Mpox

Michigan Department of Health and Human Services (MDHHS) Immunization Information Systems (IIS) Mpox Program

Provider Addendum

The Michigan Department of Health and Human Services (MDHHS) appreciates your organization's (*organization name*) participation in the MDHHS Mpox virus (MPV) Program. With use of the JYNNEOS™ and ACAM2000® vaccines and tecovirimat (TPOXX) for treatment provided at no cost by the U.S. government, the provider *(provider name)* and provider's *(organization name)* will be deemed to have agreed to comply with the requirements of this addendum. Any provider/organization working with the MPV program is subject to compliance with the terms of this addendum.

The vaccine and medical countermeasures available for treatment are federal assets and remain property of the U.S. government and are subject to the terms of the HHS Provider Agreement until the dose is administered or dispensed to the recipient. The MDHHS IIS Mpox Program Provider Addendum is an addendum that establishes specific requirements for Mpox vaccine providers and providers administering treatment of therapeutics in Michigan. All terms in the HHS Provider Agreement apply as well as the requirements set forth in the MDHHS IIS Mpox Program Provider Addendum.

MDHHS IIS Mpox Program Provider Addendum Requirements:

1. Organization must administer vaccine in accordance with all relevant requirements and recommendations of the CDC and CDC's Advisory Committee on Immunization Practices (ACIP) (including those in the CDC Interim Clinical Considerations for JYNNEOS Mpox Vaccination and any MDHHS Emergency Use Authorization (EUA)), and remain 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.[1]

   Tecovirimat for treatment of mpox must be dispensed in accordance with the CDC's Expanded Access IND Protocol: Use of Tecovirimat for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children. Additionally, providers agree to complete and submit all required documentation to the CDC:
   a. Informed Consent Form. The patient or patient guardian signature may be written or electronic and may be emailed back to the health care provider. Alternative Short Form Consent and Written Summary may be used instead. (Provide copy to patient and retain a copy as part of patient record, **do not send to CDC**.)
   b. Tecovirimat IND Online Registry. (Submit to CDC within seven calendar days of treatment initiation.)
   c. Patient Intake Form. (Submit to CDC within seven calendar days of treatment initiation.)
   d. Medwatch Serious Adverse Events Form. (Submit to CDC within 72 hours of awareness or sooner.)

2. This addendum incorporates all information included in weblinks within this addendum as they may be revised from time to time. MDHHS reserves the right to update this addendum at any time by posting updates for the MDHHS IIS Mpox Program Provider Addendum at: https://www.michigan.gov/mdhhs/keep-mi-healthy/communicablediseases/diseasesandimmunization/mpvw. The organization must monitor the MDHHS website for updates and comply with posted updates.
   a. *For guidance on JYNNEOS providers steps see the: MDHHS JYNNEOS Vaccine Operational Guide.*
   b. *For guidance on requesting and dispensing tecovirimat (TPOXX) see the: Steps for Ordering TPOXX for Michigan Health Care Providers.*

[1] ACAM2000 uses for prevention of mpox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug (IND) applications, authorized by FDA. IND Applications for Clinical Treatment (Expanded Access): Overview | FDA.

[2] As noted in footnote one, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination.

3. This addendum covers JYNNEOS, ACAM2000 and tecovirimat (TPOXX). MDHHS, for the purpose of the addendum and current outbreak, will be providing information and guidance on the use of JYNNEOS vaccine and any medical countermeasure available for treatment.

4. In order to be a provider in the MDHHS Mpox Program the organization must be registered in the Michigan Care Improvement Registry (MCIR) before administering JYNNEOS vaccine or dispensing tecovirimat (TPOXX). Once a MCIR user, the provider must receive access to the MCIR Outbreak Module.
    a. MCIR Provider Site Usage Agreement

    Ensure that health care professionals who may administer vaccine, dispense tecovirimat, or look up records, have MCIR user access. These requests for access are performed by the MCIR Site Administrator at your facility. Site Administrator- Providers – mcir.org. For assistance and training on MCIR work with your Regional MCIR Staff.

5. The organization is accountable for JYNNEOS and tecovirimat (TPOXX) inventory and must account for both in MCIR. Since both products are provided through the Strategic National Stockpile (SNS), MDHHS will be placing the orders for JYNNEOS to be delivered to one of the MPV hubs, whereas tecovirimat will be distributed by MDHHS to local health departments (LHD) for further redistribution or directly to the requesting provider.

    The organization is not responsible to submit JYNNEOS or tecovirimat (TPOXX) orders. The organization will need to request vaccine through the LHD. Whereas, requests for tecovirimat (TPOXX) may be made to either LHDs or through MDHHS' Steps for Ordering TPOXX for Michigan Health Care Providers.

