



# Clinician FAQs

Updated August 11, 2022

Questions and Answers About Monkeypox for Healthcare Professionals

Please refer to CDC's Information for Healthcare Professionals and Considerations for Monkeypox Vaccination for more information.

# Monkeypox Transmission, Risk, and Strains

How is monkeypox transmitted?

Monkeypox is transmitted by symptomatic individuals through close contact with lesions, bodily fluids, or respiratory secretions and objects that have had contact with lesion crusts or bodily fluids (e.g., contaminated linens, bandages, dishes). (See: Transmission | Monkeypox | Poxvirus | CDC)

When is someone with monkeypox contagious?

Stage of Disease	Transmissibility	Symptom monitoring or isolation?
Incubation Period	Not contagious	Monitor for symptoms
Prodrome	Possibly contagious	Isolate (at home or in a healthcare facility, as clinically indicated)
Rash	Contagious*	Isolate (at home or in a healthcare facility, as clinically indicated)

<sup>\*</sup> A person is contagious until after all the scabs on the skin have fallen off and a fresh layer of intact skin has formed.

Who is at increased risk for severe monkeypox disease?

Young children (<8 years of age), individuals who are pregnant or immunocompromised, and individuals with history of atopic dermatitis or eczema may be at especially increased risk for severe outcomes from monkeypox disease.

CDC lab experts have found at least two variants of monkeypox virus circulating in this outbreak. Both variants share common ancestors with strains present in Nigeria since 2017. It is likely that there were at least two separate events where the monkeypox virus spread from animals to people in Nigeria, and then began to spread person-to-person through close contact.

CDC lab experts are continuing to use genetic sequencing to better understand how cases might be linked to other cases in the US or in other countries.

# Clinical Guidance

What should prompt clinical suspicion for monkeypox infection?

Clinicians should be alert to patients presenting with a new characteristic rash or if the patient meets one of the epidemiologic criteria and there is a high clinical suspicion for monkeypox. The rash associated with monkeypox can be confused with other rashes encountered in clinical practice including herpes, syphilis, and varicella. Patients co-infected with *Monkeypox virus* and other infectious agents (e.g., varicella zoster, herpes, syphilis) have been reported. Clinicians should therefore have monkeypox on their differential diagnosis when presented with an STI-associated or STI-like rash, even if it is localized and not (yet) diffuse. Please refer to CDC's Case Definitions for use in the 2022 Monkeypox Response.

I diagnosed my patient with another infection (e.g., a sexually transmitted infection). Can I assume that they don't have monkeypox?

The cases of monkeypox described in the current outbreak have some atypical features. The rash may start in the genital and perianal areas, the rash may not always disseminate to other parts of the body and typical prodromal symptoms may be mild or absent. These features of the newest monkeypox cases can easily be confused with sexually transmitted infections (STI). It is important to comprehensively evaluate patients presenting with genital or perianal ulcers for STIs. However, co-infections with monkeypox and STIs have been reported and the presence of an STI does not rule out monkeypox. Patients with a new characteristic rash or who meet one or more of the epidemiologic criteria and in which there is a high suspicion should be tested for monkeypox.

My patient's orthopox or monkeypox test result is pending. What should I tell them to do in the meantime?

Instruct patients with suspected monkeypox infection to isolate themselves and avoid close contact with other people and animals, including pets. Patients who do not require hospitalization, but who are potentially infectious to others, should be isolated at home. (See When a patient is isolating in their home, what should they do?)

I suspect my patient has been exposed to monkeypox. What should I do?

- Clinicians should first consult their state health department (State Contacts ) as soon as a monkeypox exposure is suspected. A risk assessment will need to be conducted to determine if post-exposure medication or vaccination is recommended. Unique circumstances (e.g., immunocompromise) can be factored into the risk determination, but these decisions should be made on a case-by-case basis. For more information about exposures, refer to CDC's Monitoring People Who Have Been Exposed.
- Clinicians should advise the patient to isolate at home while diagnosis is being confirmed. See When a Patient is Isolating at Home What Should They Do?

- Patients who have been exposed to monkeypox, even if they do not have symptoms, may be eligible for post-exposure vaccination. For more information about available medications and vaccination, please refer to CDC's Monkeypox and Smallpox Vaccine Guidance.
- After exposure, the patient should be educated about the clinical presentations of monkeypox infection (see How should I counsel a patient with suspect or confirmed monkeypox on the expected course of illness) and instructed to contact their physician if they exhibit any of these clinical signs and symptoms as soon as possible.

