Centers for Disease Control and Prevention

Monkeypox

# Treatment Information for Healthcare Professionals

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## Interim Clinical Guidance for the Treatment of Monkeypox

The ongoing monkeypox outbreak in the United States is caused by Clade IIb of the monkeypox virus. Patients with monkeypox benefit from supportive care and pain control that is implemented early in the illness (Clinical Considerations for Pain Management of Monkeypox). 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 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[1]
- Pediatric populations, particularly patients younger than 8 years of age[2]
- Pregnant or breastfeeding people[3]
- 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.

## Medical Countermeasures Available for the Treatment of Monkeypox

Currently there is no treatment approved specifically for monkeypox virus infections. However, antivirals developed for use in patients with smallpox may prove beneficial against monkeypox. The following medical countermeasures are currently available from the Strategic National Stockpile (SNS) as options for the treatment of monkeypox:

## Tecovirimat (also known as TPOXX, ST-246)

Tecovirimat is an antiviral medication that is approved by the United States Food and Drug Administration (FDA) [PDF – 24 pages] for the treatment of smallpox in adults and children. Data are not available on the effectiveness of tecovirimat in treating monkeypox 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 monkeypox virus showed the drug had an acceptable safety profile; the effectiveness of tecovirimat was not studied in this trial. CDC holds an expanded access New Investigational Drug protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat monkeypox during an outbreak. Tecovirimat is available as a pill or an injection.

> **More details:** Guidance for Tecovirimat Use; How to Obtain and Use Tecovirimat

## Vaccinia Immune Globulin Intravenous (VIGIV)

VIGIV is licensed by FDA [PDF – 18 pages] for the treatment of complications due to vaccinia vaccination. CDC holds an expanded access protocol that allows the use of VIGIV for the treatment of orthopoxviruses (including monkeypox) in an outbreak.

Data are not available on the effectiveness of VIGIV in treatment of monkeypox virus infection. Use of VIGIV has no proven benefit in the treatment of monkeypox and it is unknown whether a person with severe monkeypox infection will benefit from treatment with VIGIV. However, healthcare providers may consider its use in severe cases.

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

## Cidofovir (also known as Vistide)

Cidofovir is an antiviral medication that is approved by the FDA [PDF – 6 pages] for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS). Data are not available on the effectiveness of cidofovir in treating human cases of monkeypox. However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies. CDC holds an expanded access protocol that allows for the use of stockpiled cidofovir for the treatment of orthopoxviruses (including monkeypox virus) in an outbreak. It is unknown whether or not a person with severe monkeypox infection will benefit from treatment with cidofovir, although its use may be considered in such instances. Brincidofovir 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.

## Brincidofovir (also known as CMX001 or Tembexa)

Brincidofovir is an antiviral medication that was approved by the FDA [PDF – 21 pages] on June 4, 2021 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 cases of monkeypox in people. However, it has shown to be effective against orthopoxviruses in *in vitro* and animal studies. CDC is currently developing an EA-IND to help facilitate use of brincidofovir as a treatment for monkeypox. However, brincidofovir is not currently available from the SNS.

### Related Links

Monkeypox and Smallpox Vaccine Guidance for Clinicians

Smallpox Vaccination Information for Health Professionals

Smallpox Vaccine Information for the General Public

# 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]Jezek Z, Szczeniowski M, Paluku KM, Mutombo M. Human monkeypox: clinical features of 282 patients. J Infect Dis. 1987 Aug;156(2):293-8. doi: 10.1093/infdis/156.2.293. PMID: 3036967.

[3] 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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