



August 8, 2022

Current Therapeutic Guidance on Monkeypox

On August 4, 2022, the White House declared monkeypox a public health emergency. On July 23, 2022, the World Health Organization (WHO) determined that the current multi-country outbreak of monkeypox constitutes a Public Health Emergency of International Concern.¹

Monkeypox Vaccination – CDC Recommendations:

The CDC recommends vaccination for people who have been exposed to monkeypox and people who are at higher risk of being exposed to monkeypox, including:

- **Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)** - People who have been identified by public health officials as a contact of someone with monkeypox.
- **Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)++** (Also known as “individual-directed PEP”, “expanded PEP”, “PEP plus-plus”, or “PEP++”) - People who may have been exposed to monkeypox, such as:
 - People aware that one of their sexual partners in the past 2 weeks has been diagnosed with monkeypox
 - People who had multiple sexual partners in the past 2 weeks in an area with known monkeypox
- **Monkeypox Vaccine Pre-Exposure Prophylaxis (PrEP)** - People [whose jobs may expose them to orthopoxviruses](#), such as:
 - Laboratory workers who perform testing for orthopoxviruses
 - Laboratory workers who handle cultures or animals with orthopoxviruses
 - Some designated healthcare or public health workers
 - *At this time, most U.S. clinicians and laboratorians not performing the orthopoxvirus test to diagnose orthopoxviruses, including monkeypox, are not advised to receive monkeypox vaccine PrEP.*^{2,3}
 - **When more JYNNEOS vaccine is available, broader vaccination of people who may be at risk for future monkeypox exposure may be considered.**

The CDC has released recent clinical guidance for healthcare professionals covering the following scenarios:

1. **Pediatric Considerations (7/26/2022)^{4, 10}**
 - Monkeypox should be considered when children or adolescents present with a rash that could be consistent with the disease, especially if epidemiologic criteria are present.
 - Young children, children with eczema and other skin conditions, and children with immunocompromising conditions may be at increased risk of severe disease.
 - Treatment should be considered on a case-by-case basis for children and adolescents with suspected or confirmed monkeypox who are at risk of severe disease or who develop complications of monkeypox. Tecovirimat is the first-line medication to treat monkeypox, including in children and adolescents.
 - Children and adolescents with exposure to people with suspected or confirmed monkeypox may be eligible for post-exposure prophylaxis (PEP) with vaccination, immune globulin, or antiviral medication.
 - The monkeypox vaccine, JYNNEOS, is licensed by the FDA for use in the prevention of smallpox or monkeypox in people ages 18 years and older. Use in younger populations currently requires requesting and obtaining a single patient EUA from the FDA for each person under 18 years. CDC is developing an [Expanded Access Investigational New Drug](#) protocol to allow broader use of JYNNEOS in the pediatric population.
2. **Considerations for People with HIV (7/21/2022)⁴**
 - People with advanced HIV or who are not virologically suppressed with antiretroviral therapy can be at increased risk of severe disease related to monkeypox virus infection.
 - Post-exposure prophylaxis and antiviral treatments are available for persons exposed to monkeypox or with monkeypox virus infection. Vaccination with JYNNEOS is considered safe for people with HIV, and antiviral treatments have few interactions with antiretroviral therapy.
3. **Pregnancy Considerations (7/18/2022)⁴**
 - Monkeypox virus can be transmitted to the fetus during pregnancy or to the newborn by close contact during and after birth.
 - While most non-pregnant adults with a monkeypox virus infection experience mild illness and recover spontaneously, pregnant, recently pregnant, and breastfeeding people should be prioritized for medical treatment if needed. This is because of the probable increased risk of severe disease during pregnancy, risk of transmission to the fetus during pregnancy or to the newborn by close contact during and after birth, and risk of severe infection in newborns.

