Official websites use .gov A .gov website belongs to an official government organization in the United States. Secure .gov websites use HTTPS A lock ( ) or https:// means you've safely connected to the .gov website. Share sensitive information only on official, secure websites. Two vaccines may be used to prevent mpox: JYNNEOS is a third-generation vaccine based on a live, attenuated orthopoxvirus, Modified Vaccinia Ankara (MVA). MVA is a live virus that does not replicate efficiently in humans. JYNNEOS is known internationally as Imvamune® or Imvanex®; it is manufactured by Bavarian Nordic. It is fully licensed in the U.S. for subcutaneous administration in individuals 18 years of age and older. As of April 1, 2024, JYNNEOS is commercially available in the U.S. In addition, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) in August 2022 to allow JYNNEOS vaccine to be used: ACAM2000 is a second-generation vaccine that contains a live vaccinia virus that replicates efficiently in humans. It is manufactured by Emergent Bio Solutions and is indicated for the prevention of smallpox. It has been made available for use against mpox in the current outbreak under an Expanded Access Investigational New Drug (EA-IND) protocol, which requires informed consent along with completing additional forms. Available evidence supporting the use of smallpox vaccine for mpox prevention is derived from experience with Dryvax®, the vaccine used during smallpox eradication. Dryvax was a first-generation smallpox vaccine manufactured by Wyeth Laboratories. Routine use of this vaccine ended in the United States in 1972, and smallpox was declared eradicated globally in 1980 by the World Health Assembly. The license for Dryvax was withdrawn in 2008 and no supplies of this vaccine remain. Although the United States has a large supply of ACAM2000, this vaccine has more side effects and contraindications than JYNNEOS. *Public health authorities determine whether there is an mpox outbreak; a single case may be considered an mpox outbreak at the discretion of public health authorities. Other circumstances in which a public health response may be indicated include ongoing risk of introduction of mpox into a community due to disease activity in

another geographic area. The mpox outbreak that started in 2022 is still ongoing. †This recommendation is on the CDC's Adult Immunization Schedule (for people 19 years of age and older) and Child & Adolescent Immunization Schedule (for people 18 years of age). Currently, CDC does not recommend routine immunization against mpox for the general public. JYNNEOS is not recommended as a routine vaccination for healthcare personnel unless sexual risk factors are present. Recommendations by the Advisory Committee on Immunization Practices (ACIP) are available for laboratory personnel and health care worker response teams who may be at risk for exposure to orthopoxviruses. Evaluating and counseling patients who could benefit from mpox vaccination is critical. To do so, healthcare professionals should perform a comprehensive social and sexual history. Attention should be paid to sexual behaviors (e.g. frequency and types of sex) and partners (e.g. number and frequency), due to the populations that have been disproportionately affected by the current mpox outbreak. Such evaluation should have health equity principles as a foundation and allow individuals to self-attest vaccine eligibility (i.e., providing mpox vaccination without requiring individuals to specify which criterion they meet). A Guide to Taking a Sexual History National Coalition for Sexual Health (NCSH) Tools for Educating Patients Mpox vaccine can be given as post-exposure prophylaxis (PEP) both to people with known or presumed exposure to monkeypox virus (MPXV). Mpox vaccine can also be given to people with certain risk factors and recent experiences that might make them more likely to have been exposed to mpox. As PEP, vaccine should be given as soon as possible, ideally within four days of exposure; administration 4 through 14 days after exposure may still provide some protection against mpox. After 14 days, clinicians should consider the benefits of receiving vaccine on a case-by-case basis; benefits might still outweigh risks when administering vaccine in some clinical situations (e.g., for a severely immunosuppressed person with a recent sex partner confirmed to have mpox). Any person with ongoing risk of mpox exposure should be offered vaccination, even if previously exposed, and regardless of time since

exposure, as long as they have not yet developed signs or symptoms of mpox. Vaccination given after the onset of signs or symptoms of mpox, after a diagnosis of mpox, or after recovery from mpox is not expected to provide benefit. At this time, naturally acquired mpox is believed to confer immune protection, although duration of immunity is unknown. JYNNEOS vaccine is licensed as a series of two doses administered 28 days (4 weeks) apart. The standard regimen involves a subcutaneous (Subcut) route of administration with an injection volume of 0.5mL. The standard regimen is the FDA-approved dosing regimen. Since August 9, 2022, the standard regimen has also been authorized for people aged <18 years under an Emergency Use Authorization. An alternative regimen may be used for people age ≥18 years under an Emergency Use Authorization which was issued on August 9, 2022, to make more doses available at a time when vaccine supply was limited. The authorized alternative regimen involves an intradermal (ID) route of administration with an injection volume of 0.1mL. Results from a clinical study showed that the lower intradermal dose was immunologically non-inferior to the standard subcutaneous dose [Frey SE et al., Vaccine, 2015; 33(39):5225-5234]. Recently published studies show similar vaccine effectiveness for vaccines administered subcutaneously or intradermally. Either the standard (0.5mL subcutaneous) or the alternative (0.1mL ID) regimen may be used. There is currently adequate supply of JYNNEOS vaccine. Therefore, clinicians can preferentially administer JYNNEOS via the subcutaneous route. 1For patients less than 6 months of age, Vaccinia Immune Globulin Intravenous (VIGIV) should be considered in lieu of JYNNEOS vaccine. Clinicians should first contact their jurisdictional health department (Jurisdictional Contacts). Jurisdictional health departments can facilitate consultation with CDC and access to VIGIV. Peak immunity is expected to be reached 14 days after the second dose of JYNNEOS vaccine. Administration of additional vaccine doses (more than 2 doses) is currently not recommended for most people. For people at risk for occupational exposure to orthopoxviruses (e.g., certain research

