JYNNEOS Vaccine Operational Guide

This operations guide is to ensure providers administering JYNNEOS vaccine are prepared to properly store, handle, and administer intradermal or subcutaneous injections. JYNNEOS providers should use this checklist as a comprehensive overview to support vaccination efforts and confirm compliance with requirements expected. Completion of this checklist is REQUIRED *prior to* performing JYNNEOS vaccination. Storage and handling, along with administration guidance are required to be followed on a daily basis.

Instructions: This is intended to be used as an electronic checklist, allowing direct links to resources. These resources can also be found at **Michigan.gov/MPV.** Bookmark this website for support and frequent updates. In the JYNNEOS Vaccine Operational Guide there is a column for the local health department (LHD) to conduct a checkoff when ensuring a provider is eligible to become a JYNNEOS vaccine provider. There is also a checklist column for the JYNNEOS provider to use to ensure they meet the steps needed in order to become a JYNNEOS vaccine provider. Use this tool to ensure the provider meets the requirements for managing JYNNEOS vaccine.

MCIR SITE REGISTRATION, USER ACCESS, MCIR DATA ENTRY PREPARATION

LHD JYNNEOS Provider Checkoff	JYNNEOS Provider Office Checklist	
☐	☐	Providers must be registered in MCIR before receiving and administering JYNNEOS vaccine. For more information on how to register visit the Provider Site Usage Agreement. Provider must have access to the MCIR Outbreak Module.
☐	☐	Ensure MCIR user access for individuals at your facility who may administer vaccine or look up records. • These requests for access are performed by the MCIR Site Administrator at your facility. To request user access, associate users, etc., view tip sheets, and videos, the Site Administrator Manual is available here. If you do not know who your Site Administrator is, contact your MCIR Regional staff.
☐	☐	At minimum, providers must designate one Primary Vaccine Coordinator and one Backup (Secondary) Vaccine Coordinator per facility. Guidelines are listed in the VFC Primary and Back-up Staff Responsibilities (michigan.gov) and must be followed.
☐	☐	Establish a process for the documentation of JYNNEOS vaccine administration into your clinic's medical record system and MCIR within 24 hours, but no longer than 72 hours. (e.g., HL7 VXU from EHR, Upload to MCIR, Direct Data Entry into MCIR).
☐	☐	Work with Regional MCIR staff for assistance and training on MCIR.

BILLING AND VACCINE CODE SETS

<table>
<tr><th>LHD JYNNEOS Provider Checkoff</th><th>JYNNEOS Provider Office Checklist</th><th></th></tr>
<tr><td>☐</td><td>☐</td><td>Patients must not be denied MPV vaccine for any reason relating to billing and reimbursement.
Insured Patients
Only the administration fee, and not the cost of the vaccine, can be submitted to insurance for reimbursement. Currently, there is no billing cap for administration fees billed through private and publicly funded insurance.
Uninsured Patients
Providers must ~~do~~ not seek any reimbursement, including through balance billing. Providers are prohibited from charging patients for administration fees of the vaccine if they have no insurance.</td></tr>
<tr><td>☐</td><td>☐</td><td>JYNNEOS vaccine IIS | Code Sets | CPT | Vaccines | CDC.
<table>
<tr><th>CPT CODE</th><th>CPT Description</th><th>CVX Code</th><th>Vaccine Name</th><th>Comments</th><th>Last Updated Date</th></tr>
<tr><td>90611</td><td>Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use</td><td>206</td><td>Vaccinia, smallpox monkeypox vaccine live, PF</td><td>CPT Code to be used for JYNNEOS vaccine</td><td>7/27/2022</td></tr>
</table></td></tr>
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STORAGE AND HANDLING

