Updated Protocol on TPOXX (Tecovirimat) for Treatment of Monkeypox

Date: July 22, 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 7/19, NJDOH sent out a LINCS message about use of TPOXX for the treatment of monkeypox. CDC holds an intermediate-size patient population EA-IND to allow access to and use of TPOXX (also known as tecovirimat) for orthopoxvirus infections, including monkeypox. Considerations on when treatment may be indicated can be found here. On July 21, 2022, CDC IRB approved an amendment [123KB, 1 page] and continuation [105KB, 1 page] of Protocol 6402 [430KB, 21 pages]. CDC announced this new streamlined process in a COCA Now on July 22, 2022. (Attached). Clinicians, care facilities, hospitals providing TPOXX can immediately transition to the revised protocol and forms.

Information from the CDC on the revised protocol can be found here: Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC. Required documents for the revised protocol are also listed below.

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 email DOH-MPOX@doh.nj.gov and copy CDSVectorTeam@doh.nj.gov. In the email, include the provider name and contact information, an address where TPOXX needs to be delivered, a point of contact (name and phone number) to receive doses at address provided, and doses requested.**

Healthcare providers should contact NJDOH at **CDSVectorTeam@doh.nj.gov** if they would like to request the intravenous (IV) administration formulation of TPOXX.

Local Health Departments should share this guidance document with healthcare providers if they contact LHDs with inquiries on how to obtain TPOXX.

Required Documents (Send to CDC)

1. **Informed Consent Form [214KB, 5 pages]:** Obtain prior to treatment.
2. **Patient Intake Form [321KB, 3 pages]:** Baseline assessment.

3. **FDA Form 1572 [1MB, 2 pages]:** One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
4. **Clinical Outcome Form [279KB, 4 pages]:** Progress information during and post treatment.
5. **Serious Adverse Events :** Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [226KB, 3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible.

Completed IND protocol forms 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
- Email: regaffairs@cdc.gov
- Fax: 404-902-5921

Resources

https://www.nj.gov/health/cd/topics/monkeypox.shtml
https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
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