LakeCounty
Health Department and
Community Health Center

Tecoviramat for the Treatment of Monkeypox (MPV)

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Purpose and Rationale for TPOXX to Treat a Monkeypox Infection

Monkeypox (MPV) is a rare disease caused by infection with the monkeypox virus, which is in the same family of viruses (orthpoxvirus) that causes smallpox. Monkeypox symptoms are like smallpox symptoms, but milder, and rarely severe and fatal. The initial site of infection may be the skin, a mucosal surface, or the respiratory tract. Severe disease may manifest as encephalitis, severe inflammatory response syndrome, respiratory failure, painful head and neck lymph node swelling with or without associated airway and/or swallowing compromise, extensive dermal disruption during rash phase, and/or other septic syndromes.

Effective therapeutic options are important to limit severity and complications. Tecoviramat (TPOXX) is a FDA-approved treatment for smallpox but has been granted expanded access in CDC's Investigational New Drug (IND) program, to allow for treatment of monkeypox in adults and children. While the effectiveness of TPOXX in treating monkeypox is unknown, it may be reasonable to anticipate potential treatment benefit based on animal efficacy data that supported FDA-approval for smallpox treatment.

The purpose of this expanded access IND (compassionate use) program is to provide TPOXX treatment of non-variola orthopoxvirus infections (e.g., vaccinia, monkeypox, cowpox or other human virus infection identified as an orthopoxvirus) and secondary treatment of complications from replication-competent vaccinia vaccine in adults and children.

Tecoviramat for the Treatment of Monkeypox (MPV)

Workflow for Community Providers to Refer Patients for TPOXX to Treat a MPV Infection

1. Non-LCHD Primary Care Provider (PCP) identifies patients who have tested positive for MPV and would benefit from TPOXX treatment at their medical appointment.
2. Non-LCHD PCP calls the LCHD Communicable Disease (CD) team at 847.377.8130, Option #1, to request TPOXX for the patient. LCHD CD Team will consult with the non-LCHD PCP to assess the need for TPOXX for MPV treatment.
3. Once the non-LCHD PCP and the LCHD CD Team recommend TPOXX treatment, the LCHD CD Team will send an email to KLake@lakecountyil.gov to schedule an appointment for the patient.
4. LCHD STI Program team member will call the patient to schedule their appointment with the LCHD FQHC Provider designated for TPOXX treatment.
5. The LCHD Medical Epidemiologist will complete Form 1572 for experimental use of TPOXX for Monkeypox with the scheduled provider listed as sub-investigator.
6. All appointments will be completed through General Medicine in the Belvidere Medical Building (BMB) in Waukegan or the Midlakes Clinic (MLC) in Round Lake Beach, depending on provider availability and convenience for patient. All appointments will be completed via telehealth. The patient will be instructed on the process for their telehealth visit, including needing to be onsite of the clinic for their visit in order to receive the medication after the telehealth visit with the provider.
7. At the time of the patient's appointment, clinic staff will call to register the patient for their FQHC appointment from their vehicle to minimize exposures to Monkeypox.
8. The LCHD FQHC provider designated for TPOXX treatment will speak to the patient over the phone and complete the Patient Intake Form.
9. LCHD FQHC Provider designated for TPOXX Treatment will determine if the patient meets indications for use TPOXX and does not have contraindications for treatment with TPOXX. The indication and endorsement of no contraindications for use should be documented in the electronic health record (EHR).
10. During the appointment for TPOXX, the LCHD FQHC provider will discuss and document in the EHR:
    a. Why treatment is indicated
    b. Patient education on transmission and isolation guidelines for MPV infection
    c. Education about TPOXX (what it is, how taken, for how long, etc.)
    d. Risks of TPOXX
    e. Benefits of TPOXX
    f. Potential side effects of TPOXX
    g. Determination if the patient is amenable for treatment with TPOXX. If so, the provider will give the patient the Informed Consent for signature. Informed consent can be discussed verbally or emailed for telehealth appointments using these alternative forms: short form & written summary.
11. After assessing the patient as appropriate for treatment, a member of the clinical staff will walk the oral treatment to the patient's vehicle while wearing proper PPE, including a mask and gloves, and place the medication in the trunk of the patient's vehicle.
12. Patient will be given a follow-up telehealth appointment between day 4–7 of treatment, and then again on day 15, following the completion of treatment. The referring provider will

examine the patient for lesions that have scabbed over AND formed new skin in order to release the patient from isolation. All visits must be documented on the Clinical Outcome Form and in the EHR.

