TPOXX Expanded Access Investigational New Drug (EA-IND) Protocol

Treatment for monkeypox

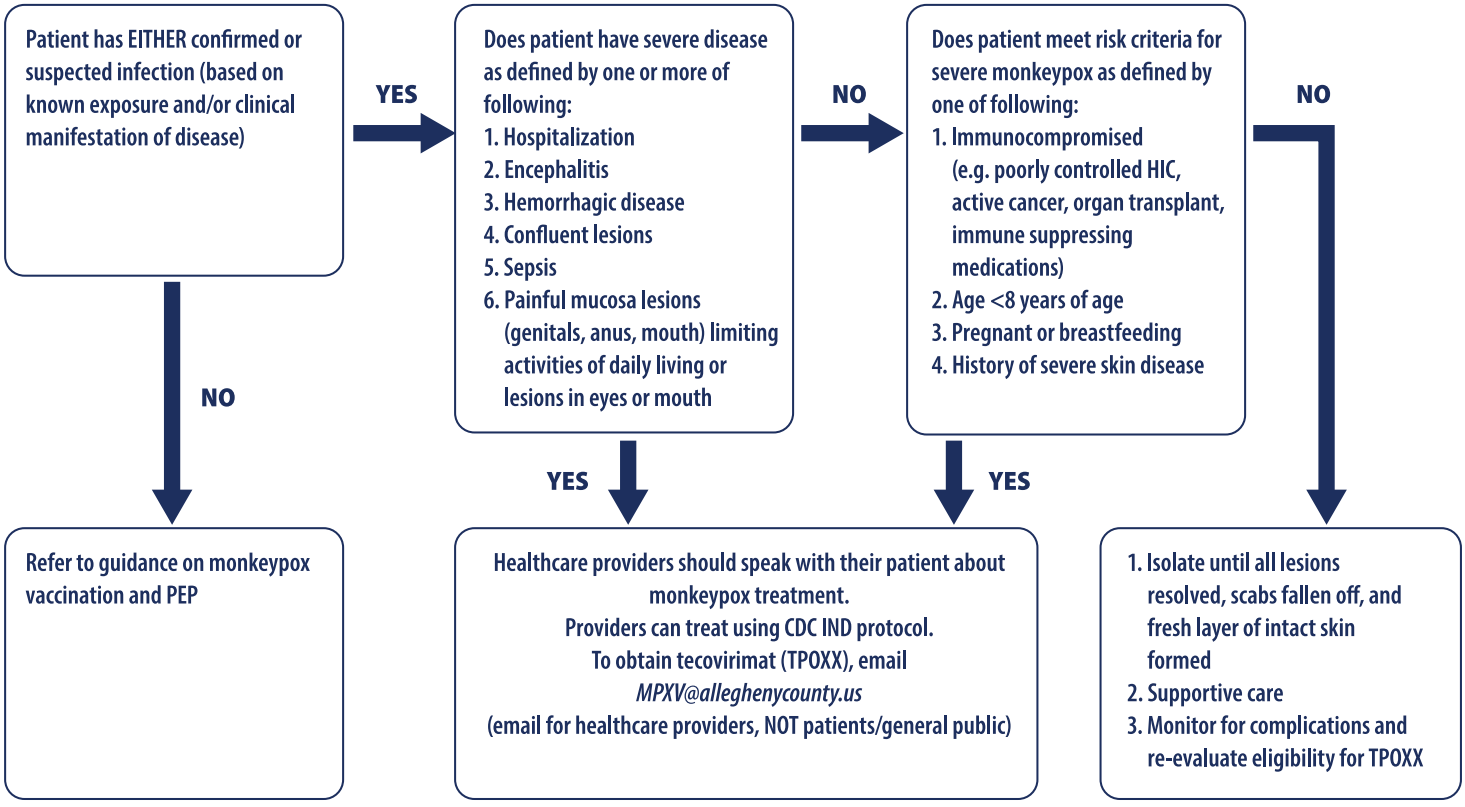
Currently, there is no treatment approved specifically for monkeypox virus infections. However, antivirals developed for use in patients with smallpox may prove beneficial against monkeypox. Smallpox is caused by the variola virus which is a member of the same family of viruses as monkeypox.

