHOAC system.**
d. Expired TPOXX will need to be either quarantined or destroyed. **We ask that clinics use their own protocols to either quarantine or waste expired treatment products.** Please document how many treatments are quarantined/destroyed.

5. **How can we down-size TPOXX doses in clinic?**
    a. Please reach out to your local public health department. Space permitting, you may be able to transfer unexpired TPOXX to another provider or back to the local public health department. The CDPH warehouse cannot take TPOXX back at this time.