Centers for Disease Control and Prevention

Mpox

Mpox Home

Treatment Information for Healthcare Professionals

Updated March 22, 2023

Patients are still developing severe mpox. A March 3, 2023, MMWR provides updated clinical treatment considerations about using therapeutics to treat severe mpox cases, including ocular infections, neurologic complications, myopericarditis, complications associated with mucosal lesions, and complications from uncontrolled viral spread.

Interim Clinical Guidance for the Treatment of Mpox

The ongoing mpox outbreak in the United States is caused by Clade IIb of the mpox virus. Patients with mpox benefit from supportive care and pain control that is implemented early in the illness (Clinical Considerations for Pain Management of Mpox). Illness depends on a person's immune response. For most patients with intact immune systems, supportive care and pain control may be enough. For information about skin and wound care for individuals with mpox lesions, please visit Mpox: Caring for the Skin and Mpox: Treating Severe Lesions. 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; a large number of lesions such that they are confluent; necrotic lesions; severe lymphadenopathy that can be necrotizing or obstructing (such as in airways); involvement of multiple organ systems and associated comorbidities (for example, pulmonary involvement with nodular lesions; sepsis; encephalitis; myocarditis; 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 anorectum with the potential for causing strictures or requiring catheterization; anorectal 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[1]
- Pediatric populations, particularly patients younger than 1 year of age
- Pregnant or breastfeeding people[2]
- 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.

Current CDC Mpox Studies

Virologic and Immunologic Characteristics of Severe Mpox in People with Advanced HIV (VIRISMAP)

People with advanced HIV who contract mpox have an increased risk of severe manifestations of mpox and mortality; CDC published "Interim Clinical Considerations for Severe Manifestations of Mpox" in MMWR to provide guidance for these cases. CDC is also collaborating with the National Institutes of Health to study the extent of mpox viral spread and immunologic markers in people with advanced HIV. The goal of the study is to determine why some patients experience severe mpox manifestations and to increase understanding of mpox pathogenesis. The study results may inform treatment and prevention of severe illness and deaths associated with mpox in people with advanced HIV.

The study will include U.S. residents 18 years of age or older who have HIV with CD4 counts of < 200 cells/mm^3 and are hospitalized with probable or confirmed mpox. During hospitalization, clinicians will collect physical exam data and samples for further analysis.

Clinicians whose patients meet the above criteria and are interested in participating in the study may contact the study investigators by emailing poxvirus@cdc.gov.

Medical Countermeasures Available for the Treatment of Mpox

Currently there is no treatment approved specifically for mpox virus infections. However, United States Government (USG)-stockpiled antivirals, developed for use in patients with smallpox, may be beneficial against mpox. The medical countermeasures currently available from the Strategic National Stockpile (SNS) as options for the treatment of mpox include tecovirimat, brincidofovir, and vaccinia immune globulin. Cidofovir is also available commercially.

Clinicians should first consider tecovirimat in treating mpox virus infections in people. Patients should be informed about the clinical trial for tecovirimat (STOMP clinical trial) and encouraged to consider enrollment. For patients who are not eligible for STOMP or who decline to participate, tecovirimat can also be provided under an expanded access protocol.

STOMP Clinical Study

Learn about the Study of Tecovirimat for Human Mpox Virus (STOMP) , a NIAID-funded clinical trial to evaluate the effectiveness of the antiviral tecovirimat, also known as TPOXX.

CDC is providing this information as a resource for people who may be interested in the NIH-funded tecovirimat study.

Additional medical countermeasures can be considered as additive or alternative therapy for treating mpox virus infections in certain situations such as:

1. People experiencing severe disease at initial presentation to healthcare or at high risk for progression to severe disease
2. People experiencing clinically significant disease progression while receiving tecovirimat or who develop recrudescence (initial improvement followed by worsening) of disease after an initial period of improvement on tecovirimat
3. People experiencing severe immunocompromise
4. People for whom there is concern for the development of resistance to tecovirimat
5. People allergic to or otherwise unable to receive tecovirimat

Decisions on whether and when to use these medical countermeasures must be made individually for each person and can depend on a variety of clinical and other parameters. Healthcare providers preferring a clinical consultation with CDC or have patient management questions may contact the CDC Emergency Operations Center [EOC] at (770) 488-7100

Tecovirimat (also known as TPOXX, ST-246)

Tecovirimat is an antiviral medication that is approved by the United States Food and Drug Administration (FDA) [565 KB, 24 pages] for the treatment of smallpox in adults and children. Data are not available on the effectiveness of tecovirimat in treating mpox infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopoxviruses. A clinical trial focused on safety in healthy people without mpox virus showed the drug had an acceptable safety profile; the effectiveness of tecovirimat was not studied in this trial. As mentioned above, there is an ongoing clinical trial (STOMP) to assess the effectiveness of tecovirimat for the treatment of mpox. CDC holds an expanded access Investigational New Drug (IND) protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat mpox during an outbreak. Tecovirimat is available as a pill or an injection.

