Updated Information on TPOXX (Tecovirimat) for Treatment of Monkeypox

Date: September 29, 2022

Public Health Message Type: ☐ Alert ☐ Advisory ☒ Update ☐ Information

Intended Audience: ☒ All public health partners ☒ Healthcare providers ☒ Infection preventionists ☒ Local health departments ☐ Schools/Childcare centers ☐ ACOs ☐ Animal health professionals ☐ Other

This message is being sent to provide updated guidance to healthcare providers and local health departments for use of TPOXX (tecovirimat) for the treatment of monkeypox. For up-to-date information on monkeypox including how to order testing please see CDS webpage. The current monkeypox outbreak and response activities are rapidly evolving. NJDOH will continue to update recommendations and guidance as the situation evolves.

On September 15, 2022, the CDC updated its interim guidance for Tecovirimat use. The EA-IND protocol remains the same since August 2022 https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html [cdc.gov]. Providers should visit these websites periodically to monitor for any changes.

1. **At this time, the clinical considerations for the use of TPOXX have been updated to highlight the following**:
   - Based on recently released data from the Food and Drug Administration as well as previously published data, there is some concern that **broad use of the drug TPOXX could lead to viral resistance** and loss of effectiveness for some patients.
   - For many patients with intact immune systems, supportive care and pain control may be sufficient. **All patients with Monkeypox benefit from early supportive care and management of symptoms**. Guidance for symptomatic and pain management has been provided.
   - **Some patients should be considered for antiviral treatment with TPOXX**. These patients include:
     - Individuals with **severe disease** including those with hemorrhagic disease, confluent lesions, sepsis, encephalitis, eye involvement, or other infections such as extensive secondary bacterial infections that require hospitalizations.
     - Individuals with **involvement of anatomic areas such as the pharynx, genital and anal region, which might result in serious sequelae** including scarring or strictures.
     - People who are at **high risk of severe disease** including those with immunocompromise due to co-morbid conditions or medical treatments, children (especially those younger than 8 years of age), those with a condition affecting skin integrity, and those who are pregnant or breastfeeding.
   - **When TPOXX is indicated, early administration is advised**. See below for information on how to obtain TPOXX.

2. New Jersey Department of Health has received doses of oral TPOXX through the Strategic National Stockpile (SNS). **In order to request oral TPOXX for a patient that meets criteria for TPOXX use, healthcare providers should send a secure email to DOH-MPOX@doh.nj.gov and copy cds.mpxepi@doh.nj.gov with the following information:**

- Verification that FDA Form 1572 has been submitted to CDC (one per facility covers all patients)
- Copy of Informed Consent Form signed by patient, submitted as an attachment
- Copy of Patient Intake Form, submitted as an attachment
- Dosage Requested (Please note: any request for IV TPOXX must go through CDC approval process)
- Requestor Name/Contact Information (Phone, email if different from sender)
- Address for Delivery (provider only, no direct deliveries to patients)
- Point of Contact for Delivery: name, email, direct dial number
- Secondary Point of Contact for Delivery (if applicable): name, email, direct dial number
- Office Hours for Delivery/Special Instructions

3. **Required Documents (Healthcare providers should send to CDC)**
   - **Informed Consent Form:** Obtain prior to treatment.
     - Form is available in multiple languages and can be found here.
   - **Patient Intake Form:** Baseline assessment.
   - **FDA Form 1572:** One signed 1572 and treating clinician's CV per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
   - **Serious Adverse Events:** Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [956 KB, 5 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)
   - **Completed paperwork** can be returned to the CDC using one of the following methods:
     - Secure Share File for lesion photos and large file sizes: https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697
     - Encrypted Email: regaffairs@cdc.gov

4. In addition to TPOXX availability via the EA-IND, **the National Institute of Allergy and Infectious Diseases has also opened a study of TPOXX for Monkeypox treatment in adults and children.**

5. Additional medical countermeasures may be available at this time on a case-by-case basis via the CDC. Please contact NJDOH at cds.mpxepi@doh.nj.gov if additional guidance is requested.

Resources

https://www.nj.gov/health/monkeypox/
https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html
https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC