Steve Sisolak
Governor

Richard Whitley, MS
Director

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH

Helping people. It's who we are and what we do.

Lisa Sherych
Administrator

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

Technical Bulletin

Date:	**September 30, 2022**
Topic:	**Monkeypox Virus Guidance for Health Care Providers – Clinical Considerations for Treatment, Pain Management and Severe Manifestations of Monkeypox among Immunocompromised Persons**
Contact:	**Melissa Peek-Bullock, State Epidemiologist, Office of State Epidemiology**
To:	**Health Care Providers, Hospitals, Laboratories, and Local Health Authorities**

Background

Since May 2022, more than 25,000 monkeypox cases have been identified in the United States. **Patients with monkeypox benefit from supportive care and pain control that is implemented early in the illness.** Illness depends on a person's immune response; for most patients with intact immune systems, supportive care and pain control may be enough. However, because prognosis for monkeypox 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. The Centers for Disease Control and Prevention (CDC) recently updated their Interim Clinical Guidance for the Treatment of Monkeypox.

Treatment should be considered for use in patients who have the following clinical manifestations[1]:

- Severe disease – consider severe disease when a patient has conditions such as hemorrhagic disease; a 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 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[1]:

- 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, 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)

[1] https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html

Tecovirimat (TPOXX or ST-246)

The CDC holds a non-research Expanded Access Investigational New Drug (EA-IND) protocol that allows for the use of TPOXX for primary or early empiric treatment of non-variola *Orthopoxvirus* infections, including monkeypox, in adults and children of all ages. Data from the published literature and additional recently released data from the FDA suggest that there may be a low barrier to virus developing resistance to TPOXX; indiscriminate use could promote resistance and render TPOXX, first line treatment for orthopoxviruses, ineffective for patients. When considering the use of TPOXX, clinicians and patients should understand 1) the lack of TPOXX effectiveness data to date in people with monkeypox; 2) the lack of data indicating which patients might benefit the most from TPOXX; and 3) the concern for the development of resistance to TPOXX, which could render the drug ineffective. **Therefore, TPOXX should not be used indiscriminately for treatment of TPOXX but should be considered for use in patients as outlined above.**

TPOXX is available for oral or intravenous therapy but is not readily available through pharmacies at this time. TPOXX has been prepositioned within the state making it available at locations in Clark, Carson City, Elko and Washoe counties. Supply at these locations can be reallocated to other areas as needed.

How to Obtain TPOXX

Clinicians with patients who may benefit from treatment for monkeypox infection or health care facilities that would like to have TPOXX available at their location should contact their local public health authority for coordination (see reporting section below). Treatment with TPOXX can begin upon receiving the medication and after completing the informed consent form. No pre-registration is required for clinicians or facilities to begin treatment. Forms requested under the EA-IND can all be returned to CDC ***after*** treatment begins.

To prescribe TPOXX, health care providers should do the following:

1. Obtain informed consent prior to treatment at the CDC link here.
2. Conduct a baseline assessment and complete the Patient Intake Form linked here.
3. Sign the FDA Form 1572 linked here. One signed Form 1572 per facility suffices for all (including future) TPOXX treatments administered under the EA-IND at the same facility.
4. Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form linked here and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible.

Additional information is available at https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html.

Other Treatment Options

Additional treatment options include Vaccinia Immune Globulin Intravenous (VIGIV), Brincidofovir and Cidofovir. These therapies are not widely recommended due to the potential for increased risk of side effects; however, they may be considered in the treatment of severe monkeypox cases on a case-by-case basis through CDC clinical consultation. Visit the CDC web page here for additional treatment options..

Clinical Considerations for Pain Management of Monkeypox[2]

Monkeypox can commonly cause severe pain and can affect vulnerable anatomic sites, including the genitals and oropharynx, which can lead to other complications. Mucosal lesions have been reported in more than 40% of patients. In a multinational study, 30% of hospitalized patients were admitted for pain management.

Health care professionals should assess pain in all patients with monkeypox virus infection and recognize that substantial pain may exist from mucosal lesions not evident on physical exam. Topical and systemic strategies should be used to manage pain:

- OTC medications (e.g., acetaminophen, NSAIDS) are recommended for general pain control.
- Topical steroids and anesthetics such as lidocaine could also be considered for local pain relief.
    - Topical lidocaine or other topical anesthetics should be used with caution on broken skin or on open or draining wounds.

[2] https://www.cdc.gov/poxvirus/monkeypox/clinicians/pain-management.html

    - Persons applying topical medications to lesions should use disposable gloves and practice hand hygiene to minimize the risk of autoinoculation.
- In some circumstances, prescription pain medications such as gabapentin and opioids have been used for short-term management of severe pain not controlled with other treatments including acetaminophen, NSAIDS and/or topical medications.
    - Consider risk of side effects (constipation) and other risks (potential for unintended long-term use of opioids, development of an opioid use disorder or overdose).
    - Consider patient's comorbid medical conditions, concurrent medications, values/preferences related to opioids and other factors related to safety of such medications.

Visit the CDC web page linked here for more information..

Severe Manifestations of Monkeypox among People who are Immunocompromised Due to HIV or Other Conditions[3]

Some patients with monkeypox in the United States have experienced prolonged hospitalizations or substantial morbidity; deaths have also occurred. As the monkeypox outbreak has progressed, an increasing proportion of cases have been identified among Black and Hispanic/Latino people. Black and Hispanic/Latino people are disproportionately affected by HIV. A CDC Health Alert Network (HAN) Health Advisory was released on September 29, 2022, to inform health care providers and is available at this link.

Severe manifestations of monkeypox can occur in both immunocompetent and immunocompromised people; however, most people diagnosed with monkeypox have had mild to moderate clinical courses. Of the people with severe manifestations of monkeypox for whom CDC has been consulted, the majority have had HIV with CD4 counts <200 cells/ml, indicating substantial immunosuppression. Health care providers should recognize underlying risk factors for severe disease, optimize immune function and, when appropriate, initiate medical countermeasures (such as TPOXX and vaccinia immunoglobulin) early to prevent or mitigate severe disease. CDC is available for clinical consultations for the treatment of monkeypox, particularly with severe cases. Contact your local health authority to arrange.

In addition, because persons with HIV-associated immunocompromise are at risk for severe manifestations of monkeypox, **CDC recommends that the HIV status of all sexually active adults and adolescents with suspected or confirmed monkeypox should be determined.**

Reporting of Possible Cases

To report possible cases or to request a clinical consultation with CDC, contact your local health authority.

Health Department	County	Phone Number to Report
Southern Nevada Health District (SNHD)	Clark	(702) 759-1300 (24 hours)
Washoe County Health District (WCHD)	Washoe	(775) 328-2447 (24 hours)
Carson City Health and Human Services (CCHHS)	Carson City, Douglas and Lyon	(775) 887-2190 (24 hours)
Nevada Division of Public and Behavioral Health (DPBH)	All other counties	(775) 684-5911 (M-F 8 am to 5 pm) (775) 400-0333 (after hours)

Questions: *For updated guidance, visit the DPBH Technical Bulletin website. Email stateepi@health.nv.gov for other questions regarding monkeypox.*

Lisa Sherych, Administrator
Division of Public and Behavioral Health

Ihsan Azzam, Ph.D., M.D.
Chief Medical Officer

[3] https://emergency.cdc.gov/han/2022/han00475.asp