Process to Provide Tecovirimat (TPOXX) for Treatment of Monkeypox

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. Data are not available on the effectiveness of tecovirimat in treating monkeypox infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopoxviruses. Clinical trials in people showed the drug was safe and had only minor side effects. CDC holds an expanded access protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat monkeypox during an outbreak. Tecovirimat is available as a pill or an injection.

Healthcare providers who determine that their patients require treatment can submit a request for TPOXX delivery and/or call the monkeypox phone line 562-570-7907.

Considerations for use of Tecovirimat (TPOXX)
- Treatment should be considered on a case-by-case basis for adults and children with suspected or confirmed monkeypox who exhibit severe symptoms, are at risk of severe disease or who develop complications of monkeypox. Tecovirimat is the first-line medication to treat monkeypox, including in children and adolescents.
- Clinicians can **start treatment** upon obtaining informed consent. All paperwork can be completed and submitted after starting treatment.

Required Documentation for Tecovirimat (TPOXX)
- Obtain informed consent **prior to treatment**.
  - Retain in patient medical record. It does not need to be submitted to CDC.
- Conduct a baseline assessment and complete the Patient Intake Form.
  - Send completed form to regaffairs@cdc.gov and copy tpoxx@ph.lacounty.gov
- 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 form to regaffairs@cdc.gov
- 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.

Dispensing Tecovirimat (TPOXX) Treatment
One bottle comes with 42 200mg oral capsules.

- 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)

Optional

- Clinical Outcome Form: 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. 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.

Side effects

Tecovirimat is generally well tolerated, and side effects were fairly rare and mild. There was a small increase in headache (12%) and nausea (5%) for patients taking tecovirimat as compared to placebo (8% and 4% respectively).

More information about the medication can be found here.

The EA-IND also provides liability coverage under the PREP Act for compensation to patients if injured via the Countermeasure Injury Compensation Program (CICP).

For more information, visit CDC's Clinical Considerations for Monkeypox in Children and Adolescents.

For more information, visit CDC's Treatment Information for Healthcare Professionals.

Questions about obtaining TPOXX can be routed to monkeypox@longbeach.gov with attention to Gabriela Hurtado and Andre Balanji. For afterhours requests, please contact the Public Health Emergency Management Duty Officer: 562-965-4934.