## I suspect my patient has monkeypox. What should I do?

Clinicians should first isolate their patient in a single person room if available and immediately consult their state health department (State Contacts [2]) or CDC through the Emergency Operations Center (770-488-7100) as soon as monkeypox is suspected. Prompt notification is important to facilitate testing, exposure risk assessments for close contacts, and, for the patient or close contacts, consideration of available medications and vaccination. For specific information on Infection Prevention and Control, Isolation, and Personal Protective Equipment, refer to CDC's Infection Prevention and Control of Monkeypox in Healthcare Settings. For more information about available medications and vaccination, please refer to CDC's Monkeypox and Smallpox Vaccine Guidance.

How should I counsel a patient with suspect or confirmed monkeypox on the expected course of illness?

- Monkeypox disease is characterized by an incubation period, prodrome, and rash. See Clinical Recognition |
   Monkeypox | Poxvirus | CDC for additional information.
- <u>Incubation Period</u>: Infection with monkeypox virus begins with an incubation period where the person does not have symptoms and may feel fine. The incubation period is roughly 1-2 weeks. *A person is not contagious during this period*. Physicians are currently recommended to monitor patients up to 21 days.
- <u>Prodrome</u>: People with monkeypox infection may develop an early set of symptoms (prodrome). These symptoms may include fever, malaise, headache, sore throat, or cough, and (in many cases) swollen lymph nodes. Lymphadenopathy is a characteristic feature of monkeypox, and lymph nodes may swell in the neck (submandibular & cervical), armpits (axillary), or groin (inguinal) and can occur on both sides of the body or just one. *A person may be contagious during this period*. Instruct patients to isolate if they develop symptoms.
- <u>Rash</u>: In some recent monkeypox cases, people have presented with a rash without a recognized prodrome. Many of the recent cases have only had localized lesions and have not presented with diffuse rash often seen in figures. People with monkeypox infection develop lesions that typically progress from papules, macules, vesicles, pustules, and then scabs. *A person is contagious until after all the scabs on the skin have fallen off and a fresh layer of intact skin has formed underneath*. Decisions regarding discontinuation of isolation precautions at a healthcare facility and at home should be made in consultation with the local or state health department.

## What medications can be given to treat monkeypox?

Currently there is no treatment specifically approved for monkeypox virus infections. Antivirals developed for use in patients with smallpox may prove beneficial. See clinical guidance CDC's Interim Clinical Guidance for the Treatment of Monkeypox for additional details.

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

- Available from the US Strategic National Stockpile (SNS).
- An antiviral approved by the United States Food and Drug Administration (FDA) [564 KB, 24 pages] [7] for the treatment of human smallpox disease in adults and pediatric patients.

- In laboratory tests, tecovirimat has been shown to stop the growth of the virus that causes smallpox and to be effective in treating animals that had diseases similar to smallpox (e.g., monkeypox).
- Studies have shown that tecovirimat administered in healthy people is safe and causes only minor side effects.
- CDC holds an Expanded Access Investigational New Drug Protocol (EA-IND) that allows for the use of tecovirimat for treatment of non-variola orthopoxvirus infections (including monkeypox) in an outbreak.

## Vaccinia Immune Globulin Intravenous (VIGIV)

- Available from the US Strategic National Stockpile (SNS).
- Licensed by FDA 🔀 for treatment of complications due to vaccinia vaccination such as progressive vaccinia.
- CDC holds an EA-IND that allows the use of VIGIV for treatment of orthopoxvirus infections (including monkeypox) in an outbreak.

## Brincidofovir\* (also known as Tembexa)

- Not currently available from the US Strategic National Stockpile (SNS).
- Antiviral medication approved by the FDA 🔼 [670 KB, 21 pages] 🗹 for the treatment of human smallpox disease in adult and pediatric patients, including neonates.
- In laboratory tests, has been shown to stop the growth of the virus that causes smallpox and to be effective in treating animals that had diseases similar to smallpox (e.g., monkeypox).
- When administered in people who received brincidofovir following bone marrow transplants, the most common side effects were diarrhea, nausea, vomiting, and abdominal pain.
- CDC is currently developing an EA-IND to help facilitate use of brincidofovir as a monkeypox treatment.

## Cidofovir\* (also known as Vistide)

- An antiviral medication that is approved by the FDA <a> [828 KB, 6 pages]</a> <a> for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS).</a>
- In laboratory tests, cidofovir has also been shown to stop the growth of the virus that causes smallpox and to be effective in treating animals that had diseases similar to smallpox (e.g., monkeypox).
- This drug continues to be evaluated for effectiveness and toxicity.
- CDC holds an EA-IND that allows for the use of cidofovir for treatment of orthopoxvirus infections (including monkeypox) in an outbreak.
- 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.
- \* Data is not available on the effectiveness of brincidofovir or cidofovir in treating human cases of monkeypox. Both have proven activity against poxviruses in *in vitro* and animal studies.

