Indian Health Service
National Pharmacy and Therapeutics Committee
Monkeypox Emerging Treatments Update

August 10, 2022

FDA authorizes intradermal Use of JYNNEOS vaccine for Monkeypox

On August 9, 2022, the U.S. Food and Drug Administration (FDA) authorized the intradermal administration of the Jynneos vaccine for the treatment of monkeypox. The process, approved specifically for high-risk patients, was passed under the administration's Emergency Use Authorization (EUA). It follows the decision on August 4 by the US Department of Health and Human Services to declare monkeypox a Public Health Emergency. Intradermal administration will allow providers to get five doses out of a one-dose vial. The EUA also expands use of the standard regimen to patients <18 years of age.

Vaccination Schedule

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 and is the FDA-approved dosing regimen in patients ≥18 years of age. Since August 9, 2022, the standard regimen has been authorized for people aged <18 years under an Emergency Use Authorization.

In the context of the current national Public Health Emergency, an **alternative regimen** may be used for people age ≥18 years under an Emergency Use Authorization beginning August 9, 2022. The authorized alternative regimen involves an intradermal (ID) route of administration with an injection volume of 0.1mL. This approach could increase the number of available JYNNEOS vaccine doses by up to five-fold. 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).

Table 1. Vaccination Schedule and Dosing Regimens for JYNNEOS Vaccine

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
Alternative regimen				
People age ≥18 years	ID	0.1 mL	2	28 days
Standard regimen				
People age <18 years	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

Administration

Intradermal (ID): Intradermal administration involves injecting the vaccine superficially between the epidermis and the hypodermis layers of the skin, typically of the volar aspect (inner side) of the forearm. This should produce a noticeable pale elevation of the skin (wheal). **Proper intradermal technique is critical to ensure the effectiveness of the 0.1 mL dose.** Please refer to related resources, including intradermal administration teaching tools and the Preparation & Administration Summary for the General Population for further details on intradermal vaccine administration.

A person who presents for their second JYNNEOS vaccine dose who is still experiencing erythema or induration at the site of intradermal administration of the first vaccine dose (e.g., the forearm) may have the second dose administered intradermally in the contralateral forearm.

References:
1. Medscape. FDA Authorizes Intradermal Use of Jynneos Vaccine for Monkeypox. Published August 9, 2022.
2. Centers for Disease Control and Prevention. JYNNEOS Vaccine. Updated August 9, 2022.