INSTRUCTIONS FOR OBTAINING APPROVAL TO GIVE JYNNEOS VACCINE TO MINORS
July 25, 2022

Jynneos is currently available for children <18 years old as an investigational drug under an FDA program called S-IND (single-subject IND, also known as a treatment IND).

FDA approval is required, per each child, before giving a dose of Jynneos vaccine to someone under age 18 years. Signed informed consent is also required using this specific form.

Getting prior approval from FDA for each dose affords the child/family liability protection under the PREP Act in the unlikely case of any injury due to the vaccine.

CDC is assisting providers with obtaining the S-IND approval for each individual patient. Please follow the instructions below.

> Note: CDC and FDA are working on developing an expanded-access IND for pediatric use of Jynneos. The EA-IND is not yet in place. When the EA-IND is ready, it will eliminate the step of needing prior authorization for each patient.

To obtain authorization to use a Jynneos dose in a child who is a high-risk contact to a monkeypox case --

- Please send encrypted email to CDC at eocevent482@cdc.gov and regaffairs@cdc.gov
- And cc SFDPH at monkeypox@sfdph.org

Include the following info in the email so that CDC can initiate and obtain FDA authorization on an S-IND:

1. Information on clinical and exposure history
   - Contact's initials
   - Age and gender
   - Relationship of contact to the confirmed or probable MPX (household contact, family member e.g., sister, brother, niece, nephew)
   - Information on MPX case (confirmed OPXV+ or MPXV+)
     - Case's date of symptom onset, date of diagnosis, symptoms including location of lesions
   - Detail description on the nature of the exposure to the contact
   - PEP candidate's pre-existing clinical conditions (e.g., immunocompromising conditions, atopic dermatitis)

2. Clinician/vaccine provider information
   - Name
   - Address
   - Email address
   - Telephone number
   - Fax number

Once CDC receives the FDA-required information noted above, CDC can submit a request to FDA to obtain an authorization, which can take up to a full working day for FDA's response turnaround.

To comply with the PREP act, please wait to administer the Jynneos dose until after the authorization is granted.

The informed consent form (ICF) can be used to initiate/obtain consent from the parents/guardians while the FDA's S-IND authorization is pending.