It is unknown whether a person with severe monkeypox infection will benefit from treatment with either antiviral, although their use may be considered.

• The CDC can assist physicians in the diagnosis and management of patients with suspected monkeypox. If VIGIV or antivirals are needed, or additional information is required, physicians should contact the CDC Emergency Operations Center at 770-488-7100, Monday through Friday 8 AM to 4:30 PM Eastern Standard Time; at other times call (404) 639-2888.

# Vaccination Schedule and Use

NEW People can be vaccinated after known or presumed exposure to someone with monkeypox.

The strategy of post-exposure prophylaxis (PEP) is vaccination of individuals identified by public health officials as known contacts through case investigation, contract tracing, or risk exposure assessments.

In addition to individuals described above, expanded post-exposure prophylaxis (PEP++) includes vaccination of:

- People who are aware that a recent sex partner within the last 14 days was diagnosed with monkeypox.
- Certain gay, bisexual, or other men who have sex with men, or transgender people, who have any of the following within the past 14 days: sex with multiple partners (or group sex); sex at a commercial sex venue; or sex associated with an event, venue, or defined geographic area where monkeypox transmission is occurring.

Vaccination before exposure to monkeypox, called pre-exposure prophylaxis (PrEP), is recommended for people in certain occupational risk groups (e.g., laboratory personnel performing diagnostic testing for monkeypox virus and members of health care worker response teams designated by appropriate public health and anti-terror authorities).

Learn more about Vaccination Strategies.

## Should all front-line healthcare workers get vaccinated?

NEW CDC is not currently encouraging pre-exposure vaccination for most U.S. healthcare workers. Monkeypox virus primarily spreads through close contact and does not spread as easily as respiratory viruses (e.g., influenza and SARS-CoV-2 viruses). Proper use of personal protective equipment and infection control practices are likely to be effective at reducing the risk of transmission of the monkeypox virus when examining a patient or handling contaminated materials.

The risk of monkeypox for most front-line healthcare workers is currently low. However, healthcare workers who have been exposed to monkeypox may benefit from post-exposure prophylaxis with the JYNNEOS vaccine, ideally within 4 days. CDC is working closely with partners to ensure there are enough vaccine doses available for those who are recommended to receive them.

For detailed recommendations on use of JYNNEOS and ACAM2000 vaccines, see CDC's Vaccine Considerations

## How soon after exposure to monkeypox should someone be vaccinated?

NEW Ideally, people who have been exposed to monkeypox should be vaccinated within 4 days after exposure for the best chance of preventing onset of the disease. Vaccination might be less effective if the first dose is given between 4 and 14 days after exposure. In some clinical situations, it may still be beneficial to give vaccine even if more than 14 days have passed since exposure, based on the person's risk factors.

Vaccination given after onset of signs or symptoms of monkeypox is not expected to provide benefit.

For JYNNEOS vaccine, a second dose should be given 28 days after the first dose.

Learn more about Vaccination Strategies

How soon after vaccination is someone expected to be protected from monkeypox?

NEW The effectiveness of JYNNEOS and ACAM 2000 in this outbreak is unknown. Peak immunity is expected to occur 14 days after the second dose of JYNNEOS, and 4 weeks after ACAM2000 vaccination. The duration of immunity after receipt

of either vaccine is unknown.

Because there are limitations in our knowledge about the effectiveness of these vaccines in the current outbreak, people who are vaccinated should continue to take steps to protect themselves from monkeypox by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.

Is there a difference in the dosing interval between the standard regimen (subcutaneous administration) and the alternative regimen (intradermal administration) of JYNNEOS vaccine?

No. Two doses of JYNNEOS vaccine are recommended with either dosing regimen. The recommended dosing interval between the first and second dose of JYNNEOS vaccine for both the standard (subcutaneous administration) and the alternative (intradermal administration) dosing regimens is the same, i.e., 28 days.

For further information, see Vaccination Schedule.

What if the second dose of the JYNNEOS vaccine is late or missed?

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NEW The FDA-approved dosing interval for JYNNEOS vaccine is 28 days. Based on available clinical study data, the second dose may be given up to 35 days after the first dose. However, if the second dose is delayed further beyond the 35 days, the second dose should be administered as soon as possible.

After 35 days, there is no need to restart the series or give additional doses beyond the second dose based on ACIP's general best practices.

For more information, see Dosing Intervals of JYNNEOS vaccine.

What if the second dose of the JYNNEOS vaccine is given early?

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NEW The FDA-approved dosing interval for JYNNEOS vaccine is 28 days. Doses of the JYNNEOS vaccine administered up to 4 days before the FDA-approved dosing interval of 28 days (i.e. 24 days) are considered valid.

