Centers for Disease Control and Prevention

Monkeypox

Monkeypox Vaccination Program Provider Agreement

Updated September 14, 2022

The U.S. Department of Health and Human Services (HHS) and its components the Administration for Strategic Preparedness & Response (ASPR), Strategic National Stockpile (SNS), and the Centers for Disease Control and Prevention (CDC) greatly appreciate your organization's participation in the HHS Monkeypox Vaccination Program.[1] With use of the JYNNEOS™ or ACAM2000® vaccine provided at no cost by the US government (this vaccine), the provider and provider's organization (Organization) will be deemed to have agreed to comply with the requirements of this Agreement. Any person accessing this vaccine is subject to compliance with the terms of this Agreement, including any updates to the Agreement as noted in paragraph 2 below.

This vaccine remains property of the United States government and subject to the terms of this Agreement until the dose is administered to the vaccine recipient.

[1] The HHS Monkeypox Vaccination Program includes JYNNEOS™ and ACAM2000® vaccines.

> For details on using the JYNNEOS and ACAM2000 vaccines during the 2022 U.S. monkeypox outbreak, including an alternative regimen for administering the JYNNEOS vaccine intradermally, please see CDC's Interim Clinical Considerations, as this may be updated from time to time.

Updates (Last updated on 9/14/22)

9/14/22 Update (revisions noted in bold)

- **Inventory/administered doses/wastage reporting**

Paragraph 8 is replaced with the following:

8. Organization must report weekly the number of doses of JYNNEOS/ACAM2000 vaccine that were administered, remain in inventory, or were spoiled, expired, or wasted during the previous week. These reports of inventory count and aggregate doses administered must be submitted by the Organization through **your system of record to the jurisdiction**. Future allotments of this vaccine are dependent upon Organization reporting of Vaccine Administration Data and reporting required under this paragraph.

Provider Agreement

Agreement Requirements

1. Organization must administer JYNNEOS or ACAM2000 in accordance with all relevant requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP) [2] (including those in the

CDC Interim Clinical Considerations for Monkeypox Vaccination [3] and any CDC Emergency Use Instructions [4] as they may be revised from time to time), and consistent with the scope of the Food and Drug Administration's (FDA's)

approval, authorization, and/or any applicable expanded access requirements per FDA's protocol. [5]

2. This Agreement expressly incorporates all information included in weblinks in this Agreement as they may be revised from time to time. HHS reserves the right to update this Agreement at any time by posting updates on the HHS Monkeypox Vaccination Program Provider Agreement update webpage. Organization must monitor this website for updates and comply with any such posted updates.

3. Organization must record the following Vaccine Administration Data elements in each vaccine recipient's record:

    a. Administration address (including Company)*
    b. Recipient name and ID*
    c. Recipient date of birth*
    d. Recipient sex*
    e. Recipient address*
    f. Administration date*
    g. CVX (product)*
    h. Dose number*
    i. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
    j. MVX (manufacturer)*
    k. Vaccine administering provider's name and suffix*
    l. Administering provider's address, if different than the administration address*
    m. Vaccine administration site (on the body)*
    n. Vaccine expiration date*
    o. Vaccine route of administration

4. Organization must submit the following Vaccine Administration Data [6] at least weekly through either (1) the Immunization Information System (IIS) of the state, local, or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation as may be posted on the Provider Agreement update webpage:

    a. Administered at location/facility name/ID
    b. Administered at location type
    c. Administration address (including Company)* [7]
    d. Recipient name and ID*
    e. Recipient date of birth*
    f. Recipient sex*
    g. Recipient race
    h. Recipient ethnicity
    i. Recipient address*
    j. Administration date*
    k. CVX (product)*
    l. NDC (national drug code)
    m. Dose number*
    n. Lot number (Unit of Use [UoU] or Unit of Sale [UoS])*
    o. MVX (manufacturer)*
    p. Sending organization (name of the entity submitting the report)
    q. Vaccine administering provider's name and suffix*

q. Vaccine administering provider's name and suffix

r. Administering provider's address, if different than the administration address*

s. Vaccine administration site (on the body)*

t. Vaccine expiration date*

u. Vaccine route of administration*

v. Vaccine series

5. Organization is prohibited from selling or seeking reimbursement for JYNNEOS or ACAM2000 vaccine doses and any other supplies that the federal government provides without cost to Organization.

6. Organization must administer JYNNEOS or ACAM2000 vaccine at no cost to the recipient and regardless of the vaccine recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers JYNNEOS or ACAM2000 vaccine administration fees for the vaccine recipient, such as:

   - vaccine recipient's private insurance company
   - Medicare/Medicaid reimbursement

7. Before administering JYNNEOS vaccine, Organization must provide a CDC Vaccine Information Statement (VIS), or FDA Emergency Use Authorization (EUA) Fact Sheet for persons receiving JYNNEOS vaccine under EUA, as applicable, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Before administering ACAM2000 vaccine, Organization must provide an FDA Medication Guide to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. [8]

8. Organization must report weekly the number of doses of JYNNEOS/ACAM2000 vaccine that were administered, remain in inventory, or were spoiled, expired, or wasted during the previous week. These reports of inventory count and aggregate doses administered must be submitted by the Organization through your system of record to the jurisdiction. Future allotments of this vaccine are dependent upon Organization reporting of Vaccine Administration Data and reporting required under this paragraph.