13. After both follow up appointments are complete, the LCHD FQHC designated TPOXX Provider will notify STI Program staff to complete the FDA paperwork, collating and forwarding to appropriate entities within 7 days of appointment.
14. Any adverse reactions after the administration of oral medication will be reported to and managed by the LCHD FQHC provider designated for TPOXX treatment. Patient will be instructed to call 911 if they experience any adverse reactions that may be life threatening.
15. The STI Program will maintain a tracking document monitoring who prescribed the medication and if the follow up requirements are completed.

Workflow for Community Providers to Prescribe TPOXX to Treat a MPV Infection

1. Patient presents with MPV-like symptoms
2. Provider accesses CDC forms and submits MPV specimen for testing
3. Provider will complete Form 1572 for experimental use of TPOXX for Monkeypox with the scheduled provider listed as sub-investigator.
4. Provider accesses TPOXX Administration form
5. Smartsheet notifies LCHD.
6. LCHD will approve, deny, or approve with insufficient supply.
7. LCHD will coordinate delivery or pickup of TPOXX from the STI Program. Coordination will be completed by email with klake@lakecountyil.gov .
8. Provider coordinates with patient for pick-up and submits IND forms to CDC and dph.tpoxx@illinois.gov
9. Determination if the patient is amenable for treatment with TPOXX. If so, the provider will give the patient the Informed Consent for signature. Informed consent can be discussed verbally or emailed for telehealth appointments using these alternative forms: short form & written summary.
10. Provider will meet with patient in person or via telehealth, and then will complete the Patient Intake Form.
11. Patient will be given a follow-up telehealth appointment between day 4–7 of treatment, and then again on day 15, following the completion of treatment. The referring provider will examine the patient for lesions that have scabbed over AND formed new skin in order to release the patient from isolation. All visits must be documented on the Clinical Outcome Form and in the EHR.
12. After both follow up appointments are complete, the LCHD FQHC designated TPOXX Provider will notify STI Program staff to complete the FDA paperwork, collating and forwarding to appropriate entities within 7 days of appointment.
13. Any adverse reactions after the administration of oral medication will be reported to and managed by the LCHD FQHC provider designated for TPOXX treatment. Patient will be instructed to call 911 if they experience any adverse reactions that may be life threatening.

TPOXX Eligibility[1]

TPOXX is authorized for individuals:

- Who weigh at least 13 pounds
  AND

  Have laboratory confirmed orthopoxvirus infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease. **AND ONE OF THE FOLLOWING:**

- With severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- At high risk of severe disease:
  - People with immunocompromising conditions (e.g., HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)
  - Pediatric populations, particularly patients younger than 8 years of age
  - Pregnant or breastfeeding women
  - People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions (e.g., eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
  - People with one or more complication (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)
- With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where Monkeypox virus might constitute a special hazard (eg the genitals or anus)

TPOXX is not authorized under the EA-IND for individuals who:

- Are unwilling to sign an informed consent and refuse tecovirimat treatment
- Have a known allergy to tecovirimat and/or inactive ingredients in tecovirimat

[1] *https://www.cdc.gov/poxvirus/monkeypox/pdf/tecovirimat-ind-protocol-cdc-irb.pdf*

TPOXX Contraindications

TPOXX Capsules:

- None

TPOXX Injection:

- TPOXX Injection is contraindicated in patients with severe renal impairment (defined as creatinine clearance below 30mL/min)

Adverse Reactions

Oral: headache (12%), nausea (5%), abdominal pain (2%), and vomiting (2%). Neutropenia was found in one study participant.

IV: infusion site pain (73%), infusion site swelling (39%), infusion site erythema (23%), infusion site extravasation (19%), and headache (15%).

Drug-Drug Interactions

Significant interactions have been reported in healthy adults with co-administration of repaglinide (hypoglycemia) and midazolam (decreased effectiveness of midazolam).