If the second dose is administered 5 or more days before the FDA-approved dosing interval AND the patient is severely immunosuppressed, repeat the second dose. The repeat second should be spaced after the dose given in error by the recommended interval of 28 days. For persons who are not severely immunosuppressed, the second dose should not be repeated.

Providers administering JYNNEOS under the expanded use authorization are required to report vaccine administration errors whether or not associated with an adverse event to VAERS: VAERS – Report an Adverse Event (hhs.gov)

For more information, see:

- Dosing Intervals of JYNNEOS vaccine
- Vaccine Administration Errors and Deviations

Can JYNNEOS or ACAM2000 be administered with other vaccines on the same day?

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**NEW JYNNEOS vaccine** typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day. Additional considerations related to

coadministration of JYNNEOS and COVID-19 vaccines are described below.

ACAM2000 and live injectable vaccines should not be administered on the same day. Live vaccines and ACAM2000 should be separated by at least 28 days. For non-live vaccine, if possible, consider delaying other vaccines when administering **ACAM2000** due to the reactogenicity profile of ACAM2000. When deciding whether to co-administer other vaccine(s) with ACAM2000, the reactogenicity of ACAM2000 must be considered in balancing the benefits and risks of multiple vaccine doses administered at the same time.

#### COVID-19 Vaccination Before JYNNEOS or ACAM2000

If JYNNEOS or ACAM2000 is recommended for prophylaxis in the setting of an orthopoxvirus (e.g., monkeypox) outbreak, the orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary.

#### COVID-19 Vaccination After JYNNEOS or ACAM2000

People, particularly adolescent or young adult males, might consider waiting 4 weeks after receiving JYNNEOS or ACAM2000 before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis after receipt of ACAM2000 orthopoxvirus vaccine, mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and/or pericarditis after JYNNEOS.

For more information, see

- Coadministration of JYNNEOS vaccine with other vaccines
- Coadministration of ACAM2000 vaccine with other vaccines

## Can I vaccinate patients with underlying medical conditions?

NEW JYNNEOS vaccine is contraindicated (not recommended) in persons with history of severe allergic reaction after a previous dose of JYNNEOS. It is also contraindicated in persons with a history of severe allergic reaction to a component of the vaccine (except gentamicin, ciprofloxacin, and chicken or egg protein) should not receive JYNNEOS.

People who have a history of a severe allergic reaction (e.g., anaphylaxis) to: gentamicin; ciprofloxacin; or to chicken or egg protein AND who are currently avoiding exposure to all chicken or egg products may receive JYNNEOS under certain conditions, and should be observed for 30 minutes after vaccine administration.

ACAM2000 vaccine has more serious side effects and should not be given to people with the following conditions:

- Congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people with HIV (regardless of immune status)
- Eczema or other exfoliative skin conditions, and people with a history of these conditions
- · Pregnancy or breastfeeding
- Infants younger than age 12 months
- Cardiac disease, meaning three or more of the following major cardiac risk factors: hypertension, diabetes, hypercholesterolemia, heart disease at age ≤50 years in a first-degree relative, or smoking
- Eye disease treated with topical steroids
- Severe allergic reaction (e.g., anaphylaxis) after a previous dose or component of ACAM2000

For more information, see:

Safety (JYNNEOS)

# My patient is currently sick. Can they receive JYNNEOS or ACAM2000 vaccine?

NEW Since vaccination given after the onset of signs or symptoms of monkeypox is not expected to provide benefit, patients who are currently ill with monkeypox do not need to be vaccinated.

Patients with a moderate or severe acute illness, with or without fever, not caused by monkeypox disease may consider deferring vaccination with JYNNEOS or ACAM2000 until the illness has improved.

If JYNNEOS or ACAM2000 is recommended due to an exposure to monkeypox virus, persons with mild illnesses, not attributed to monkeypox, such as a cold, should be vaccinated.

For more information, see Safety (JYNNEOS)

If someone received smallpox vaccination when they were younger, do they need to be vaccinated  $\triangle$  again now?

NEW Previous smallpox vaccination probably provides some protection, but it may not be lifelong. During the current outbreak, vaccines and other medical measures should be given to eligible people, even if they were previously vaccinated against smallpox.

Longstanding ACIP guidance includes a recommendation to administer booster doses to laboratory and health care personnel designated to be at risk for ongoing occupational exposure to monkeypox viruses every 2 years, or replication-competent vaccinia viruses every 10 years.

For more information, see ACIP recommendations

## Can JYNNEOS or ACAM2000 be administered with other vaccines on the same day?

JYNNEOS vaccine typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day. Additional considerations related to coadministration of JYNNEOS and COVID-19 vaccines are described below.

