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CITY OF PHILADELPHIA

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Health Update

Tecovirimat Treatment for Monkeypox

August 22, 2022

SUMMARY POINTS

- CDC and FDA have again shortened the process for healthcare providers to provide tecovirimat treatment with the expanded access investigational new drug (EA-IND).
- Treatment may begin once consent is obtained.
- If there is a high suspicion for disease, treatment may begin before test results return.

The protocol for obtaining Tecovirimat available under EA-IND for treatment of monkeypox has again been shortened. Clinical outcome forms and follow up visits are now optional.

Treatment should be considered in people infected with Monkeypox virus who have severe disease, are at risk for severe disease, or those 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).

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

Required

1. Informed consent. Obtain prior to treatment. The alternative Short Form Consent and Written Summary can be used to obtain consent as well.
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.

Optional

- Clinical outcome form. This was previously required but is now optional. It addresses progress information during and post treatment.
- **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

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.

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.

Resources:

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