Tecovirimat can be considered for prophylactic use in an exposed person with severe immunodeficiency in T-cell function for which smallpox or mpox vaccination following exposure to mpox virus is contraindicated.

> **More details:** Guidance for Tecovirimat Use; Tecovirimat IND; STOMP Clinical Study

Brincidofovir (also known as CMX001 or Tembexa)

Brincidofovir is a prodrug of cidofovir that is approved by the FDA [670 KB, 21 pages] for the treatment of human smallpox disease in adult and pediatric patients, including neonates. Data are not available on the effectiveness of brincidofovir in treating mpox virus infection in people. However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies. Brincidofovir should not be used simultaneously with cidofovir.

Brincidofovir is made available from the SNS for treatment of mpox to clinicians who request and obtain an FDA-authorized single-patient emergency use IND (e-IND). Brincidofovir can be considered for use under an e-IND for treatment of human mpox disease in adults and pediatric patients (including neonates) with positive results of human mpox viral testing who:

- Have severe disease **OR** are at high risk for progression to severe disease,
- **AND meet either of the following:**
  - Experience clinically significant disease progression while receiving tecovirimat or who develop recrudescence (initial improvement followed by worsening) of disease after an initial period of improvement on tecovirimat, *OR*
  - Are otherwise ineligible or have a contraindication for oral or intravenous tecovirimat

Clinicians with mpox patients necessitating brincidofovir treatment may submit an e-IND request to FDA by email (DDI.EIND@fda.hhs.gov) or phone 301-796-3400 or 1-855-543-3784 during normal business hours (8 am-4:30 pm ET M-F) or completing an electronic request to FDA. During after hours, call the FDA Emergency Coordinator at 1-866-300-4374 or 301-796-8240 or email CDER-EIND@fda.hhs.gov and call the CDER Emergency Coordinator at 301-796-9900.

Vaccinia Immune Globulin Intravenous (VIGIV)

VIGIV is licensed by FDA [196 KB, 18 pages] for the treatment of complications due to vaccinia vaccination. However, it is not approved for treatment of mpox. Therefore, CDC holds an expanded access IND protocol [409 KB, 27 pages] that allows the use of stockpiled VIGIV for the treatment of orthopoxviruses (including mpox) in an outbreak.

Data are not available on the effectiveness of VIGIV in treatment of mpox virus infection in people. Use of VIGIV has no proven benefit in the treatment of mpox and it is unknown whether a person with severe mpox infection will benefit from treatment with VIGIV. However, healthcare providers may consider its use in severe cases where the development of a robust antibody response may be impaired.

VIGIV can be considered for prophylactic use in an exposed person with severe immunodeficiency in T-cell function for which smallpox or mpox vaccination following exposure to mpox virus is contraindicated.

VIGIV is not prepositioned by the USG. It is available upon clinician request to CDC on a case-by-case basis. To request VIGIV, clinicians can contact the CDC Clinical Consultation Team by email (poxvirus@cdc.gov) during business hours, or for urgent clinical situations, contact the CDC Emergency Operations Center (770-488-7100). An informed consent [278 KB, 6 pages] must be obtained prior to administration. The remaining VIGIV IND fillable forms will be provided to clinicians requesting VIGIV.

Cidofovir (also known as Vistide)

Cidofovir is an antiviral medication that is approved by the FDA [828 KB, 6 pages] for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS), and is commercially available as an injection. Data are not available on the effectiveness of cidofovir in treatment of mpox virus infection in people. However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies. It is unknown whether a person with severe mpox infection will benefit from treatment with cidofovir, although its use may be considered in such instances. Brincidofovir (a prodrug of cidofovir) may have an improved safety profile over cidofovir. Serious renal toxicity or other adverse events have not been observed during treatment of cytomegalovirus infections with brincidofovir as compared to treatment using cidofovir. Cidofovir should not be used simultaneously with brincidofovir.

Related Links

Mpox Vaccine Considerations for Health Professionals

References

[1]Ogoina D, Iroezindu M, James HI, Oladokun R, Yinka-Ogunleye A, Wakama P, Otike-Odibi B, Usman LM, Obazee E, Aruna O, Ihekweazu C. Clinical Course and Outcome of Human Monkeypox in Nigeria. Clin Infect Dis. 2020 Nov 5;71(8):e210-e214. doi: 10.1093/cid/ciaa143. PMID: 32052029.

[2] Mbala PK, Huggins JW, Riu-Rovira T, Ahuka SM, Mulembakani P, Rimoin AW, Martin JW, Muyembe JT. Maternal and Fetal Outcomes Among Pregnant Women With Human Monkeypox Infection in the Democratic Republic of Congo. J Infect Dis. 2017 Oct 17;216(7):824-828. doi: 10.1093/infdis/jix260. PMID: 29029147.

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