laboratorians§), booster doses are recommended at 2-10 years depending on the type of work being performed. (ACIP Smallpox and Mpox Vaccine Recommendations | CDC). §Research laboratory personnel are those who directly handle cultures or animals contaminated or infected with monkeypox virus (MPXV). Vaccination is not routinely recommended for clinical laboratory personnel who perform routine chemistry, hematology, and urinalysis testing, including for patients with suspected or confirmed MPXV infection, healthcare personnel who care for patients with mpox or administer ACAM2000. Recommended infection prevention and control practices are effective in minimizing transmission. Vaccination can be offered based on site- and activity- specific biosafety risk assessments (e.g., identification of laboratory procedures with a high likelihood of generating aerosols or inadequate PPE availability). Recommended interval: The second dose of JYNNEOS vaccine should be given 28 days (4 weeks) after the first dose. Based on available clinical study data [13 MB, 93 pages], the second dose may be given up to 7 days later than the minimum interval of 28 days (i.e., up to 35 days after the first dose). Maximum interval: If the second dose is not administered during the recommended interval, it should be administered as soon as possible based on ACIP’s general best practices. There is no need to restart or add doses to the series if there is an extended interval between doses. Minimum interval: The vaccine manufacturer advises against giving the second dose before the minimum interval of 28 days. However, based on ACIP’s general best practices, a dose may be administered up to 4 days before the minimum interval of 28 days (known as the “grace period,” which would be a minimum of 24 days after the first dose). Vaccine doses should not be administered before the minimum interval (i.e., 28 days). Nevertheless, if the second dose is inadvertently administered before the minimum interval, the dose may not need to be repeated. Please refer to “Table 7. Vaccine Administration Errors and Deviations.” Subcutaneous administration involves injecting the vaccine into the fatty tissue, typically over the triceps in people aged 12 months and older, or in the anterolateral

thigh for people younger than age 12 months. CDC offers a short training video about subcutaneous vaccine administration and job aid [PDF – 1 page, 200KB]. Learn about intradermal administration of JYNNEOS. In eligible individuals, the dosing regimens are interchangeable. For example, a person aged 18 years or older who received one JYNNEOS vaccine dose intradermally may receive a second dose subcutaneously at the recommended interval (i.e., 28 days) to complete the vaccination series. There is currently adequate supply of JYNNEOS vaccine. Therefore, clinicians can preferentially administer JYNNEOS via the subcutaneous route. Doses that were previously administered intradermally are equally effective as doses administered subcutaneously and do not need to be repeated.

Currently, there are no data on administering JYNNEOS vaccine at the same time as other vaccines. Because JYNNEOS is based on a live, attenuated non-replicating orthopoxvirus, JYNNEOS typically may be administered without regard to timing of most other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines, including influenza vaccine, on the same day, but at different anatomic sites if possible. There is no required minimum interval between receiving any COVID-19 vaccine (i.e., Moderna, Novavax, or Pfizer-BioNTech) and JYNNEOS vaccine, regardless of which vaccine is administered first. People, particularly adolescent or young adult males, who are recommended to receive both vaccines might consider waiting 4 weeks between vaccines. This is because of the observed risk for myocarditis and pericarditis after receipt of ACAM2000 orthopoxvirus vaccine and COVID-19 vaccines, and the hypothetical risk for myocarditis and pericarditis after JYNNEOS vaccine. However, if a patient is at increased risk for mpox or severe disease due to COVID-19 disease, administration of JYNNEOS and COVID-19 vaccines should not be delayed. There is currently adequate supply of JYNNEOS vaccine. Therefore, clinicians can preferentially administer JYNNEOS via the subcutaneous route. Adolescents at risk for mpox may receive the JYNNEOS vaccine before an exposure. JYNNEOS is available for use as post

