PENNSYLVANIA DEPARTMENT OF HEALTH
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Revised Protocols Regarding the Use of Tecovirimat (TPOXX) for the Treatment of Monkeypox

DATE:	July 28, 2022
TO:	Health Alert Network
FROM:	Denise A. Johnson, M.D., FACOG, FACHE, Acting Secretary of Health
SUBJECT:	Revised Protocols Regarding the Use of Tecovirimat (TPOXX) for the Treatment of Monkeypox
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SUMMARY

- The CDC and FDA have made it easier for healthcare providers to provide Tecovirimat (TPOXX) treatment to patients with the diagnosis of monkeypox who meet specific criteria.
- The key protocol changes include: all patient visits may occur over telemedicine, laboratory testing is optional, lesion photos are optional, and a patient diary is optional.
- Clinicians, care facilities, and hospitals providing Tecovirimat (TPOXX) can immediately transition to the revised protocol and forms.
- All requests for Tecovirimat (TPOXX) must come through a provider. Providers should contact the local health department or the Pennsylvania Department of Health, Bureau of Epidemiology (717-787-3350).
- If you have any questions, please call Pennsylvania Department of Health, Bureau of Epidemiology (717-787-3350) or your local health department.

The Pennsylvania Department of Health is providing the following information from the CDC, in coordination with FDA, who have recently updated the expanded access investigational new drug (EA-IND) protocol for Tecovirimat (TPOXX) to help streamline the process and lessen the reporting burden.

Background

Tecovirimat (TPOXX) is an FDA approved treatment of smallpox, available under EA-IND for treatment of other orthopoxvirus infections, including monkeypox.

Treatment with tecovirimat (TPOXX) should be considered in people infected with the 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).

- Given the need for patient monitoring and completion of other EA-IND paperwork, requests for tecovirimat (TPOXX) must come from a healthcare provider. Patients who would like to receive treatment should contact their healthcare provider first. The healthcare provider should then contact the local health department or the Pennsylvania Department of Health, Bureau of Epidemiology (717-787-3350).

Tecovirimat (TPOXX) treatment protocol:

- The following is **required** to obtain and use tecovirimat (TPOXX) for the treatment of Monkeypox:

    - **Informed consent.** Obtain prior to treatment.
    - **FDA Form 1572.** One signed 1572 per facility suffices for all tecovirimat treatments administered under the EA-IND at the same facility.
    - Required patient visits.
        - Three patient visits: baseline, during treatment, and after completion of treatment
        - All patient visits can be conducted via telemedicine
    - Two patient forms to complete and return:
        - Patient Intake Form

        - Clinical Outcome Form
    - Please return all required forms to the 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)
        - Email: regaffairs@cdc.gov
        - Fax: 404-902-5921
    - Adverse event form.
        - Life-threatening or serious adverse events associated with tecovirimat (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** and returning to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile**.**

- The following is now **optional** to use tecovirimat (TPOXX) for the treatment of Monkeypox:
    - Laboratory testing
    - Lesion photos
    - Patient Diary. If feasible, give the form for patient to complete and voluntarily return it directly to CDC.

Please refer to Section 7.0 of the revised protocol that clarifies the required vs. optional components of the protocol. The revised protocol received CDC IRB approval on July 21, 2022 and is now posted on https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html. Please visit periodically for any updated information.

Clinicians, care facilities, and hospitals providing tecovirimat (TPOXX) can immediately transition to the revised protocol and forms. The revised IND case report forms can be used to transition patients whose treatments have started or completed. There is no requirement to re-consent patients whose tecovirimat (TPOXX) treatment started under the prior version of the protocol. Also, CDC IRB is providing reliance agreement for those institutions needing it.

We much appreciate the timely return of completed Patient Intake forms that we have received from providers and care teams involved in providing tecovirimat (TPOXX) treatment. This allows CDC to monitor and help ensure continued tecovirimat availability for appropriate clinical and safe use during the outbreak. On that note, a friendly reminder to also complete and return the Clinical Outcome Form within 3 working days of the patient's last follow-up visit (i.e., 7-10 days after last dose of tecovirimat).

If you have any questions, please call Pennsylvania Department of Health, Bureau of Epidemiology (717-787-3350) or your local health department.

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Health Alert: conveys the highest level of importance; warrants immediate action or attention.
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This information is current as of July 28, 2022 but may be modified in the future.