



IHS MPOX PrEP INITIATIVE Vaccine (JYNNEOS)



Background:

On August 4, 2022, the Biden Administration declared the ongoing spread of *mpox virus* in the United States a [public health emergency](#). On August 9, 2022, the U.S. Department of Health and Human Services (HHS) distributed 2,000 vials of JYNNEOS vaccine to the Indian Health Service (IHS) National Supply Service Center in support of post-exposure prophylaxis (PEP) and individual directed post-exposure prophylaxis (PEP++), in accordance with CDC [therapeutic guidance for mpox](#). In addition to these current indications for JYNNEOS vaccine, in consultation with CDC, IHS is undertaking a **mpox PrEP Initiative** to supplement PEP/PEP++ and to further reduce the potential impact of mpox in Indian Country.

Current Status & Indications:

JYNNEOS vaccine is used for the prevention of smallpox and mpox disease among people determined to be at high risk for infection and is licensed as a series of two doses administered 28 days (4 weeks) apart. On August 9, 2022, the U.S. Food and Drug Administration (FDA) [authorized the intradermal administration](#) of the Jynneos vaccine for the management of mpox, which may permit five doses to be obtained out of a one-dose vial. The Emergency Use Authorization (EUA) also expanded use of the standard subcutaneous dose regimen to patients <18 years of age.

According to [current CDC guidance](#), jurisdictional vaccine strategies should reflect national priorities to primarily employ PEP and PEP++ approaches before other vaccination strategies. **However, in some jurisdictions, consideration of mpox vaccine PrEP for individuals at increased risk of mpox from non-occupational exposure might start to be considered. Where applicable, plans to introduce mpox vaccine PrEP should focus on strategies likely to have the largest impact in slowing the current outbreak.**

In accordance with this guidance, IHS is expanding the eligibility criteria for mpox vaccination to include;

- Anyone (any sexual orientation or gender identity) who has had close physical contact with someone who has mpox in the last 14 days.
- Anyone (any sexual orientation or gender identity) who:
 - Has had multiple sexual partners in the last 14 days, or
 - Has had sexual partners they did not previously know in the last 14 days, or
 - Has had close physical contact with other people in a venue where anonymous or group sex may occur in the last 14 days, or
 - Was diagnosed with gonorrhea or syphilis in the past three months, or
 - Already uses or is eligible for HIV PrEP (medication to prevent HIV, e.g. Truvada or Descovy or Apretude), or
 - Engages in commercial and/or transactional sex (e.g. sex in exchange for money, shelter, food, and other goods or needs).
- Anyone (any sexual orientation or gender identity) identified by public health as a known high-risk contact of someone who has mpox.

IHS will continue to revisit criteria for mpox vaccination; eligibility may continue to change as supply from the federal government increases.

Availability, Prioritization, Reporting, and Scalability:

Due to initial supply-chain limitations, I/T/U mpox PrEP sites will be prioritized based on site readiness and factors that promote need and equity such as geographic region, proportion of persons identified as high risk, and the epidemiology of current outbreaks. Participating sites will be expected to regularly report inventory and utilization (e.g. HHS Health Partner Ordering Portal, IHS National Pharmacy & Therapeutics Committee Emerging Treatments Survey) in support of continuing distributions. As supply increases, the goal is to scale-up mpox PrEP operations where applicable based on the trajectory of the outbreak, including sharing of best practices by participating sites.

Criteria for Participation as an IHS mpox PrEP I/T/U site:

1. Plan to prioritize JYNNEOS vaccine for PEP and PEP++, in accordance with current CDC guidance.
2. Assessment of local epidemiology and identification of high-risk patients (pursuant to all applicable Privacy Act, HIPAA, and other privacy-related policies and requirements).
3. Site requesting JYNNEOS as part of the IHS mpox PrEP Initiative will undertake a **self-assessment** of readiness to administer the product as PrEP (including current policies/procedures in place). At a minimum, elements of self-assessment shall include;
 - Adherence to all components of the FDA product approval and Emergency Use Authorization,
 - Patient Access & Vaccine Administration Logistics
 - [Monitoring & Risk Assessment for Persons Exposed to mpox](#)
 - Process for tracking & reporting [Adverse Vaccine Events](#) to VAERS or in accordance with EUA.
4. Self-identify as a participating mpox PrEP site to the IHS National Pharmacy and Therapeutics Committee by submitting an e-mail (Subject Line: mpox PrEP Site) to IHSMedsafety@IHS.gov.
5. Site will participate in all storage, dispensing, utilization, inventory management, and other reporting requirements per HHS and IHS policy related to the mpox PrEP Initiative.