exposure prophylaxis (PEP) for children and adolescents under 18 years determined to be at high risk for mpox under the Emergency Use Authorization (EUA) issued by the US Food and Drug Administration. Vaccination with JYNNEOS for children and adolescents aged <18 years should be administered via subcutaneous injection. For patients <6 months of age, Vaccinia Immune Globulin Intravenous (VIGIV) should be considered in lieu of JYNNEOS vaccine. Clinicians should first contact their jurisdictional health department (Jurisdictional Contacts). Jurisdictional health departments can facilitate consultation with CDC and access to VIGIV. Available human data on JYNNEOS administered to people who are pregnant are insufficient to determine if there are any vaccine-associated risks in pregnancy. Studies of JYNNEOS vaccine in animals have shown no evidence of harm to a developing fetus. While there are no data for people who are breastfeeding, animal data do not show evidence of reproductive harm; breastfeeding is not a contraindication to receiving JYNNEOS. 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. However, because JYNNEOS vaccine is replication-deficient, it likely does not present a risk of transmission to breastfed infants. JYNNEOS can be offered to people who are pregnant or breastfeeding who are otherwise eligible. The risks and benefits of JYNNEOS should be discussed with the patient using shared clinical decision-making. Studies evaluating JYNNEOS in people with atopic dermatitis have demonstrated immunogenicity in eliciting a neutralizing antibody response. No concerning safety signals were revealed. Administer 0.5mL subcutaneously. Administer as indicated based on age and history of keloids. Previous smallpox vaccination probably does provide some protection, but it may not necessarily be lifelong. During the 2003 mpox outbreak and during the current outbreak, several people who were infected with mpox had previously been vaccinated against smallpox decades prior. In response to the current outbreak, vaccines and other medical measures should be given to eligible people who were previously vaccinated

against smallpox. In the context of the current mpox outbreak the following are exceptions to the recommended two-dose series: Recipients should be informed of the risks and benefits of JYNNEOS prior to vaccination. Healthcare providers should determine the medical history of recipients to appropriately decide whether intradermal administration would be appropriate if it is being considered. Recipients should be counseled about possible side effects from vaccination and be provided with a JYNNEOS vaccine information statement (VIS) or FDA JYNNEOS EUA Fact Sheet, as applicable. Side effects after vaccination can vary from person to person. Before vaccination, each recipient should be counselled on the possibility of experiencing the following side effects: Local Side Effects: Systemic Side Effects: Local side effects may be more severe with intradermal administration compared with subcutaneous administration. Side effects may appear soon after vaccination, and some local reactions, such as hyperpigmentation, may persist for several weeks or months. One study noted mild injection site skin discoloration lasting greater than six months for some individuals receiving intradermal administration. Recipients should be counseled that such long-lasting local reactions are expected and may be part of the normal immune response to vaccination. Patients should also be counseled that these side effects are usually self-limiting and will generally resolve over time. While the presence of local or systemic side effects may indicate the development of a robust immune response, the absence of such reactions should not be construed as not mounting adequate immune protection, as the severity and duration of side effects can vary from person to person. Local and systemic reactions experienced after vaccination may be managed conservatively. Evidence does not support the use of antipyretics before or at the time of vaccination. However, they can be used for the treatment of fever and local discomfort that might occur following vaccination. Topical emollients, cold compresses, and oral antihistamines may be used to treat local side effects as needed. Do NOT apply topical corticosteroids or antihistamines to local reactions. Weeping or open

wounds should be covered by a sterile gauze or bandage. People who are vaccinated should continue to take steps to protect themselves from infection by avoiding close, skin-to-skin contact, including intimate contact, with someone who has mpox. JYNNEOS is contraindicated in patients with severe allergic reaction (e.g., anaphylaxis) after a previous dose, or to a vaccine component. JYNNEOS vaccine contains small amounts of gentamicin and ciprofloxacin and is produced using chicken embryo fibroblast cells. See package insert [PDF – 11 pages, 301 KB] for a full list of vaccine ingredients. Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating 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. (ACIP Adverse Reactions Guidelines for Immunization). People presenting with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill with or without fever should usually wait until they have recovered to their baseline state of health before routine vaccination; waiting might not be appropriate if vaccination is used for post exposure prophylaxis. CDC’s Clinical Immunization Safety Assessment (CISA) Project is available to provide consultation to U.S. healthcare providers and health departments about complex mpox vaccine safety questions for their patients. See Clinical Immunization Safety Assessment (CISA) Project. The Vaccine Adverse Event Reporting System (VAERS) 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: *Serious adverse events are defined as: On August 9, 2022, FDA issued an EUA for JYNNEOS mpox vaccine. It authorizes the vaccine to be administered in one of two ways: These are considered routes of vaccination. When submitting a VAERS report, ensure that you document the Route in Section 17 of the VAERS form, by

choosing “intradermal” or “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.

Source URL: https://www.cdc.gov/poxvirus/mpox/interim-considerations/overview.html