ACAM2000 and live injectable vaccines should not be administered on the same day. Live vaccines and ACAM2000 should be separated by at least 28 days. For non-live vaccine, if possible, consider delaying other vaccines when administering **ACAM2000** due to the reactogenicity profile of ACAM2000. When deciding whether to co-administer other vaccine(s) with ACAM2000, the reactogenicity of ACAM2000 must be considered in balancing the benefits and risks of multiple vaccine doses administered at the same time.

#### COVID-19 Vaccination **Before** JYNNEOS or ACAM2000

If JYNNEOS or ACAM2000 is recommended for prophylaxis in the setting of an orthopoxvirus (e.g., monkeypox) outbreak, the orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary.

#### COVID-19 Vaccination After JYNNEOS or ACAM2000

People, particularly adolescent or young adult males, might consider waiting 4 weeks after receiving JYNNEOS or ACAM2000 before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine, because of the observed risk for myocarditis and/or pericarditis after receipt of ACAM2000 orthopoxyirus vaccine, mRNA (i.e., Moderna and Pfizer-

BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis and/or pericarditis after JYNNEOS.

For more information, see

- Coadministration of JYNNEOS vaccine with other vaccines
- Coadministration of ACAM2000 vaccine with other vaccines

# Vaccination Dosage and Administration

Who should receive subcutaneous (standard regimen) versus intradermal (alternative regimen) administration of JYNNEOS vaccine?



NEW

Intradermal administration (alternative regimen) can be considered for most adults ages 18 years and older.

In children and adolescents younger than 18 years old, or people of any age who have a history of developing keloid scars, JYNNEOS should be administered by subcutaneous injection (standard regimen).

For further information, see:

- Vaccination Schedule (JYNNEOS Vaccine)
- JYNNEOS Preparation and Administration Summary (Standard Regimen) 🔼 [240 KB, 2 pages]
- JYNNEOS Preparation and Administration Summary (Alternative Regimen) 🔼 [249 KB, 2 pages]

If a patient got their first dose of JYNNEOS vaccine subcutaneously (standard regimen), can they receive the second dose intradermally (alternative regimen), and vice versa?

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Yes. If the first dose of JYNNEOS was administered subcutaneously (standard regimen), and now the patient is eligible for an intradermal dose (alternative regimen), then the second dose can be given intradermally (alternative regimen). For example, a person whose 18<sup>th</sup> birthday occurs between their first and second dose may complete the series with the alternative regimen.

Similarly, when necessary, a person who received one JYNNEOS vaccine dose intradermally (alternative regimen) may receive the second dose using subcutaneously (standard regimen).

For more information, see Interchangeability of dosing regimens (JYNNEOS)

Is there a difference in dosage of the alternative and standard regimens for JYNNEOS vaccine?



NEW The alternative regimen uses a dose of 0.1 mL injected intradermally. This is one-fifth (1/5) of a vial of JYNNEOS vaccine.

The standard regimen uses a dose of 0.5 mL injected subcutaneously. This is a full vial of JYNNEOS vaccine.

For information, please see:

- Vaccination Schedule (JYNNEOS Vaccine)
- Preparation and Administration Summary: Alternative Dosing Regimen <a> [240</a> KB, 2 pages

How soon after vaccination is someone expected to be protected from monkeypox?

NEW The effectiveness of JYNNEOS and ACAM 2000 in this outbreak is unknown. Peak immunity is expected to occur 14 days after the second dose of JYNNEOS, and 4 weeks after ACAM2000 vaccination. The duration of immunity after receipt of either vaccine is unknown.

Because there are limitations in our knowledge about the effectiveness of these vaccines in the current outbreak, people who are vaccinated should continue to take steps to protect themselves from monkeypox by avoiding close, skin-to-skin contact, including intimate contact, with someone who has monkeypox.

How is ACAM2000 administered to a patient?

NEW ACAM2000 is administered percutaneously using a bifurcated needle, and no alternative dosing regimen is authorized. Never inject ACAM2000 by the intradermal, subcutaneous, intramuscular, or intravenous route.

What should be done if the incorrect JYNNEOS vaccine dose is administered?

NEW If a higher-than-authorized JYNNEOS dose is administered, do not repeat the dose. Inform the recipient of the potential for local and systemic adverse events. Possible vaccination side effects include injection site pain, redness, swelling, induration, itching, fatigue, headache, nausea, chills, and muscle aches.

If a **lower-than-authorized** JYNNEOS dose is administered, repeat the dose immediately. However, if a half-volume dose of vaccine is administered to a patient recommended for the full volume, another half-volume dose can be administered on the same day, and the two halves can count as one full dose.