Tecovirimat (TPOXX) is an FDA-approved antiviral medication for the treatment of smallpox. The Centers for Disease Control and Prevention (CDC) holds an expanded access Investigational New Drug (EA-IND) protocol that allows for the use of stockpiled TPOXX to treat monkeypox. Tecovirimat is available for use in patients who meet the CDC's clinical criteria (see algorithm below). Informed consent is required for all patients treated with TPOXX.

While the effectiveness of TPOXX in treating monkeypox has not been evaluated, it is reasonable to anticipate potential treatment benefits based on animal efficacy data that supported FDA-approval for smallpox treatment and limited clinical uses of tecovirimat in the treatment of non-variola orthopoxvirus infected individuals.

The risk of TPOXX in people with monkeypox is not known. In the limited data available, it has only caused minor side effects. Safety and side effects have not been studied in individuals who are immunocompromised, pregnant, breastfeeding, or under age 18.

If the patient is not a candidate for pharmacological treatment of monkeypox, supportive and symptomatic care such as fluids, antipyretics and pain control is recommended. If the patient's monkeypox disease worsens, they should be re-assessed for TPOXX therapy.



Algorithm courtesy Allegheny County Health Department

Allegheny County Health Department
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Initiating TPOXX

Health care providers who determine that their patients require TPOXX treatment will complete all CDC Required Forms ***Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC*** when evaluating the patient at baseline before initiating TPOXX including:

1) Obtain **Informed Consent** prior to treatment
2) Complete the **Patient Intake Form**
3) When feasible for outpatient, give the patient the **Diary Form** to complete at home and bring to each appointment.
4) Complete **FDA Form 1572** (if not yet completed by the facility)

Home Delivery of TPOXX

Free home delivery of TPOXX will be arranged through Hilltop Pharmacy. Same-day delivery requests must be received by 4 pm on Mondays - Fridays and 1 pm on Saturdays and Sundays. In order to arrange TPOXX delivery, providers will either:

1) Call Hilltop Pharmacy (**412-431-5766** [**Mon-Fri**] or **412-605-8052** [**Sat-Sun**]) with the following information:

    a. **Patient Information**
        i. Name
        ii. Address
        iii. Phone
        iv. Date of Birth
        v. Weight
        vi. Monkeypox confirmed or empiric treatment
    b. **Provider Information**
        i. Name
        ii. NPI
        iii. Phone

2) Fax the TPOXX Home Delivery Request Form ***TPOXX-Home-Delivery-Request-Form.pdf*** (Fax- **412-431-2568** [if faxed on Sat-Sun, also call **412-605-8052** to notify of fax])

Note- If TPOXX treatment is started empirically (ie. monkeypox is not lab-confirmed), TPOXX will be delivered in two separate 7-day treatments pending pharmacy confirmation of diagnosis with Allegheny County Health Department.

Using Tecovirimat (TPOXX)

Treatment is typically 14 days long (sometimes longer). The provider may proceed with TPOXX treatment once informed consent has been obtained and the 'Patient Intake Form' has been completed.

Health care providers will comply with FDA requirements for IRB review described here ***Tecovirimat-IND-Protocol-CDC-IRB.pdf*** including following Clinical Assessment and Monitoring Parameters and completing all 'Required Forms'***Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC***.

The use of TPOXX for monkeypox is CDC IRB-approved and authorized by FDA to proceed under the Expanded Access-Investigational New Drug (EA-IND) protocol. Patient-level approval is not required from FDA to initiate treatment.

Questions?

To learn more, please email ***MPXV@AlleghenyCounty.us***.

ACHD will follow up on emails during the same business day.

Providers can also reach ACHD by calling our main number: **412- 687-2243**.

For patients outside of Allegheny County, please contact Pennsylvania Department of Health, Bureau of Epidemiology: **717-787-3350**.

For more information, please visit the Allegheny County Health Department Monkeypox Information page: *alleghenycounty.us/monkeypox*.