9. Organization must make records related to participation in the HHS Monkeypox Vaccination Program available for immediate inspection upon request by HHS, its relevant component agencies, and relevant state, tribal, territorial, or local public health authorities.

10. Organization must comply with CDC requirements for JYNNEOS/ACAM2000 vaccine management:

    a. Organization must store and handle JYNNEOS/ACAM2000 vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with CDC guidance regarding monkeypox vaccines in the CDC Vaccine Storage and Handling Toolkit Addendum [2.58 MB, 70 pages] and in CDC Monkeypox Vaccine Storage and Handling Summary [1.14 MB, 2 pages]

    b. Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance located in CDC Monkeypox Vaccine Storage and Handling Summary

    c. Organization must comply with CDC Monkeypox Vaccine Storage and Handling Summary guidance for dealing with temperature excursions

    d. Organization must monitor and comply with JYNNEOS and ACAM2000 vaccine expiration dates and beyond-use date timeframes as noted in CDC Monkeypox Vaccine Storage and Handling Summary guidance

    e. Organization must preserve all records related to JYNNEOS and ACAM2000 vaccine management and administration for a minimum of 3 years, or longer if required by state, local, or territorial law.

11. Organization must report all SERIOUS ADVERSE EVENTS (AEs) following administration of JYNNEOS or ACAM2000 vaccine and VACCINE ADMINISTRATION ERRORS to the Vaccine Adverse Event Reporting System (VAERS) :

    The vaccination provider is responsible for MANDATORY reporting of the following listed events following JYNNEOS or ACAM2000 vaccination to VAERS:

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events* (irrespective of attribution to vaccination)
- Cases of cardiac events including myocarditis and pericarditis
- Cases of thromboembolic events and neurovascular events

*Serious adverse events are defined as:

- Death
- A life-threatening adverse event
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect
- An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above

Providers are encouraged to also report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

12. Organization's JYNNEOS and ACAM2000 vaccination services must be conducted in compliance with:

    a. All applicable local, state, and federal vaccination laws
    b. CDC's guidance on vaccine administration
    c. CDC's General Best Practice Guidelines for Immunization

13. Organization is prohibited from transferring JYNNEOS and ACAM2000 vaccine doses to another provider unless authorized by HHS or the relevant public health jurisdiction.

14. Upon request by HHS or the relevant public health jurisdiction, Organization must return all JYNNEOS and ACAM2000 vaccine doses not yet used.

15. Effective August 15, 2022, vaccine allocation decisions by HHS will be made based on the expectation that vaccine will be administered to individuals over 18 years of age via intradermal injections at 0.1mL per injection. This route of administration is authorized by the FDA through Emergency Use Authorization since, as a two-dose intradermal regimen, it safely provides a similar immune response against monkeypox as the approved two-dose subcutaneous regimen.
    While a subcutaneous route of administration utilizing 0.5 mL per injection is still permitted (per original FDA approval), it should only be utilized for those who have a contraindication to intradermal injection (e.g., those with a history of keloid formation or those unable to tolerate intradermal injections).
    For individuals under 18 years of age, subcutaneous administration utilizing 0.5 mL per injection is also authorized.

Non-compliance with the terms of Agreement may result in suspension or termination from the HHS Monkeypox Vaccination Program and imposition of criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

[2] See the HHS Monkeypox Vaccination Program Provider Agreement update webpage (https://www.cdc.gov/poxvirus/monkeypox/provider-agreement.html) for comprehensive information on CDC/ACIP recommendations.

[3] Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

[4] HHS Monkeypox Vaccination Program Provider Agreement

[5] ACAM2000 uses for prevention of monkeypox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug applications , authorized by FDA. Updates to this Agreement will be posted on the HHS Monkeypox Vaccination Program Provider Agreement update website when such uses are authorized by FDA.

website when such uses are authorized by FDA.

[6] Additional Vaccine Administration Data elements may be required to be reported by the provider to the Immunization Information System. Check with your IIS.

[7] Data elements marked with an asterisk must also be recorded in the vaccine recipient's medical record as required under paragraph 3.

[8] As noted in footnote 5, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination. Updates to the provider agreement website will be posted when FDA authorizes such uses.

Original Provider Agreement Posting Date–8/19/22.

Refer to the Updates section of the provider agreement update webpage for any revisions to this agreement (Monkeypox Vaccination Program Provider Agreement | Monkeypox | Poxvirus | CDC).

Download or Print: HHS Monkeypox Vaccination Program Provider Agreement [4 pages, 425 KB]

Related Pages

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