Information for Health Care Professionals about the Screening Checklist for the JYNNEOS Vaccine
Updated: October 28, 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.html.

1. **Have you been diagnosed with the Monkeypox virus (MPV) since May 17, 2022?**
   If the patient was diagnosed with Monkeypox virus between their first and second dose, or since the beginning of the Monkeypox outbreak in the United States beginning on May 17, 2022, the individual is not recommended to be vaccinated at this time, as the Monkeypox virus infection likely confers additional immune protection.

   An individual who is immunocompromised and was diagnosed with Monkeypox virus infection after their first dose of JYNNEOS may still be vaccinated on a case-by-case shared decision-making basis based on the clinical judgment of the health care provider.

2. **Will you be under the age of 18 on the day of your appointment?**
   The JYNNEOS vaccine is FDA approved to use subcutaneously in individuals 18 years and older, as well as EUA approved for those under 18. The JYNNEOS vaccine was also approved under an EUA for use intradermally in individuals 18 years and older on August 9, 2022.

3. **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. However, if a person has been referred for vaccination due to an exposure to monkeypox, they should be vaccinated regardless of concurrent illness.

4. **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, or do you have a history of developing keloid scars?**
   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 a history of a severe allergic reaction after a previous dose of JYNNEOS, should not receive further doses.

   Individuals with an immediate allergic reaction to benzonase, gentamicin,ciprofloxacin, or egg protein have a precaution to the JYNNEOS and should be counseled on the benefits and risks of vaccination. Vaccination can be delayed for an allergist/immunologist consultation, but the impact of delaying vaccination should be considered. If a person with a benzonase, gentamicin, ciprofloxacin, or egg protein allergy is vaccinated, consider observing the person for 30 minutes after vaccination.

   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.

   Patients who develop keloid scars should receive subcutaneous injections only.

5. **Have you had a JYNNEOS vaccine in the last four (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. It is not recommended to give the second dose before the minimum interval of 28 days, but it can be given four (4) days before the minimum interval of 28 days at 24 days.

   The second dose can be given seven (7) days (or 35 days after the first dose), but if there is a delay in administering the second dose, give the second dose as soon as possible and do not restart the series.

6. **Have you had a COVID-19 mRNA vaccine (Pfizer or Moderna) within the last four (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 four (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 four (4) weeks of each other.

7. **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.

8. **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 the 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.

9. **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 two (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.

10. **Have you read and reviewed the Vaccine Information Statement (VIS) or Emergency Use Authorization (EUA) fact sheet for the JYNNEOS vaccine? (JYNNEOS dated 6/1/22): https://www.fda.gov/media/160774/download?**
    If yes, make sure they do not have any questions related to the document. If they answer no, then provide the VIS if they are 18 years or older and received the 0.5 mL dose subcutaneously or the EUA fact sheet if they are 17 years or younger or if they are 18 years and older and received the 0.1 mL dose intradermally. These documents are also available in Spanish: https://www.immunize.org/vis/pdf/spanish_smallpox_monkeypox.pdf (and) https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/jynneos-factsheet-recipients-caregivers-spanish.pdf.

11. **JYNNEOS vaccine is available to help protect against MPXV infection and is recommend for those who are at risk of becoming infected. Do you understand the risks and benefits of the JYNNEOS vaccine and consent to receiving the vaccine?**
    If yes, proceed with vaccination. If they answered no, then address their questions and concerns. If they consent to vaccination, proceed with vaccination. For more information regarding the current outbreak, and how MPXV is spreading in New York State, please visit the NYSDOH Monkeypox Vaccine Information webpage: https://health.ny.gov/diseases/communicable/zoonoses/monkeypox/.

12. **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?**
    Individuals under the age of 19 will have their immunization records automatically sent to NYSIIS, where their records will be available to their health care providers. Those over the age of 19 have the choice to opt in to vaccine release to NYSIIS for this vaccination. Answering no to this question does not affect vaccine eligibility. Patients who do not wish to release their information to NYSIIS are still eligible for vaccination. For individuals who do wish to release their information to NYSIIS, the provider who administered the vaccine must input the information in to the patient's record.