

## OHA Interim monkeypox (hMPXV) Vaccination Guidance

Aug. 22, 2022

This interim guidance updates recommendations for the use of the Jynneos vaccine as post-exposure prophylaxis (PEP) and pre-exposure prophylaxis (PrEP) against hMPXV in Oregon (Table). We will no longer use the terms “expanded PEP” or “PEP+.” The ultimate goal of the Oregon Health Authority (OHA) vaccine strategy is for everyone who wants a vaccine to receive a vaccine. However, given the limited availability of the Jynneos vaccine, we have developed the following vaccine eligibility criteria to meet the needs of those at highest risk of hMPXV infection.

### A. Eligibility

Method	Standard post-exposure prophylaxis (PEP)	Pre-exposure prophylaxis (PrEP)
Inclusion Criteria	<ol style="list-style-type: none"> <li>1. Contacts of people with presumptive or confirmed hMPXV as identified through local public health authority (LPHA) partner and field services</li> <li>2. Contacts of people with presumptive or confirmed hMPXV in another jurisdiction</li> <li>3. Vaccination can also be considered for contacts of people with suspected hMPXV if the index of suspicion for hMPXV in the case is high and timely vaccination of contacts may not otherwise be possible</li> </ol>	<ol style="list-style-type: none"> <li>1. Cisgender men, transgender men, transgender women and non-binary people who have sex with men and who:               <ol style="list-style-type: none"> <li>a. have had more than one sex partner in an area experiencing community transmission in the prior two weeks,</li> <li>b. are taking HIV pre-exposure prophylaxis,</li> <li>c. are living with HIV and/or</li> <li>d. have been diagnosed with a sexually transmitted infection in the prior three months</li> </ol> </li> <li>2. People of any gender or sexual orientation engaged in sex work or other forms of transactional sex</li> </ol>
Timeline for Implementation	Now	Now

- a. **PEP** is to be used in any area where contacts of people with presumptive or confirmed hMPXV are identified through local public health authority (LPHA) case investigation and contact tracing in Oregon. In addition, people who self-report contact with someone with presumptive or confirmed hMPXV outside of Oregon may be eligible for PEP. Vaccination of contacts of people with suspected hMPXV can also be considered if the index of suspicion for hMPXV in the case is high and to ensure PEP administration within 14 days. PEP prioritizes those with [high- and intermediate-risk exposures](#).
- b. **PrEP** is based on characteristics of people diagnosed with hMPXV that indicate an increased risk of hMPXV infection. Cisgender men, transgender men, transgender women and non-binary people who have sex with men and who have had more than one sex partner in an area experiencing community transmission in the prior 2 weeks are taking HIV pre-exposure prophylaxis (either oral or injectable), are living with HIV and/or have been diagnosed with a sexually transmitted infection in the three months prior to infection are eligible

for PrEP. In addition, people of any gender or sexual orientation engaged in sex work or other forms of transactional sex including the exchange of sex for money, drugs or other things of value, including but not limited to food, shelter, protection, bills/rent, gifts and childcare.

**People eligible under prior expanded PEP or PEP+ criteria are eligible for PrEP**, including people with more than one anonymous partner and/or more than one partner at a bathhouse, sex club, sex party, adult bookstore or any other sex-on-site venue in an area experiencing community transmission in the 2 weeks prior to infection.

