Jynneos® (smallpox and monkeypox vaccine, live, nonreplicating) – Emergency use authorization granted

- On August 9, 2022, the FDA issued an emergency use authorization (EUA) for Jynneos (smallpox and monkeypox vaccine, live, nonreplicating), for active immunization by subcutaneous (SC) injection for prevention of monkeypox disease in individuals less than 18 years of age determined to be at high risk for monkeypox infection, and for active immunization by intradermal injection for prevention of monkeypox disease in individuals 18 years of age and older determined to be at high risk for monkeypox infection.

    - Jynneos is FDA-approved for the prevention of smallpox and monkeypox disease by SC injection in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection.
    - There are 441,000 vials of Jynneos currently in the strategic national stockpile and supply is less than current demand.
    - The new lower dose and route of administration provided by the EUA will increase supply of vaccine and provide over 2.2 million doses under the new administration method.

- Monkeypox disease is caused by the monkeypox virus, an orthopoxvirus related to variola (the virus that causes smallpox disease). Individuals develop painful lesions that may occur anywhere on the body and may be limited to a single site or may be disseminated across many sites. Individuals may or may not experience prodromal symptoms (eg, chills, lymphadenopathy, malaise, myalgias, or headache). Respiratory symptoms (eg, sore throat, nasal congestion, or cough) can also occur. The clinical presentation of monkeypox disease is typically milder than smallpox disease but can be fatal, particularly in severely immunocompromised individuals who do not receive antiviral therapy.

    - As of August 9, 2022, there have been 9,492 confirmed monkeypox cases in the U.S. and no fatalities have been reported.

- On August 4, 2022, the U.S. Department of Health and Human Services (HHS) Secretary declared the ongoing spread of monkeypox virus in the United States a Public Health Emergency (PHE). The PHE allows for granting of an EUA that modifies the dosing regimen and route of administration and thus extends the current Jynneos supply for use by more individuals.

    - No other vaccine or other alternatives are approved for prevention of monkeypox disease, and the US supply of Jynneos is insufficient to meet public health needs during the monkeypox PHE when the vaccine is administered according to the approved dosing regimen.
    - No vaccine or other alternative is approved for prevention of monkeypox disease in individuals less than 18 years of age.

- The efficacy of Jynneos given intradermally was demonstrated in a clinical study of 358 smallpox vaccine-naïve individuals. Individuals received 2 doses (0.1 mL) given intradermally 4 weeks apart or 2 doses (0.5 ml) given SC 4 weeks apart.

    - Intradermal administration produced a similar immune response to SC administration.

- The authorization of Jynneos in the pediatric population is based on safety and effectiveness data from clinical trials in adults and efficacy data from animal challenge studies and historical data with use of live vaccinia virus smallpox vaccine in pediatric populations.

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- Warnings and precautions for Jynneos include severe allergic reactions, altered immunocompetence, and limitations of vaccine effectiveness.

- The most common adverse reaction (> 10%) with Jynneos use in smallpox-naïve adults who received Jynneos intradermally were erythema at injection site, induration at injection site, itchiness, pain at injection site, feeling tired, headache, muscle aches, nausea, underarm pain, change in appetite, joint pain, chills, and underarm swelling.

- The recommended dose of Jynneos under the EUA in adults 18 years of age and older is two doses (0.1 mL each) given intradermally 4 weeks apart.

    — The Centers for Disease Control and Prevention have provided information and educational materials aimed at training health care workers and providers on how to administer the vaccine intradermally.
    — The FDA-approved dose of Jynneos in adults 18 years of age and older is two doses (0.5 mL each) given SC 4 weeks apart.

- The recommended dose of Jynneos under the EUA in individuals less than 18 years of age is two doses (0.5 mL each) given SC 4 weeks apart.

- Bavarian Nordic's Jynneos is available free from HHS' Administration for Strategic Preparedness and Response (ASPR) Strategic National Stockpile.

What's Next?

- Currently Jynneos vaccine administration is through public health departments. Unlike with COVID-19 vaccines, pharmacists are not authorized to administer Jynneos. However, pharmacist organizations have requested that the federal government invoke the Public Readiness and Emergency Preparedness Act in order to authorize pharmacists to administer Jynneos.

- If pharmacists receive permission to order and administer the vaccine, payers will need to ensure reimbursement for services.

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