The compiled CDC clinical guidance for healthcare professionals can be accessed [here](#).⁴

Tecovirimat for the Treatment of Monkeypox Disease:⁵

Tecovirimat (also known as TPOXX) is FDA-approved for the treatment of human smallpox disease caused by Variola virus in adults and children. However, its use for other orthopoxvirus infections, including monkeypox, is not approved by the FDA. The CDC holds a non-research expanded access [Investigational New Drug \(EA-IND\) Protocol](#) that allows for the use of tecovirimat for primary or early empiric treatment of monkeypox in adults and children of all ages. ***IHS facilities may utilize tecovirimat for the treatment of monkeypox in eligible patients consistent with the stipulations of the EA-IND protocol, not requiring IHS Institutional Review Board action.***

Tecovirimat may be considered for treatment in people infected with monkeypox;

- With severe disease
- Who are at high risk of severe disease (e.g. immunocompromising conditions, pediatric populations, pregnant or breastfeeding women, people with history of atopic dermatitis or other active exfoliative skin conditions, people with one or more complications of infection)
- With aberrant infections involving accidental implantation in the eyes, mouth, genitals, or anus

CDC-required forms and guidance for all healthcare providers administering tecovirimat (TPOXX) can be [viewed here](#) in its entirety and includes the: (1) [Informed Consent Form](#), (2) [Patient Intake Form](#), (3) [FDA Form 1572](#), (4) [Clinical Outcome Form](#), and (5) [MedWatch Form \(**for serious adverse events\)](#). Forms shall be submitted by the healthcare provider to CDC via email (regaffairs@cdc.gov) or uploading to [ShareFile](#). Serious adverse events shall be reported within 72 hours of awareness or sooner, if possible. ***Federal, Tribal, and Urban programs are all encouraged to enter "IHS" into field #26 of Medwatch reporting forms.***

Availability:

The IHS National Supply Service Center (NSSC) has received an initial allocation of JYNNEOS vaccine for use by federal, tribal, and Urban Indian Organization programs for post-exposure prophylaxis of eligible high-risk persons. NSSC has also received an initial allocation of oral tecovirimat for the outpatient management of eligible patients with suspected or confirmed monkeypox. Currently, to request a distribution of either JYNNEOS or TPOXX, the individual facility should submit an IHS-413 form to aaron.wyatt@ihs.gov and cathy.thomas2@ihs.gov, with andrea.klimo@ihs.gov included in the e-mail request. The product ships directly to the facility from the NSSC Oklahoma City, OK warehouse.

Further information:

- The CDC hosted a Clinical Outreach and Community Activity Call on July 26, 2022 – Monkeypox Outbreak: Updates on the Epidemiology, Testing, Treatment, & Vaccination (recording available [here](#))⁶
- Information on how to obtain and current monkeypox therapeutics is available via a recently distributed IHS NPTC document: [Access to Available Monkeypox Therapies](#)⁷.
- Additional information, including background, transmission, signs and symptoms, pre-exposure prophylaxis, and post-exposure treatment is available through the IHS NPTC's recently distributed document, [Emerging Treatment Update: Monkeypox Potential Pre- and Post-Exposure Therapies](#)⁸.

References:

1. World Health Organization, [Second meeting of the International Health Regulations \(2005\) \(IHR\) Emergency Committee regarding the multi-country outbreak of monkeypox](#), Published July 23, 2022
2. Centers for Disease Control and Prevention. [Prevention](#). Published July 11, 2022.
3. Centers for Disease Control and Prevention. [Considerations for Monkeypox Vaccination](#). Published June 30, 2022.
4. Centers for Disease Control and Prevention. [Clinical Guidance](#). Updated July 21, 2022.
5. Centers for Disease Control and Prevention. [Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Cases](#). Updated August 3, 2022.
6. Centers for Disease Control and Prevention. [Monkeypox Outbreak: Updates on the Epidemiology, Testing, Treatment, and Vaccination](#), Recorded July 26, 2022.
7. Indian Health Services National Pharmacy and Therapeutics Committee. [Access to Available Monkeypox Therapies](#), July 21, 2022.
8. Indian Health Services National Pharmacy and Therapeutics Committee. [Emerging Treatment Update: Monkeypox Potential Pre- and Post-Exposure Therapies](#), June 30, 2022.
9. Centers for Disease Control and Prevention. [Considerations for Monkeypox Vaccination](#). Published July 28, 2022.
10. Department of Health and Human Services. [Biden-Harris Administration Bolsters Monkeypox Response: HHS Secretary Becerra Declares Public Health Emergency](#). Published online August 4, 2022.