## B. Implementation

- a. **Intersectional implementation of PrEP** through clinics and organizations that serve Black, Indigenous, Latinx, Native Hawaiian/Pacific Islander and Asian people, sex workers, people experiencing houselessness or incarceration, people living with HIV and people who use methamphetamines may make vaccine distribution **more equitable and effective** at the population level. OHA will convene community partners and providers serving the queer community with an intersectional lens to guide equitable vaccine access and distribution.
- b. **LPHAs and community partners may adapt PrEP criteria** based on local hMPXV epidemiology with OHA consultation.
- c. Based on CDC guidance, we will transition to **intra dermal (ID) administration** for most people to increase the number of vaccine doses available for PEP and PrEP. Please see the [OHA Jynneos Immunization Protocol](#) for details. We anticipate that depending on the dead space associated with the needle and syringe combination to administer ID doses, each 0.5 mL vial will provide about three to five doses. Once the vial is punctured, all vaccine must be administered within eight hours. Batching appointments for vaccination during clinic sessions or vaccination events may reduce the risk of wasted doses. However, it is not always possible to anticipate missed appointments or other reasons for leftover doses. **To maximize the use of all vaccine doses, we recommend planning ahead to identify and contact people who can receive a vaccine dose prior to the end of a vaccination clinic session, including:**
  - i. People eligible for PrEP who have not yet received a first dose (e.g., on a waiting list of eligible people awaiting first doses)
  - ii. People who received a first dose at least 28 days prior (e.g., on a list of people who have already received first doses), prioritizing those who received their first dose earliest
  - iii. People who may not be eligible by the current PrEP criteria and who could benefit from vaccination (e.g., one new sex partner in the prior two weeks, STI in the prior six to 12 months, employees of bathhouses, sex clubs and other sex-on-premises venues and/or dancers in adult entertainment clubs)
  - iv. Clinical providers and staff who have cared for more than one patient who tested positive for orthopox virus or hMPXV
- d. **OHA will continue to employ a strategy that prioritizes first vaccine doses until supply increases.** OHA will prioritize rapid vaccination of as many people at risk for hMPXV as possible. This strategy means that people eligible for PEP and PrEP will be provided a first dose of Jynneos followed by a second dose about three months later. People will not need to re-start the vaccine series if the second dose is administered more than 28 days after the first.
- e. While over 90% of people generate an antibody response two to four weeks after the [first dose](#), two doses provide the best protection against hMPXV with peak antibody response reached two weeks after the second dose. Vaccine providers should counsel people on reducing the risk of hMPXV infection as they await their second dose. **As early as the beginning of September, OHA will work with partners to provide second doses as close to the recommended schedule as possible.**

The available scientific evidence supports prioritizing first doses, including:

- [First-generation live vaccinia virus vaccines](#) given to people exposed to smallpox virus
  - Prevented smallpox disease when given within three days of exposure
  - Prevented smallpox disease when given within 12 days of exposure **and prior to appearance of rash**
- In a 2019 [New England Journal of Medicine](#) report, scientists compared immune responses in people given either Jynneos or ACAM2000. The researchers found that 14 days after a single dose, the levels of neutralizing antibodies (the key measure of protection against hMPXV) were similar and over 90% proportion of experiencing seroconversion in both study arms.
- In another [study](#) comparing Jynneos to ACAM2000, Jynneos appeared to elicit an immune response, including neutralizing antibodies and CD8 cells, more rapidly (on day seven versus day 10) and blunted hMPXV replication more robustly after a viral challenge at four days post-vaccination based on viremia and severity of clinical illness.
- [Similarly](#), Jynneos administered on either the same day as, or two days after, a lethal challenge with ectromelia virus (a variola-related murine virus) fully protected immune-suppressed mice.

Per an article in [Science magazine](#), “Bavarian Nordic CEO Paul Chaplin, an immunologist, also embraces the single dose plan. Studies have shown that immune responses triggered by a single shot of the [Jynneos] vaccine declines after two years, which is why the approved vaccine schedule calls for a second shot. But Chaplin says immune memory is so robust after a single dose that a booster given two years later leads to the same immune response as the standard schedule. If countries decide to use single shots now, they have a long time to add the booster and still achieve the durability benefit, he believes. ‘There are a lot of data to support the single shot,’ Chaplin says.”

Therefore, single-dose PEP with Jynneos given within 14 days of an exposure to hMPXV and prior to the appearance of rash could prevent illness (if given on days 0–4) or reduce disease severity and transmissibility (if given on days 5–14). **Paired with other prevention measures**, PEP and PrEP are important tools to prevent further hMPXV transmission.

**For people who may not respond as well to vaccination**, including pregnant people, people living with [HIV with CD4 counts less than 200 cells/mm<sup>3</sup>](#) or other forms of moderate to severe immunosuppression, we will continue to offer second doses as close to 28 days after the first dose as possible.

People living with other forms of moderate to severe immunosuppression include those who:

- Are receiving active cancer treatment for tumors or cancers of the blood
- Received an organ transplant and are taking medicine to suppress their immune system
- Received chimeric antigen receptor (CAR)-T-cell therapy (a treatment to help the immune system attach to and kill cancer cells) or received a stem cell transplant within the last two years
- Have moderate or severe primary immunodeficiency (such as DiGeorge syndrome or Wiskott-Aldrich syndrome)
- Are receiving active treatment with high-dose corticosteroids or other drugs that may suppress their immune response

We will continue to update hMPXV vaccine guidance pending the course of hMPXV spread and as more vaccine becomes available in Oregon.