LHD JYNNEOS Provider Checkoff	JYNNEOS Provider Office Checklist	
☐	☐	Review storage and handling specific to JYNNEOS vaccine: • JYNNEOS Smallpox and Monkeypox Vaccine Storage and Handling Summary (cdc.gov) • Vaccine comes in packages of 20 vials • Do NOT store on dry ice or below -50°C (-58°F) • Store in original package to protect from light • Please note that the JYNNEOS manufacturer has provided **a letter** indicating **expanded storage at refrigerated temperatures that is not indicated in the package insert**. • MDHHS JYNNEOS Resource guide:

Indication for Use	Standard regimen (subcutaneous): • People under 18 years of age • People of any age with history of keloid scarring • Prior to administration for people younger than 6 months, provider should first contact jurisdictional HD	Alternative regimen (intradermal): • People 18 years and older
Number of Doses in Series	2 doses	2 doses
Interval Between Doses	28 days	28 days
Preparation of Vaccine	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use.[3,4]	Allow vaccine to thaw approximately 10 minutes to reach room temperature before use.[3,4]
Administration	**Subcutaneous (Subcut) Injection**[5] (standard regimen) preferably into the anterolateral thigh for infants less than 1 year of age, or into the upper arm (fatty tissue over triceps) for individuals 1 through 17 years of age.	**Intradermal (ID) Injection**[6] (alternative regimen): Placement site: volar aspect (inner side) of forearm Alternative sites: deltoid, or upper back below scapula
Reconstitution	DO NOT DILUTE	DO NOT DILUTE
Dosing Volume	0.5 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows one dose per vial).	0.1 mL- Swirl the vial gently for at least 30 seconds (this dose volume allows up to five doses per vial).
Storage Time in Syringe	**Draw vaccine up right before use - DO NOT PRE-DRAW.**	**Draw vaccine up right before use - DO NOT PRE-DRAW.**
Storage Requirements in Freezer* -25°C to -15°C (-13°F to +5°F)[3]	Expiration: on carton label[7]/look up[8]	Expiration: on carton label[7]/look up[8]
Storage Requirements in Refrigerator **(DO NOT REFREEZE)*** +2°C to +8°C (+36°F to +46°F)[3]	Unpunctured Vial: Expiration **8 weeks** Beyond Use Date(BUD).[4,7] Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of puncture/vial cap removal.[3]	Unpunctured Vial: Expiration **8 weeks** Beyond Use Date(BUD).[4,7] Punctured Vial: DO NOT PRE-DRAW, must discard within 8 hours of the first puncture.[3] (refrigerate after each use)

*__Important note:__ All vaccine, whether received refrigerated or frozen, is originally frozen from the manufacturer. If you receive refrigerated vaccine, it is thawed vaccine. Do NOT refreeze, store it in the refrigerator. Thawed vaccine must be used within 8 weeks (BUD) from thawing.

[1] Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC
[2] Vaccination Administration Considerations for Specific Populations | Monkeypox | Poxvirus | CDC
[3] Fact Sheet for Healthcare Providers for JYNNEOS
[4] JYNNEOS Smallpox and Monkeypox Vaccine Storage and Handling Summary (cdc.gov)
[5] How to administer intramuscular and subcutaneous vaccine injections (immunize.org)
[6] How to administer a JYNNEOS vaccine intradermally (video)
[7] MVA- BN Information Letter (hhs.gov)
[8] Monkeypox (hhs.gov)

☐ ☐ If vaccine is **soon to expire,** please notify your Local Health Department/Immunization Field Representative within a one-to-two-week time period prior to expiration for redistribution.

- **Expiration date is printed on the vaccine carton, not individual vials.** Expiration dates, along with the corresponding lot and NDC numbers can be found at: Monkeypox (hhs.gov)
- Beyond Use Date (**BUD**): The BUD replaces the manufacturer's expiration date and must be noted on the label along with the initials of the person making the calculation.
- Manufacturer-shortened expiration date: when moving JYNNEOS from freezer to refrigerator, the new expiration date, **BUD**, is 8 weeks. The vaccine must never be returned back to the freezer for any reason once it has been placed in refrigerated storage.
- **Note:** The BUD must never be documented in MCIR, only the original expiration date provided by the manufacturer.

