



# Standing Orders for Administering JYNNEOS (Mpox) Vaccine by Subcutaneous Injection to Persons 18 Years of Age and Older\*

# **Purpose**

To reduce morbidity and mortality from mpox by vaccinating people who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP).

# **Policy**

Where authorized under state law, standing orders enable eligible nurses and other health care professionals (e.g., pharmacists) to assess and vaccinate people who meet the criteria in the "Procedure" section below without the need for clinician examination or direct order from the attending provider at the time of the interaction.

## **Procedure**

- 1. Assess people 18 years of age and older for need for vaccination with JYNNEOS (Mpox) vaccine against mpox based on the following criteria:
  - Gay, bisexual, and other men who have sex with men, transgender or nonbinary people who in the past 6 months have had one of the following:
    - » A new diagnosis of 1 or more sexually transmitted infection
    - » More than one sex partner
    - » Sex at a commercial sex venue
    - » Sex in association with a large public event in a geographic area where mpox transmission is occurring
  - · Sexual partners of people with the risks described above
  - People who anticipate experiencing any of the above

Mpox infection history: A person who would be eligible for vaccination but has been diagnosed with mpox is not recommended to be vaccinated at this time, because mpox infection likely confers immune protection.

### 2. Screen for contraindications and precautions

#### Contraindication

Do not give mpox vaccine to a person who has experienced a severe allergic reaction (e.g., anaphylaxis) to a
previous dose of vaccine or to any of its components. Mpox vaccine contains small amounts of gentamicin and
ciprofloxacin and is produced using chicken embryo fibroblast cells. For a list of vaccine components, refer to
the manufacturer's package insert (see <a href="https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccineslicensed-use-united-states">https://www.fda.gov/vaccines-blood-biologics/vaccines/vaccineslicensed-use-united-states</a>).

#### Precaution

Moderate or severe acute illness with or without fever

## 3. Provide Vaccine Information Statements

- Provide all patients with a copy of the most current federal Vaccine Information Statement (<u>VIS</u>). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/translations/ (For information about how to document that the VIS was given, see section 5 titled "Document Vaccination.")
- \* JYNNEOS may be administered by subcutaneous injection to children and adolescents under 18 years of age determined to be at high risk for mpox under the <a href="Emergency Use Authorization (EUA)">Emergency Use Authorization (EUA)</a> issued by the US Food and Drug Administration. For more information see: Vaccination | Mpox | Poxvirus | CDC

### 4. Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

Age	Needle Gauge	Needle Length	Injection Site
18 years and over	23-25	5/8"	upper-outer triceps area

Administer mpox vaccine, 0.5 mL, via the subcutaneous (subcut) route, according to the table below.

#### Schedule for routine vaccination

HISTORY OF PREVIOUS MPOX VACCINATION	DOSE AND SCHEDULE FOR ADMINISTRATION OF MPOX
Unvaccinated (0 documented doses)	Give a 2-dose series. Administer Dose 1 now. Administer Dose 2 at least 4 weeks (28 days) after Dose 1.
1 previous dose of JYNNEOS	Give Dose 2 at least 4 weeks (28 days) after Dose 1.

Note: For individuals who would be eligible for their first or second dose of JYNNEOS but have been diagnosed with mpox, it is not recommended to be vaccinated at this time, because mpox infection likely confers immune protection.

#### 5. Document Vaccination

Document each patient's vaccine administration information in the following places:

- **Medical record:** The vaccine and the date it was administered, manufacturer, lot number vaccination site and route of administration, name and title of the person administering the vaccine
- Vaccination record for recipient: Date of vaccination, product name/manufacturer, lot number, and name/ location of the administering clinic or health care professional
- Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state or local IIS, if available.

#### 6. Be Prepared to Manage Medical Emergencies

### Observe Patients after Vaccination

- Vaccination providers should observe patients for 15 minutes after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope.
- Vaccine providers should be familiar with identifying immediate allergic reactions, including anaphylaxis, and be prepared to treat these events at the time of vaccine administration.
  - » Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.
  - » Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for several hours is advised, even after complete resolution of symptoms and signs.

## 7. Report Adverse Events to VAERS

The <u>Vaccine Adverse Event Reporting System (VAERS)</u> is the nation's early warning system that monitors the safety of vaccines after they are authorized or licensed for use by the U.S. Food and Drug Administration. VAERS accepts and analyzes reports of adverse events following vaccination. The following requirements are stipulated as part of the HHS mpox vaccine provider agreement:

- For JYNNEOS vaccine administered under the <a href="HHS Mpox Vaccination Program Provider Agreement">HHS Mpox Vaccination Program Provider Agreement</a>, the vaccination provider is responsible for mandatory reporting of the following listed events after JYNNEOS vaccination to VAERS:
  - » Vaccine administration errors, whether or not associated with an adverse event
  - » Serious\* adverse events (irrespective of attribution to vaccination)
  - » Cases of cardiac events, including myocarditis and pericarditis
  - » Cases of thromboembolic events and neurovascular events

\*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above
- Providers are encouraged to also report to VAERS any additional clinically significant adverse events following vaccination, even if they are not sure if vaccination caused the event.

When submitting a VAERS report, ensure that you document the Route of Vaccination in Section 17 of the VAERS form (e.g., "subcutaneous") from the selection menu.

For information on how to submit a report to VAERS, visit VAERS—Report an Adverse Event (hhs.gov) or call 1-800-822-7967.

# **Standing Orders Authorization**

effective	until rescind	led or until	(name of practice or clinic)
(dat		(date)	
Medical director (or	other authorized practi	tioner)	
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Adapted with appreciation from the Immunize.org standing orders