Providers administering JYNNEOS under the expanded use authorization (EUA) are required to report vaccine administration errors, whether or not associated with an adverse event to VAERS: VAERS – Report an Adverse Event (hhs.gov)

For information, please see Vaccine Administration Errors and Deviations

What should be done if JYNNEOS vaccine is inadvertently given intramuscularly?

NEW Inadvertent intramuscular (IM) administration of the standard dose (0.5 mL) of JYNNEOS is a vaccine administration error, but does not need to be repeated and the dose can be counted as valid. The patient may experience increased local reactogenicity at the vaccine site due to the inadvertent IM administration.

Providers administering JYNNEOS under the expanded use authorization are required to report vaccine administration errors whether or not associated with an adverse event to VAERS: VAERS – Report an Adverse Event (hhs.gov)

Inadvertent IM doses also need to be reported to the manufacturer, Bavarian-Nordic, at drug.safety@bavarian-nordic.com.

For more information, see Vaccine Administration Errors and Deviations

# **Vaccine Safety**

NEW JYNNEOS vaccine is contraindicated (not recommended) in persons with history of severe allergic reaction after a previous dose of JYNNEOS. People with a history of severe allergic reaction to a component of the vaccine (except gentamicin, ciprofloxacin, and chicken or egg protein) should not receive JYNNEOS.

People who have a history of a severe allergic reaction (e.g., anaphylaxis) to: gentamicin; ciprofloxacin; or to chicken or egg protein AND who are currently avoiding exposure to all chicken or egg products may receive JYNNEOS under certain conditions, and should be observed for 30 minutes after vaccine administration.

For more information, see Safety (JYNNEOS)

What are the contraindications and precautions for the ACAM2000 vaccine?

**NEW** ACAM2000 is contraindicated (not recommended) for people with the following medical conditions:

- Congenital or acquired immune deficiency disorders including those taking immunosuppressive medications and people living with HIV (regardless of immune status)
- Cardiac disease (meaning three or more of the following major cardiac risk factors: hypertension, diabetes, hypercholesterolemia, heart disease at age ≤50 years in a first-degree relative, or smoking)
- Eye disease treated with topical steroids
- Atopic dermatitis/eczema and people with a history of these conditions or other acute or exfoliative skin conditions
- Infants less than 12 months of age
- Pregnancy
- History of a severe allergic reaction (e.g. anaphylaxis) after a previous dose of ACAM2000
- History of a severe allergic reaction (e.g. anaphylaxis) to a component of ACAM2000

For more information, see Safety (ACAM2000)

Do I need to observe patients after they receive JYNNEOS vaccination?

Yes. Vaccination providers should observe patients after vaccination to monitor for the occurrence of immediate adverse reactions, including syncope. Most patients should be observed for 15 minutes, but those with a history of anaphylaxis to gentamicin, ciprofloxacin, and chicken or egg protein should be observed for 30 minutes following vaccination.

For more information, see Safety (JYNNEOS)

My patient experienced fever or injection-site swelling after a dose of the JYNNEOS vaccine. Should they get the second dose?

NEW Patients who experienced fever and injection-site swelling with their first dose of JYNNEOS vaccine can receive a second dose, because these are commonly observed adverse reactions after JYNNEOS vaccination.

If a person is still experiencing erythema and induration from the first dose administered by intradermal injection (alternative regimen) when they present for the second dose, they can receive the second JYNNEOS vaccine dose intradermally in the contralateral forearm.

For more information, see Administration (JYNNEOS)

# Vaccination and Monkeypox Infection

Should someone who has had monkeypox as part of this outbreak be vaccinated?

NEW CDC does not recommend that those diagnosed with monkeypox during this outbreak, which was detected in the United States on May 17, 2022, be vaccinated at this time. Having had monkeypox once likely confers immune protection. Immune protection would reduce the chance of getting monkeypox again in the future.

For more information, see Vaccination Administration Considerations for Specific Populations

If someone had the first dose of JYNNEOS and then gets monkeypox, should they get the second dose?

NEW In most cases no. A person who is diagnosed with monkeypox after receiving a first dose of JYNNEOS vaccine is not recommended to receive the second dose, because *Monkeypox virus* infection likely confers additional immune protection.

However, an immunocompromised person who is diagnosed with monkeypox after their first dose of JYNNEOS may be eligible to receive the second dose on a case-by-case basis, using shared decision making, and clinical judgement of the healthcare provider.

For more information, see Vaccination Administration Considerations for Specific Populations

# People who are Immunosuppressed

Should someone who has had monkeypox as part of this outbreak be vaccinated?

NEW People with immunocompromising conditions might be less likely to mount an effective response after any vaccination, and as a result they might be at increased risk for severe disease if they contract monkeypox.

