Department of Public Health
CITY OF PHILADELPHIA

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Health Update

Tecovirimat Treatment for Monkeypox

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SUMMARY POINTS

- CDC and FDA have made it easier for healthcare providers to provide tecovirimat treatment with the expanded access investigational new drug (EA-IND).
- Treatment may begin once consent is obtained.

Tecovirimat is an FDA approved treatment of smallpox, available under EA-IND for treatment of other orthopoxvirus infections, including monkeypox. It is available under oral and IV formulations. IV treatment should be considered for those who cannot take the capsules. The capsules may be opened and mixed with milk, formula or food.

Treatment should be considered in people infected with Monkeypox virus who meet one of the following criteria:

- With severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- Who are 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* infection might constitute a special hazard (e.g., the genitals or anus)

The CDC has implemented flexibilities in the protocol to facilitate access to tecovirimat while still collecting safety and clinical benefit information needed. To request tecovirimat for a patient in Philadelphia please call the Philadelphia Department of Public Health Division of Disease Control at 215-685-6741 during normal business hours and 215-686-4514 on the weekends.

Treatment of tecovirimat can begin after obtaining informed consent. Forms requested under the EA-IND can all be returned to CDC after treatment begins.

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.

Required

1. **Informed consent**. Obtain prior to treatment.
2. **FDA Form 1572.** One signed 1572 per facility suffices for all tecovirimat treatments administered under the EA-IND at the same facility.
3. **Patient intake form.**
4. **Adverse event form.** Life-threatening or serious adverse events associated with TPOXX use should be reported to CDC (regaffairs@cdc.gov) within 24 hours of occurrence, or as soon as possible by completing a **PDF MedWatch Form.**
5. **Clinical outcome form**. The number of required visits has been reduced and all may be telemedicine visits. Visits are required once during and once after treatment.

Optional

- **Photos of lesions.** Ideally, a photograph of at least 1 lesion prior to tecovirimat treatment and then the same lesion photographed again during treatment between days 7 and 14 (indicated dates on photos). Provide photo(s) of any new lesions that develop during or up to 7 days after completion of TPOXX treatment.
- **Samples of lesions for molecular testing.** Ideally, a sample from at least 1 lesion prior to tecovirimat treatment but only if baseline diagnostic testing wasn't performed, as well as samples from any new lesions that develop during TPOXX treatment or up to 7 days afterwards to assess for development of antiviral resistance mutations. Submit samples to CDC with CDC Form 50.34, and indicate Poxvirus Molecular Detection (CDC-10515) as the test order (code).
- **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 for instructions on collection, storage, and submission of samples.

Please return all required forms above to CDC using one of the following methods:

- Secure Share File for lesion photos and large file sizes (please zip multiple files and use filenames with patient identifier, hospital name, and date): https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697
- Email: regaffairs@cdc.gov
- Fax: 404-902-5921

Resources:

- https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html