U.S. FOOD & DRUG ADMINISTRATION

Intradermal JYNNEOS Monkeypox Vaccine Fast Facts

- **Making vaccine available to all at risk for monkeypox infection is a top USG priority**
- **JYNNEOS can be safely given by either the subcutaneous or the intradermal route**
- **The immune responses are similar using the two different routes of administration**
- **Intradermal administration allows the broadest protection of the community right now**

The rapidly evolving monkeypox outbreak has necessitated that all available vaccine options be explored to provide immunologic protection for populations at risk. The number of currently available doses of the JYNNEOS monkeypox vaccine were determined to be inadequate to fully vaccinate those who could benefit with the approved two dose regimen given four weeks apart by subcutaneous (SC) injection. Use of other vaccines for monkeypox was determined to be inadvisable at this time due to side effects. Consideration was also given to delaying second JYNNEOS vaccine doses by 3 to 6 months. However, following careful review of available evidence, and acknowledging the absence of precisely applicable data for this strategy, this option was determined to be inadvisable because it might both be insufficiently protective between doses and could provide individuals with a false sense of security that they were protected against monkeypox when they were not.

To address the mismatch between supply and demand, vaccine administration by the intradermal (ID) route was considered as a strategy to extend inventory. Some vaccines can be given in smaller amounts between the layers of the skin and produce a very similar immune response as when they are given into the tissue beneath the skin.[1] The virus used in JYNNEOS, Modified Vaccinia Ankara (MVA), was originally administered in the 1970's by the ID route to thousands of children and adults, and it has been administered ID since that time in clinical trials in combination with other vaccines.[2] Additionally, JYNNEOS was evaluated as a two-dose series given ID compared to SC in a study sponsored by the National Institute of Allergy and Infectious Diseases (NIAID). Individuals who received the vaccine ID received a dose adjusted for injection between skin layers; the ID dose evaluated was 1/5 the volume (0.1mL) than the SC dose (0.5mL).

The results of the NIAID study demonstrated that ID administration produced a very similar immune response to SC administration based on several tests of antibody response and demonstrated that the SC and ID routes generated similar, though not identical, cellular immune responses.[3] ID administration did result in more redness, firmness, itchiness and swelling at the injection site, but less pain, and these side effects were manageable. Of interest, the side effect profile reported with ID administration of JYNNEOS in the NIAID study very closely mirrored the side effect profile described when MVA was given ID in the 1970's.[2]

Based on a careful review of the totality of available evidence and considering all available options, FDA determined that the Emergency Use Authorization (EUA) criteria were met to allow the administration of JYNNEOS by the ID route in individuals 18 years of age and older determined to be at high risk of infection, as well as to allow those under age 18 years determined to be at high risk of infection to receive the vaccine SC.[4]

Based on stability information, the authorized vaccine can now be stored for up to 8 weeks after it is thawed at +2°C to +8°C (+36°F to +46°F). After a vial is punctured and a dose is withdrawn, if it is not used in its entirety, it should be stored at +2°C to +8°C (+36°F to +46°F) and discarded within 8 hours of the first puncture. Low dead volume syringes and needles (27 gauge) should be used to maximize the number of doses obtained from each vial.[5]

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1 Hickling JK et al. Bull World Health Organ 2011; 89:221-226.
2 Stickl HA, Preventive Medicine, 1974; 3:97-101; Stickl H et al. Dtsch med Wschr 1974; 99:2386-2392.
3 Frey SE et al. Vaccine 2015; 33:5225-5234; Frey SE et al. J Infect Dis; 2021; 224:1372-1382.
4 EUA materials including the review memoranda and fact sheets are available on-line.
5 Please see DHCP Letter of August 10, 2022, for additional information and resources regarding administration