☐ ☐ Ensure storage equipment meets CDC requirements*. Before any equipment is used for designated vaccine storage only, work with your local health department (LHD) for guidance and approval on appropriate storage equipment. Current guidance includes CDC's recommendation for vaccine storage units, **in the order of preference**.

- Purpose-built or pharmaceutical/medical-grade units (preferred storage units).
- Stand-alone refrigerator and/or stand-alone freezer units—these units can vary in size from a compact, under-the-counter style to a large, stand-alone, pharmaceutical-grade storage unit.
- Combination household refrigerator/freezer unit, using only the refrigerator compartment to store vaccines—a separate stand-alone freezer must then be used to store frozen vaccines. **Use of the freezer compartment of a household combination unit is prohibited.**

***Do not use a dormitory-style or bar-style storage unit under any circumstances!**

☐ ☐ Utilize certified, calibrated digital data loggers (DDLs) for continuous temperature monitoring on all units, also have a backup for transport, or in case one of the DDLs needs to be repaired or recalibrated.

		• When positioning a DDL in a permanent vaccine storage unit, place the buffered probe in the center of the unit with the vaccines surrounding it, and attach the temperature display to the outside of the unit. • Use DDLs with a current and valid certification of calibration. • Ensure appropriate logging interval is setup: It must log temperatures at least every 30 minutes. It is recommended that intervals be more frequent, such as every 5 minutes. Download, review, and save data weekly, or anytime an alarm or out-of-range temperature is identified.
☐	☐	Utilize temperature logs, check and document temperatures twice daily: 1. Upon arrival to the office: "current" temperature and "min/max" temperature. 2. 30 to 60 minutes prior to departure: "current" temperature. Temperature logs must be kept for a minimum of three years.
☐	☐	Verify unit is stable prior to vaccine ordering or storage (do NOT risk a vaccine loss). It may take 2-7 days to stabilize the temperature in a newly installed refrigerator and 2-3 days for a freezer. Check and record temperatures each day for 2-7 days. Once you have 2 consecutive days of in-range temperatures, your unit is considered stable. At the LHD's discretion, additional days of monitoring may be required.
☐	☐	Storing JYNNEOS vaccines correctly in a vaccine storage unit is also critical to protect the vaccine and reduce the chance of vaccine administration errors. Best practices include: • Place water bottles on the top shelf, floor, and in the door racks of vaccine storage units to help maintain stable temperatures that might be disrupted by frequently opening and closing unit doors. (Note: Water bottles are not recommended for use in in ultra-cold freezers or in some purpose-built or pharmaceutical-grade units—see manufacturer guidance.) • Avoid placing or storing any items other than vaccines, refrigerated diluents, and water bottles inside storage units. Food and beverages should never be stored in the unit with vaccines. If other biologics are stored in the unit, vaccines should be stored on the shelf above them. • Store vaccines and diluents in original packaging. • Position vaccines and diluents two to three inches from the storage unit walls, air-vent, ceiling, floor, and door. If using a household-grade unit, avoid storing vaccines and diluents in any part of the unit that may not provide stable temperatures or sufficient air flow (i.e., doors or drawers). • Arrange vaccines and diluents in rows and allow space between them to promote air circulation. • Create a Vaccine Management Plan, update when changes occur and review/sign annually. Post in visible location for easy access by staff.

