Information for Health Care Professionals about the Screening Checklist for the JYNNEOS Vaccine

Updated: July 13, 2022

Note: For summary information on contraindications and precautions to vaccines, go to the ACIP’s General Best Practice Guidelines for Immunization at www.cdc.gov/vaccines/hcp/acip-recs/general-recs/contraindications.htm.

1. Have you had a known exposure to a suspected or confirmed monkeypox case within the past 14 days?

2. Are you at high risk of having had a potential recent exposure to monkeypox (within the past 14 days)? This may include intimate, or skin-to-skin contact, with others in areas where monkeypox is spreading.

3. Do you feel that you may be at risk of future exposure to monkeypox, even though you are not at high risk of a recent exposure to monkeypox within the past 14 days?

4. Will you be under the age of 18 on the day of your appointment?
The JYNNEOS vaccine is only approved for individuals 18 years and older.

5. Are you feeling sick today?
If yes, refer to the vaccination site health care provider for assessment of current health status. If patient is feeling moderately or severely ill, do not vaccinate at this time. Ask the patient to return when symptoms improve.

6. Have you ever had an immediate allergic reaction, such as hives, facial swelling, difficulty breathing, or anaphylaxis, to any vaccine, injection, or antibiotic, or to any component of the JYNNEOS vaccine?
Persons who experienced a severe allergic reaction following a previous dose of JYNNEOS or following exposure to any component of JYNNEOS may be at increased risk for severe allergic reactions after JYNNEOS. Individuals with an immediate allergic reaction to benzonase, gentamicin, ciprofloxacin, or egg protein should not be vaccinated. The risk for a severe allergic reaction should be weighed against the risk for disease due to monkeypox. Please refer to: https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination.html.

7. Have you had a JYNNEOS vaccine in the last 4 weeks?
The JYNNEOS vaccine is a two-dose vaccine separated by 28 days. If the patient already had the first dose of JYNNEOS, be sure it was at least 28 days ago. If the patient's first dose of JYNNEOS was received more than 28 days ago, do not repeat the first dose and continue to administer the second dose as soon as possible after 28 days following the first dose.

8. Have you had a COVID-19 mRNA vaccine (Pfizer or Moderna) within the last 4 weeks, or are you planning on receiving a COVID-19 mRNA vaccine within the next 4 weeks?
If a JYNNEOS vaccine is recommended for prophylaxis in the setting of an outbreak, administration of JYNNEOS vaccine should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.
However, because of the unknown risk for myocarditis after JYNNEOS, people might consider waiting 4 weeks after JYNNEOS vaccination before receiving an mRNA COVID-19 vaccine, particularly young adult males and in non-outbreak settings. Patients should be counseled on the potential risk of myocarditis following the administration of JYNNEOS and an mRNA vaccine within 4 weeks of each other.

9. **Are you currently pregnant, planning to become pregnant or breastfeeding?**
   If yes, ask the patient if they would like to have a discussion with a health care provider at the site for counseling on the risks and benefits of vaccine during pregnancy. All pregnancies have a risk of birth defect, loss, or other adverse outcomes. In the US general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively. Available human data on JYNNEOS administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy.

   It is not known whether JYNNEOS is excreted in human milk. Data are not available to assess the effects of JYNNEOS in the breastfed infant or on milk production/excretion. Patient should be counseled regarding the unknown risk of fetal harm and should be weighed against the risk for disease due to smallpox or monkeypox. Patient may be vaccinated if they choose.

10. **Are you moderately or severely immunocompromised due to one or more of the medical conditions or receipt of immunosuppressive medications or treatments?**
    If yes, counsel patient that individuals with severe immunodeficiency or on immunosuppressive therapies may have a diminished immune response from the JYNNEOS vaccine. These individuals may include persons who are undergoing bone marrow transplantation or persons with primary or acquired immunodeficiency states who require isolation. The risk for experiencing a diminished immune response must be weighed against the risks of vaccination side effects or for experiencing a potentially severe monkeypox infection.

11. **Do you have a history of myocarditis (inflammation of the heart muscle) or pericarditis (inflammation of the lining around the heart)?**
    If yes: counsel the patient that JYNNEOS has the potential risk for increased incidence of cardiac adverse events of special interest (AESIs) included any cardiac signs or symptoms, ECG changes determined to be clinically significant, or troponin-I elevated above 2 times the upper limit of normal during clinical trials. The risk for experiencing serious vaccination complications must be weighed against the risks for experiencing a potentially serious or fatal monkeypox infection.

12. **Have you read and reviewed the Vaccine Information Statement (VIS) for the JYNNEOS vaccine (JYNNEOS dated 6/1/22):** [https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.pdf).

13. **Do you understand the risks and benefits of the JYNNEOS vaccine and consent to receiving the vaccine?**

13. **If you are 19 or older: Do you consent to release your immunization record to NYSIIS where it will be available to your health care provider?**
   If yes, the patient’s vaccine will be reported to the NYS Immunization Information System (NYSIIS).