JYNNEOS can be administered to people with immunocompromising conditions.

ACAM2000 should not be given to people with congenital or acquired immune deficiency disorders, including those taking immunosuppressive medications and people with HIV, regardless of immune status.

In the context of limited vaccine supply, JYNNEOS vaccine doses should be prioritized for people who are at high risk for severe disease from monkeypox (including, but not limited to, people with HIV infection, pregnancy, or other immunocompromising conditions) or serious adverse events with ACAM2000.

For more information, see:

- Vaccination Administration Considerations for Specific Populations
- Safety (JYNNEOS)
- Safety (ACAM2000)

# Considerations Involving Pregnant or Breastfeeding Women and Children

## Can pregnant or breastfeeding women be vaccinated?

NEW JYNNEOS is a live, non-replicating viral vaccine licensed for prevention of both smallpox and monkeypox disease. JYYNNEOS can be offered to people who are pregnant or breastfeeding who are otherwise eligible.

ACAM2000 is a replicating viral vaccine licensed for prevention of smallpox. Vaccination with ACAM2000 is contraindicated in people who are pregnant or breastfeeding, due to risk of pregnancy loss, congenital defects, and vaccinia virus infection in fetuses and newborns and the availability of a non-replicating viral vaccine.

#### **JYNNEOS**

Pregnant patients: Available human data on JYNNEOS administered to pregnant people are insufficient to determine vaccine-associated risks in pregnancy. Animal models, including rats and rabbits, have shown no evidence of harm to a developing fetus.

Breastfeeding patients: The safety and efficacy of JYNNEOS has not been evaluated in breastfeeding patients. It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the impact of JYNNEOS on milk production or the safety of JYNNEOS in breastfed infants. Because JYNNEOS vaccine is replication-deficient, it likely does not present a risk of transmission to breastfed infants and can be administered to patients who are breastfeeding if vaccination is critical.

#### ACAM2000

Pregnant patients: ACAM2000 has not been studied in pregnant patients. However, fetal vaccinia has been reported in fetuses and newborns of pregnant patients vaccinated with replication-competent smallpox vaccines. Smallpox vaccine may rarely cause infection in an unborn baby if the mother is vaccinated during pregnancy. This infection usually results in stillbirth or death. For this reason, ACAM2000 should not be administered to people who are pregnant or may be pregnant (Pregnancy Category D).

Breastfeeding patients: ACAM2000 has not been studied in persons who are lactating, so it is unknown whether the vaccine virus or antibodies are secreted in human milk. Live vaccine virus can be inadvertently transmitted from a lactating mother to her infant. Infants are at high risk of developing serious complications from live vaccinia smallpox vaccination. Vaccinated persons who have close contact with infants, e.g., breastfeeding, must take precautions to avoid inadvertent transmission of ACAM2000 live vaccinia virus to infants.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Visit the VAERS website at www.vaers.hhs.gov or call 1-800-822-7967. VAERS is only for reporting reactions, and VAERS staff members do not give medical advice.

For more information, see Vaccination Administration Considerations for Specific Populations and Clinical Considerations for Monkeypox in People Who are Pregnant or Breastfeeding

# Can children receive the monkeypox vaccine?

NEW Children and adolescents younger than 18 years are authorized to receive JYNNEOS vaccine, 0.5mL administered subcutaneously (standard regimen) only. ACAM2000 should not be administered to an infant younger than age 12 months.

CDC clinicians should be consulted if either JYNNEOS or ACAM2000 vaccination is being considered for children and adolescents younger than 18 years old.

For more information, see Vaccination Administration Considerations for Specific Populations

# Advice for Monkeypox Patients to Reduce Transmission

How long does my patient need to isolate?

Patients with monkeypox should continue to isolate and follow prevention practices until cleared by public health officials after all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed. The illness typically lasts 2-4 weeks. Decisions regarding discontinuation of isolation precautions at a healthcare facility should be made in consultation with the local or state health department. Please refer to CDC's Isolation and Prevention Practices for People with Monkeypox.

When my patient is isolating in their home, what should they do?