☐	☐	Transport must be minimized. If transport is necessary due to an emergency temperature excursion or offsite mass vaccination clinic, it must be performed with qualified pack-out methods, using DDLs to ensure viability is maintained. Document temperatures using a DDL at least every hour, starting with the time of pack-out. Ensure a temperature log and DDL are used for EACH cooler.
		• Develop a Vaccine Management & Emergency Response Plan for transporting vaccines and include procedures and protocols for packing and transport.
		• Materials for transport of vaccine include:
		  ○ Portable vaccine storage units (refrigerator/freezer units - preferred).
		  ○ Qualified vaccine-specific coolers or pack-out containers (Cool Cube, TempArmour, etc.).
		  ○ Coolant materials such as phase change materials (PCMs) for vaccine-specific coolers.
		  ○ Hard-sided insulated containers or Styrofoam™ (for emergency transport only).
		  ○ Frozen water bottles that can be conditioned to maintain appropriate vaccine storage ranges.
		  ▪ **Conditioned water bottle transport method is for emergency transport only.**
		  ○ A digital data logger for each cooler/refrigerator (certified and up-to-date calibration).
		  ▪ Remember to reset the minimum/maximum temperature display.
		  ▪ Place buffered probe as close as possible to vaccines in the transport container.
		  ▪ Do not place buffered probe directly next to ice packs or other coolants.
		  ▪ Attach temperature display to the outer lid of the transport container.
		  ○ Insulating materials: bubble wrap and cardboard.
		• Emergency Transport: Follow guidelines for: Materials for transport of vaccine (above).
		  ○ Printed out guidance on Packing for Emergency Transport.
		  ○ The provider must have an identified backup location even if a generator is on-site.
		  ▪ Alternative storage locations should be inspected prior to an emergency to validate that proper vaccine storage conditions can be maintained.
		  ▪ Ensure 24-hour access to the alternative facility (e.g., Hospitals, Urgent Care Centers).
		  ▪ All staff should be aware of location of the backup unit and the Vaccine Management & Emergency Response Plan.
		  ○ Utilize MDHHS Vaccine Transport Temperature Logs.
		  ○ Temperatures should be documented before, during, and after transport.
		
		Do **NOT** use dry ice, coolant packs from shipments, or soft-sided food/beverage coolers.
		Examples: Image Sources for the transportation of vaccines:
		• Portable Vaccine Refrigerator/Freezer Image: SPRF26M | Accucold® Medical Refrigerators
		• Qualified Container & Pack-out Image: Cool Cube™ 08 at Refrigerator Temps - VeriCor, LLC (vericormed.com)
		• Conditioned Water Bottle Method Image (for emergency transport only): https://www.cdc.gov/vaccines/recs/storage/downloads/emergency-transport.pdf
		
		MDHHS does not endorse certain products, brands, manufacturers, etc.
		
		For more detailed information, please see CDC's Vaccine Storage and Handling Toolkit-Updated with COVID-19 Vaccine Storage and Handling Information, Addendum April 12, 2022 (cdc.gov)

☐	☐	How to identify and manage temperature excursions, including contacting the manufacturer(s): ▪ Implementing routine monitoring activities can help you identify temperature excursions quickly and take immediate action to correct them, preventing loss of vaccines and the potential need for revaccination of patients. Any temperature reading outside the range recommended by the manufacturer is considered a temperature excursion and **requires immediate action**. ▪ Stop vaccinating patients with affected vaccine until viability determination has been made. ▪ Do not discard vaccines until viability determination has been made. ▪ Label the vaccine "Do Not Use." ▪ Continue to store at the recommended temperature range until you receive manufacturer guidance. If it is a frozen vaccine that has been thawed, store in the refrigerator between 2°C and 8°C (36°F and 46° F) until you receive manufacturer guidance, as refreezing the vaccine may damage it. ▪ Document the date and length of time of the excursion, the storage unit temperature (minimum/maximum, if available), and inventory affected on the Emergency Response Worksheet. ▪ Contact the Manufacturer (Bavarian Nordic) for guidance: o **Phone:** 1-844-422-8274 o **Email:** medical.information_us@bavarian-nordic.com ▪ Contact the immunization program (Local Health Department) for guidance on whether to use affected vaccines and whether patients need to be recalled for revaccination. ▪ Maintain documentation of the event and all actions taken. Save documentation for three years.
☐	☐	For additional storage and handling guidance, review the CDC's Vaccine Storage and Handling Toolkit-Updated with COVID-19 Vaccine Storage and Handling Information, Addendum April 12, 2022 (cdc.gov)