6. Organizations seeking to become a JYNNEOS vaccine provider or access tecovirimat (TPOXX) will need to reach out to their LHD for assistance in this process. The organization must meet guidelines (some listed below) to ensure proper management of JYNNEOS or tecovirimat (TPOXX) before signing an MDHHS IIS Mpox Provider Addendum. For JYNNEOS, providers must also comply with the HHS MPox Provider Agreement. The HHS Mpox Provider Agreement link will be shared every time a JYNNEOS vaccine order is placed or anytime JYNNEOS vaccine is sent to an approved JYNNEOS provider.

    In order to become a JYNNEOS vaccine provider or dispense tecovirimat (TPOXX) in Michigan:
    a. Must ensure provider is enrolled in MCIR and has access to the MCIR Outbreak Module.
    b. **(Vaccine only)** Must comply with the HHS Mpox Provider Agreement.
    c. Must sign and comply with an MDHHS IIS Mpox Provider Addendum.
    d. **(Vaccine only)** Must ensure provider will store the vaccine properly and must ensure provider is trained on storage and handling of JYNNEOS vaccine.

7. **(Vaccine only)** Organization should not redistribute JYNNEOS vaccines to another provider without consulting the LHD to ensure the provider meets the requirements to become a JYNNEOS vaccine provider.
    a. JYNNEOS vaccine is a scare resource, and each provider will need to be reviewed to ensure JYNNEOS vaccine management and storage capabilities.
    b. Organization must work with the LHD/JYNNEOS vaccine hub regarding other potential JYNNEOS providers.

8. **(Vaccine only)** Once determined to be a vetted mpox vaccine provider, the JYNNEOS vaccine hub will redistribute JYNNEOS vaccine. Inventory must be managed in MCIR and account for all JYNNEOS vials transferred. Transfer of vaccine is performed utilizing the appropriate inventory transactions in MCIR. The new JYNNEOS provider site must manually enter JYNNEOS vials into the MCIR Outbreak Inventory as whole vials.
    a. Before redistribution of JYNNEOS vaccine to another provider the JYNNEOS hub/LHD must ensure the provider seeking JYNNEOS vaccine meets the qualification to manage JYNNEOS vaccine.

[1]ACAM2000 uses for prevention of mpox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug (IND) applications, authorized by FDA. IND Applications for Clinical Treatment (Expanded Access): Overview | FDA.

[2]As noted in footnote one, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination.

9. Organization must comply with MDHHS/MCIR Inventory Management of JYNNEOS vaccine and tecovirimat (TPOXX).
    a. When JYNNEOS vaccine arrives to the location the JYNNEOS vials and tecovirimat (TPOXX) bottles must be manually entered into the MCIR Outbreak Inventory.
        I. MDHHS is counting JYNNEOS vaccine inventory as a whole vial.
        II. MDHHS is counting tecovirimat (TPOXX) inventory as a bottle.
        III. For questions on how to manually enter doses into MCIR Outbreak Inventory, please contact the MCIR Regional staff.
    b. **(Vaccine only)** When administering a dose of JYNNEOS vaccine it will be either by the standard or preferred alternative regimen.
    c. Once JYNNEOS vaccine has been administered or tecovirimat (TPOXX) dispensed, document the dose administered into MCIR. For JYNNEOS, MDHHS is requiring the organization to document the route used and the volume of vaccine administered.
        I. Recommended to document the dose into MCIR within 24 hours to ensure accurate inventory management.
    d. Organization recommended to balance JYNNEOS vaccine and tecovirimat (TPOXX) inventory daily to ensure accurate inventory management.
    e. **(Vaccine only)** MDHHS has established that the organization should follow the preferred method for administration of JYNNEOS vaccine.
        I. The preferred method is the alternative regimen in which 0.1 ml is administered.
        II. With the alternative regimen you will be able to obtain up to five 0.1 mL doses out of the single dose vial.
        III. There will be times when the standard regimen will be used, and 0.5 mL will be administered (i.e., for persons less than 18 years and persons who have a history of keloid scars).
    f. **(Vaccine only)** MDHHS has established inventory management in MCIR to account for inventory based on 0.1ml or 0.5mL.

10. Before administering JYNNEOS vaccine, organization must provide a MDHHS Vaccine Information Statement (VIS): Smallpox/Mpox VIS 11-14-22, or the MDHHS 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.[2]

11. Organization must record the following data elements in each vaccine recipient's record and in MCIR. It is recommended to record in MCIR within 24 hours of administration of the vaccine, but no longer than 72 hours:
    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*
    j. MVX (manufacturer)*
    k. 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 volume*
    p. Vaccine route of administration*

[1]ACAM2000 uses for prevention of mpox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug (IND) applications, authorized by FDA. IND Applications for Clinical Treatment (Expanded Access): Overview | FDA.

[2]As noted in footnote one, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination.

12. Organization is prohibited from selling or seeking reimbursement for JYNNEOS, ACAM2000, tecovirimat (TPOXX), and any other supplies that the federal government provides without cost to organization.

