TPOXX (Tecovirimat) Protocol Updates for Treatment of Monkeypox

Date: November 14, 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 please see CDS webpage.

Please be advised that the tecovirimat (TPOXX) EA-IND protocol has been updated as of October 24, 2022. In addition to the amended protocol, the CDC has transitioned to an electronic Online Registry for providers and electronic IND forms. Below are the key changes. Please refer to the CDC website for full details.

Please note: Providers should inform patients about the Study of Tecovirimat for Human Monkeypox Virus (STOMP) for their voluntary participation. Providers should maximize the opportunity to provide tecovirimat treatment to patients through enrollment in STOMP. If enrollment in STOMP is not feasible for a patient (e.g., a clinical trial site is not geographically accessible), tecovirimat use under the expanded access protocol should be in concert with CDC's guidance for treatment.

Amendments to the Tecovirimat IND protocol:

- Added information on the Study of Tecovirimat for Human Monkeypox Virus (STOMP) randomized controlled clinical trial. **Tecovirimat use under the EA-IND protocol should only be for patients whose voluntary participation in STOMP is not feasible** (e.g., a clinical trial site is not geographically accessible).
- Clarified the labeled contraindication of intravenous tecovirimat use in patients with severe renal impairment, with certain exceptions.
- Updated tecovirimat oral dose and preparation instructions for infants (33.3 mg dose for < 3kg) and children; Attachment 3 updated accordingly.
- Clarified guidance on treatment duration extensions beyond the standard 14-day course.
- Added selected adverse events of interest (seizure, tremor and/or tingling sensation, purpura, renal function abnormalities, or hepatic function abnormalities) for monitoring and reporting to CDC.
- Updated instructions regarding submitting Optional Lesion Samples to CDC for Resistance Testing.

Obtaining Tecovirimat:

New Jersey Department of Health continues to distribute doses of oral TPOXX through the Strategic National Stockpile (SNS) for patients who are not eligible/able to be enrolled in the STOMP clinical trial. 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:

- Statement that **FDA Form 1572** (one form per facility will cover all patients) and the **Patient Intake Form** have been submitted electronically to CDC. These forms, along with the optional **Clinical Outcome Form** are available on CDC's website for any new providers and affiliated facilities to register as participating providers under the EA-IND protocol. Providers who returned required IND forms prior to the online registry are grandfathered in as participating providers under the EA-IND. **Any providers with valid email addresses on record should have received emails providing them access to the electronic Patient Intake and Clinical Outcome forms via secure, tokenized links starting October 25, 2022**.
- Statement that Informed Consent has been obtained from the patient. A copy of the signed informed consent form should be maintained at the treating facility/institution, but it does not need to be submitted to NJDOH.
- 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

Reporting Serious Adverse Events:

Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX. Please be advised that reporting Serious Adverse Events will also transition to an electronic-based form during the month of November. Access to the electronic SAE reporting form will be through a tokenized link just like the Patient Intake and Clinical Outcomes forms. Until then, please continue reporting any occurrence of SAEs and/or selected Adverse Events of interest by completing a PDF MedWatch Form and returning to CDC via email (regaffairs@cdc.gov).

Questions/Further Guidance:

- Any questions regarding online registry and electronic tecovirimat IND Patient Intake and Clinical Outcome forms can be directed to CDC IMS TPOXXIND mailbox at eocevent477@cdc.gov.
- Please contact NJDOH at **cds.mpxepi@doh.nj.gov** if other additional guidance is needed.

Resources:

https://www.nj.gov/health/monkeypox/

CDC Monkeypox Treatment Information for Healthcare Professionals
https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

CDC Guidance for Tecovirimat Use
https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html