VACCINE PREPARATION AND ADMINISTRATION (Intradermal and Subcutaneous)

LHD JYNNEOS Provider Checkoff	JYNNEOS Provider Office Checklist	
☐	☐	JYNNEOS vaccine now has two methods for vaccine administration. In the context of the current national Public Health Emergency (PHE) JYNNEOS may be administered via: • Intradermal (ID) route (alternative regimen) with an injection volume of 0.1mL per the Emergency Use Authorization (EUA). 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. • Subcutaneous (Subcut) route (standard regimen) with an injection volume of 0.5mL is the FDA-approved dosing regimen. Under the EUA on August 9, 2022, the subcutaneous route of administration of 0.5mL is authorized for people aged 17 years of age and younger and people of any age who have a history of developing keloid scars. Note: Don't miss the opportunity to vaccinate. If at the end of the day a patient arrives for a JYNNEOS vaccination, and there is no open/partially used vial and no other patients waiting for vaccine, administer a full dose of 0.5mL subcutaneously to avoid wasting vaccine.

☐	☐	Review JYNNEOS Vaccine Preparation and Administration Guidance: • MDHHS JYNNEOS Resource guide: For more information see the Storage and Handling section of the document located on page 2.
☐	☐	Vaccine Preparation and Administration Summary: Intradermal Vaccine Preparation and Administration Summary: Alternative Dosing Regimen (Adults in the general population) • Preferred administration to maximize the number of doses available. ○ Utilize ID vaccine syringe and needle specific for ID administration. ○ Once punctured the vial must be discarded after 8 hours. Label the vial with the time punctured and time to discard. ○ Do not predraw doses. ○ Vial should be placed in refrigerator between preparation of doses. ○ Do not use 2 vials to create one dose. Subcutaneous Vaccine Preparation and Administration Summary: Standard Regimen (Adults with certain medical conditions and children) • Standard regimen should be used for people aged 17 years of age and younger and people of any age who have a history of developing keloid scars.
☐	☐	Review available resources on intradermal (ID) vaccine administration (18 years and older): • Administration of JYNNEOS Intradermally (ID) • Video: How to administer a JYNNEOS vaccine intradermally - YouTube
☐	☐	Review available resources on subcutaneous (SC or Subcut) vaccine administration for adults and children: • Needle gauge and length tip sheet • How to administer intramuscular and subcutaneous vaccine injections (immunize.org) • Video: Subcutaneous (SC or Subcut) Injection: Administration - YouTube
☐	☐	Have standing orders in place to help streamline your practice workflow by eliminating the need to obtain an individual physician's order to vaccinate each patient. • JYNNEOS Smallpox and Monkeypox Vaccine Standing Orders for Administering Vaccine Intradermally: ALTERNATIVE DOSING REGIMEN (cdc.gov) • JYNNEOS Smallpox and Monkeypox Vaccine Standing Orders for Administering Vaccine Subcutaneously: STANDARD REGIMEN (cdc.gov)
☐	☐	Each individual who will handle JYNNEOS vaccine must review the You Call the Shots: Vaccines Web-based Training Course | CDC • Once completed, submit a copy of the certificate to the LHD.
☐	☐	Review guidance on additional educational key points for administering JYNNEOS vaccine: Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC
☐	☐	Use the CDC JYNNEOS Smallpox and Monkeypox Vaccine Patient Screening Form to ensure there are no true contraindications or precautions prior to vaccination. • When screening please include the question: Do you have a history of keloid formation (scarring)?
☐	☐	Document and report vaccine administration via MCIR within 24 hours of administration, but no longer than 72 hours.
☐	☐	For more resources: CDC's vaccine administration page. • Utilize the "Resource Library" for more trainings, videos, guidance documents, etc.
☐	☐	**Guidance for coadministration with other vaccines:** • JYNNEOS typically may be administered without regard to timing of other vaccines. This includes simultaneous administration of JYNNEOS and other vaccines on the same day, but at different anatomic sites if possible. See ACIP's general best practices

