

Public Health Update July 28, 2022 Availability of Tecovirimat for the Treatment of Monkeypox

Situation

Tecovirimat (also known as TPOXX or ST-246) is an antiviral medication approved by the FDA for the treatment of smallpox. In response to the current outbreak of monkeypox, the CDC has obtained an expanded access Investigational New Drug (EA-IND) protocol that allows its use for treating other orthopoxvirus infections, including monkeypox. The federal government, though its Strategic National Stockpile (SNS), is shipping this medication to pre-selected sites to serve as depots. At this time, the Southern Nevada Health District (SNHD) is the only such depot in southern Nevada (additional depots are likely to come on-line soon). Providers wishing to make it available to their patients should review the following. Please refer to future HANs for updates.

Guidelines for treatment

TPOXX may be considered for treatment in those with laboratory evidence of monkeypox infection and in those without such evidence in whom an infection is suspected based on known exposure and/or clinical manifestations of disease. Treatment should be considered in those:

- With severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- Who are at high risk of severe disease:
 - People with immunocompromising conditions (e.g., HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with 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 women
 - People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions (e.g., 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])
 - People with one or more complication (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)
- With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where *Monkeypox virus* infection might constitute a special hazard (e.g., the genitals or anus).

TPOXX may also be considered for post-exposure prophylaxis on an individual case-by-case basis in consultation with CDC: (770) 488-7100; poxvirus@cdc.gov.

Prescribing Information

TPOXX is available from the SNHD pharmacy as an oral formation only (IV formulations will soon become available at other depots). The standard oral dosing is 600 mg Q 12 hours for 14 days for children and adults weighing 40 – 120 kg. For additional prescribing information, please refer to the attachments or to the links provided below.

Requesting TPOXX

To request a treatment course of TPOXX, please send an e-prescription to the SNHD Pharmacy or fax the prescription to (702) 759-1440. Patients must review and sign-off on an Informed Consent prior to treatment and providers must complete and submit a patient intake and a clinical outcome form; these forms along with instructions for completing and submitting them are attached and available at the links below. Providers are also encouraged to obtain and submit photos and samples and provide their patients with a diary and additional instructions. Instructions for doing so are found at this same website.

Additional Information

Please refer to the following for additional information:

- Prescribing Information:
 - o label (fda.gov)
- CDC Information:

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- <u>Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during</u> 2022 U.S. Monkeypox Cases | Monkeypox | Poxvirus | CDC
- Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC

Health Alert: conveys the highest level of importance; warrants immediate action or attention

Health Advisory: provides important information for a specific incident or situation; may not require immediate action **Health Update:** provides updated information regarding an incident or situation; unlikely to require immediate action action

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