

## Monkeypox Virus Infection Treatment Update—October 10, 2022

## Summary

Cases of <u>monkeypox</u> continue to be identified across the nation with 71,096 cases being reported worldwide including 26,577 in the US, 2,410 in Texas and 90 in Bexar County as of October 10, 2022. The Centers for Disease Control and Prevention provided updated <u>Interim Clinical Guidance for the Treatment of Monkeypox</u>.

## Treatment

Patients with monkeypox benefit from supportive care and pain control that is implemented early in the illness (<u>Clinical Considerations for Pain Management of Monkeypox</u>). For most patients with intact immune systems, supportive care and pain control may be enough. However, because prognosis depends on multiple factors, such as initial health status, concurrent illnesses, previous vaccination history, and comorbidities, supportive care and pain control may not be enough for some patients (for example, those with weakened immune systems). In these cases, treatment should be considered.

Treatment should be considered for use in people who have the following clinical manifestations:

- Severe disease consider severe disease when a patient has conditions such as hemorrhagic disease; large number of lesions such that they are confluent; sepsis; encephalitis; ocular or periorbital infections; or other conditions requiring hospitalization
- Involvement of anatomic areas which might result in serious sequelae that include scarring or strictures — these include lesions directly involving the pharynx causing dysphagia, inability to control secretions, or need for parenteral feeding; penile foreskin, vulva, vagina, urethra, or rectum with the potential for causing strictures or requiring catheterization; anal lesions interfering with bowel movements (for example, severe pain); and severe infections (including secondary bacterial skin infections), especially those that require surgical intervention such as debridement.

Treatment should also be considered for use in people who are at high risk for severe disease:

- People currently experiencing severe immunocompromise due to conditions such as advanced or poorly controlled human immunodeficiency virus (HIV), leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient of a 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 people
- People with a condition affecting skin integrity conditions such as atopic dermatitis, 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)

For patients at high risk for progression to severe disease, treatment should be administered early in the course of illness along with supportive care and pain control.

Treatment options include:

- Tecovirimat (also known as TPOXX, ST-246)
- Vaccinia Immune Globulin Intravenous (VIGIV)
- Cidofovir (also known as Vistide)
- Brincidofovir (also known as CMX001 or Tembexa)

# **Obtaining Oral Treatment – TPOXX**

Fax a script for the patient to (210) 207-2007 and call (210) 207-8876 **OR** email script using encryption to <u>mpoxconsult@sanantonio.gov</u> with the following information:

- 1. Ensure the script includes patient demographic information: [patient name, DOB, phone number and address on script]
- 2. Organization Requesting TPOXX and address: [organization name and address]
- 3. POC #1 at organization: [name, email, 24/7 monitored phone #]
- 4. POC #2 at organization: [name, email, 24/7 monitored phone #]
- 5. Number of bottles of PO tecovirimat (1 full course = 2 bottles for people weighing 40–120kg, for other weight, see IND protocol page 6): [number of bottles]
- 6. You will need to have staff or the patient pick up medication at 512 E. Highland Blvd Suite 150 during office hours Monday to Friday between 8:00 am and 4:30 pm.
  - a. If staff pick up, provide day/time of pick-up: [date/time of pick-up during office hours]
  - b. If patient pick up, ensure that the CDC consent (information below) is signed by the patient prior to sending individual to Metro Health to pick-up TPOXX. Provider is still responsible for filling out and submitting the forms below to the CDC. Provide day/time of pick-up: [date/time of pick-up during office hours]

## **Obtaining IV Treatment – TPOXX**

Call 210-207-8876 to determine if IV treatment will be released and to coordinate shipping of medication.

## Forms needed to be sent to CDC

- 1. Informed Consent Form: English [238 KB, 6 pages] Obtain prior to treatment.
  - a. **Other languages:** <u>Spanish</u> [263 KB, 7 pages] | <u>Arabic</u> [308 KB, 6 pages] | <u>Korean</u> [431 KB, 7 pages] | <u>Russian</u> [245 KB, 7 pages] | <u>Simplified Chinese</u> [316 KB, 6 pages] | <u>Tagalog</u> [243 KB, 7 pages] | <u>Vietnamese</u> [338 KB, 7 pages]
  - b. Alternative Consent Forms that can be used to obtain informed consent:
    - <u>Short Form (English)</u> [155 KB, 3 pages] | <u>Spanish</u> [140 KB, 4 pages] | <u>Arabic</u> [188 KB, 3 pages] | <u>Korean</u> [304 KB, 3 pages] | <u>Russian</u> [173 KB, 4 pages] | <u>Simplified</u> <u>Chinese</u> [211 KB, 3 pages] | <u>Tagalog</u> [121 KB, 4 pages] | <u>Vietnamese</u> [225 KB, 4 pages]
    - <u>Written Summary (English) [229 KB, 5 pages] | Spanish [284 KB, 6</u>
      - pages] | Arabic [290 KB, 5 pages] | Korean [462 KB, 6 pages] | Russian [364 KB, 6
      - pages] | <u>Simplified Chinese [</u>347 KB, 5 pages] | <u>Tagalog [</u>249 KB, 6
      - pages] | <u>Vietnamese [</u>466 KB, 6 pages]
- 2. Patient Intake Form [385 KB, 2 pages]: Baseline assessment.
- 3. **FDA Form 1572 [1 MB, 2 pages]:** One signed 1572 and treating clinician's CV per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
- 4. Serious Adverse Events: Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a <u>PDF MedWatch Form [956 KB, 5 pages]</u> and returning it to CDC via email (<u>regaffairs@cdc.gov</u>) or uploading to <u>ShareFile</u> within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from <u>the FDA website</u>. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

#### To report a suspected case of monkeypox, contact your local health department: Bexar County Residents: Residents of Other Counties:

San Antonio Metropolitan Health District Epidemiology Program Phone: (210) 207-8876 Fax: (210) 207-2007 Texas Department of State Health Services Public Health Region 8 Phone: (210) 949-2121 Fax: (512) 206-3995