- Patients should isolate until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed.
- People with monkeypox should adhere to these recommendations until cleared by public health:
  - Do not leave the home except as required for emergencies or follow-up medical care.
  - o Persons without an essential need to be in the home should not visit.
  - Avoid close contact with others.
  - Avoid close contact with pets in the home.
  - Abstain from all sexual activity.
  - Do not share items that could be contaminated by the lesions (e.g., bed linens, clothing, towels, wash cloths). Do
    not share drinking glasses or eating utensils.
  - Routinely clean and disinfect commonly touched surfaces and items (e.g., counters, light switches) using an EPA-registered disinfectant (e.g., List Q 🖸 ) in accordance with the manufacturer's instructions.
  - Wear a well-fitting mask or respirator for source control when in close contact with others at home.
  - Avoid use of contact lenses to prevent inadvertent infection of the eye.
  - Avoid shaving areas of the body with lesions as this can lead to spread of the virus.
- Bathroom usage:
  - o If possible, use a separate bathroom if there are others who live in the same household.
  - o If there is not a separate bathroom in the home, the patient should clean and disinfect surfaces (e.g., counters, toilet seats, faucets) using an EPA-registered household cleaning product (List Q ☑ ) after using a shared space if the lesions are exposed (e.g., showering, toileting, changing bandages covering the lesions). Consider disposable glove use while cleaning if lesions are present on the hands.
  - Please refer to CDC's Home Infection Control page. Infection Control: Home
- Limit exposure to others:
  - Avoid contact with unaffected individuals until lesions have resolved, the scabs have fallen off, and a fresh layer
    of intact skin has formed.
  - o Isolate in a room or area separate from other household members and pets when possible.
- Limit use of spaces, items, and food that are shared with other household members.
  - Do not share dishes and other eating utensils. It is not necessary for the infected person to use separate utensils if properly washed. Wash soiled dishes and eating utensils in a dishwasher or by hand with warm water and soap.
- Limit contamination within household:
  - Avoid direct contact with upholstered furniture and porous materials that cannot be laundered by placing coversheets, waterproof mattress covers, blankets, or tarps over these surfaces. Additional precautions such as steam cleaning can be considered if there is concern about contamination.

Hand hygiene (e.g., use of an alcohol-based hand rub or hand washing with soap and water) should be performed by infected persons and household contacts after touching lesion material, clothing, linens, or environmental surfaces that may have had contact with lesion material.

- Persons with monkeypox should wear a well-fitting mask or respirator, especially those who have respiratory symptoms (e.g., cough, shortness of breath, sore throat) or significant oral lesions if close contact with others cannot be avoided (e.g., when obtaining medical care). Other household members should wear a well-fitting mask or respirator when in the presence of the person with monkeypox.
- Changing bandages and handling of contaminated linens should be performed by the person with monkeypox while wearing disposable gloves. Hand hygiene should be performed immediately following removal of gloves.
  - As a last resort, if assistance is needed with these activities, a household member should avoid extensive contact
    and wear, at a minimum, disposable medical gloves and a well-fitting mask or respirator. Any clothing that
    contacts the lesions during dressing changes should be immediately laundered. Gloves should be disposed of
    after use and hand hygiene performed.
- Cover skin lesions to the best extent possible (e.g., long sleeves, long pants). Gloves can be considered for covering lesions on the hands when not in isolation (e.g., emergencies, medical care).
- Contain and dispose of contaminated waste (e.g., dressings, bandages, gloves); See Disinfecting Home and Other Non-Healthcare Settings.

# Additional Advice for Monkeypox Patients

How should patients clean and disinfect their home?

The CDC provides general guidance on cleaning and disinfecting non-healthcare settings (e.g., homes, cars) where an individual with monkeypox spent significant time. (See: Disinfecting Home and Other Non-Healthcare Settings)

Should patients be concerned about their pets?

- People with monkeypox should avoid contact with animals (specifically mammals), including pets.
  - 1. If possible, friends or family members should care for healthy animals until the owner has fully recovered.
  - 2. Keep any potentially infectious bandages, textiles (e.g., clothes, bedding) and other items away from pets, other domestic animals, and wildlife.
  - 3. There is currently no evidence that animals apart from mammals can become infected and transmit monkeypox.
- If you notice an animal that had contact with an infected person appearing sick (e.g., lethargy, lack of appetite, coughing, bloating, nasal or ocular secretions or crust, fever, pox lesions) contact the owner's veterinarian, state public health veterinarian, or state animal health official.

Do patients need to wear condoms if they have recovered from a monkeypox infection?

Safe sex, barrier practices (i.e., wearing condoms) are recommended, but there is little data to support the length of time patients need to wear condoms. Some other countries are recommending a minimum of 8 weeks, but we are still learning about this virus in the context of transmission through sexual contact. As public health experts learn more about monkeypox transmission this guidance will be updated.

# How can patients help the public health response against the monkeypox outbreak?

Patients should seek prompt medical care as soon as they experience signs or symptoms associated with monkeypox or believe they were exposed to a monkeypox infection.

It is important that patients inform the physician and health department officials of other individuals who may have been exposed to monkeypox by the patient (i.e., contacts) so that the public health department can talk to them, and, if needed, to seek medical care. Identifying potential contacts will help them receive the proper treatments and protect others in the community from getting infected by monkeypox.

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