13. Organization must administer vaccine (JYNNEOS or ACAM200) or tecovirimat (TPOXX) at no cost to the recipient regardless of the vaccine recipient's ability to pay administration fees, including through balance billing. Organization may seek appropriate reimbursement from a program or plan that covers administration fees for the recipient, such as:
    - Vaccine recipient's private insurance company.
    - Medicare/Medicaid reimbursement.

    CDC CPT Codes

14. **(Vaccine only)** Organization must comply with CDC and MDHHS 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 in the CDC Vaccine Storage and Handling Toolkit Addendum and in CDC's Mpox Vaccine Storage and Handling Summary.
    b. Organization should review storage and handling guidance at the MDHHS's Vaccine for Children (VFC) webpage. Resources available on the VFC webpage include storage and handling documents (e.g., temperature logs and the emergency response plan) and requirements for Michigan's VFC program. The MDHHS VFC program guidelines regarding storing vaccine are the gold standard for storage of all vaccines in Michigan.
    c. Organization must monitor vaccine storage unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Mpox Vaccine Storage and Handling Summary. Temperature logs can be found at the MDHHS VFC webpage.
    d. Organization must comply with CDC's Mpox Vaccine Storage and Handling Summary guidance for dealing with temperature excursions. Information on handling temperature excursion can be found at the MDHHS VFC webpage.
        I. Temperature excursions must be handled immediately upon knowledge of the out-of-range reading.
        II. When dealing with a temperature excursion the manufacturer must be contacted.
        III. Vaccine should remain in the appropriate storage unit and labeled, "DO NOT USE" until the manufacturer can be contacted, and determination made on the viability of the vaccine.
        IV. Do not discard vaccine until viability has been determined based on manufacture guidance.
        V. Involve the LHD for questions regarding temperature excursions.
    e. Organization must monitor and comply with JYNNEOS, and ACAM2000 vaccine expiration dates and beyond-use date timeframes as noted in CDC's Mpox Vaccine Storage and Handling Summary guidance.
        I. **Expiration date is printed on the vaccine carton, not individual vials.**
    f. Organization must preserve all records related to JYNNEOS and ACAM2000 vaccine management and administration for a minimum of three years, or longer if required by state, local, or territorial law.

15. 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).
    a. Organization administering JYNNEOS under the EUA are **required** to report the following adverse events that occur after JYNNEOS vaccination:
        I. Vaccine administration errors whether or not associated with an adverse event.
        II. Serious adverse events (irrespective of attribution to vaccination).
        III. Cases of cardiac events including myocarditis and pericarditis.
        IV. Cases of thromboembolic events and neurovascular events.
    b. Serious adverse events are defined as:
        I. Death.
        II. A life-threatening adverse event.
        III. Inpatient hospitalization or prolongation of existing hospitalization.

[1]ACAM2000 uses for prevention of mpox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug (IND) applications, authorized by FDA. IND Applications for Clinical Treatment (Expanded Access): Overview | FDA.

[2]As noted in footnote one, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination.

IV. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions.
V. A congenital anomaly/birth defect.
VI. 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.

Organization must report all serious adverse events following the use of tecovirimat (TPOXX) via Medwatch Serious Adverse Events Form within 72 hours of awareness or sooner.

16. **(Vaccine only)** Organization vaccine services for JYNNEOS and ACAM2000 must be conducted in compliance with:
    a. All applicable local, state, and federal vaccination laws.
    b. CDC guidance on vaccine administration.
    c. CDC General Best Practice Guidelines for Immunization.
    d. CDC guidance on Intradermal (ID) vaccine administration.

17. Organization must make records related to participation in the MDHHS IIS Mpox Program available for immediate inspection upon request by MDHHS, tribal, territorial, or local public health authorities.

18. Organization is prohibited from transferring JYNNEOS and ACAM2000 vaccine vials or tecovirimat (TPOXX) to another provider unless the new provider has gone through the process to ensure they are able to appropriately manage and store the vaccine. Once the provider has been verified as being an eligible JYNNEOS provider they will need to sign an MDHHS IIS Mpox Program Provider Addendum.

19. Upon request by HHS or the relevant public health jurisdiction, organization must return all JYNNEOS and ACAM2000 vaccine vials or tecovirimat (TPOXX) not yet used.

Non-compliance with the terms of Addendum may result in suspension or termination from the MDHHS Mpox Vaccination Program.

Signature
Organization/JYNNEOS Provider: _____

Date: _____

[1]ACAM2000 uses for prevention of mpox in adults and children are not FDA-approved. Thus, these "unapproved" uses are required to proceed under expanded access Investigational New Drug (IND) applications, authorized by FDA. IND Applications for Clinical Treatment (Expanded Access): Overview | FDA.

[2]As noted in footnote one, for use of ACAM2000 in adults and children, FDA must authorize expanded access IND and an informed consent will be required prior to vaccination.