		and *Epidemiology and Prevention of Vaccine-Preventable Diseases* (Pink Book) for further information. • **JYNNEOS and COVID-19 Vaccine:** Because of the observed risk for myocarditis after receipt of ACAM2000 orthopoxvirus vaccine and mRNA (i.e., Moderna and Pfizer-BioNTech) and Novavax COVID-19 vaccines and the unknown risk for myocarditis after JYNNEOS, people, particularly adolescent or young adult males, might consider waiting 4 weeks after orthopoxvirus vaccination. (Either JYNNEOS or ACAM2000) before receiving a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine. However, if an orthopoxvirus vaccine is recommended for prophylaxis in the setting of an outbreak, orthopoxvirus vaccination should not be delayed because of recent receipt of a Moderna, Novavax, or Pfizer-BioNTech COVID-19 vaccine; no minimum interval between COVID-19 vaccination with these vaccines and orthopoxvirus vaccination is necessary. Clinical Guidance for COVID-19 Vaccination | CDC
☐	☐	**BEST PRACTICE:** After the vaccine is administered, the patient will need to come back for a second dose. • Schedule appointment for 2nd dose before the patient leaves the office/clinic. • Important to provide the patient with an appointment reminder card to come back for second dose. • Do reminder calls within a few days of the upcoming appointment.

SPECIAL CONSIDERATIONS FOR INDIVIDUALS RECEIVING JYNNEOS VACCINE

LHD JYNNEOS Provider Checkoff	JYNNEOS Provider Office Checklist	
☐	☐	Review CDC's Considerations for Monkeypox Vaccination | Monkeypox | Poxvirus | CDC
☐	☐	Become familiar with the following special considerations: • **JYNNEOS has been evaluated in clinical studies involving people with HIV infection or eczema** and shown to be safe and effective in eliciting an immune response in these populations. The recommended JYNNEOS dosing schedule is the same for people who are immunocompromised; however, people with immunocompromising conditions might be less likely to mount an effective response after any vaccination, and as a result people who are immunocompromised might be at increased risk for severe disease if an infection occurs, despite vaccination. • **Individuals wanting to minimize their risk** of infection should continue to take steps to protect themselves from infection and self-isolate as soon as they develop monkeypox symptoms, such as a rash. Infections despite vaccination may occur, and there are currently no data on effectiveness of JYNNEOS from the current outbreak.
☐	☐	Become familiar with **contraindications and precautions** to JYNNEOS vaccine: • Contraindication: ○ A severe allergic reaction (e.g., anaphylaxis) after a previous dose of JYNNEOS vaccine is a contraindication to receipt of a subsequent dose. Referral to an allergist-immunologist should be considered to assess the risks versus benefits of administering another dose. • Precautions: ○ JYNNEOS vaccine contains small amounts of gentamicin and ciprofloxacin and is produced using chicken embryo fibroblast cells. ○ People who have had a previous severe allergic reaction (e.g., anaphylaxis) following gentamicin or ciprofloxacin have a precaution for receiving JYNNEOS vaccine and

		should be informed about the potential for increased risk of allergic reaction if the vaccine is administered. ▪ After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Alternatively, taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered. ○ People who have had a severe allergic reaction (e.g., anaphylaxis) to chicken or egg protein **AND** are currently avoiding exposure to all chicken or egg products have a precaution for receiving JYNNEOS vaccine and should be informed about the potential for increased risk of allergic reaction if the vaccine is administered. ▪ After discussing risks and benefits with the individual, these people may be vaccinated with a 30-minute observation period. Alternatively, after taking into account the risk of acquiring monkeypox if the vaccination is delayed, an allergist-immunologist may be consulted before the vaccine is administered. Note: Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction. (See ACIP Adverse Reactions Guidelines for Immunization | CDC)

PATIENT EDUCATION, ADVERSE EVENT REPORTING

LHD JYNNEOS Provider Checkoff	**JYNNEOS Provider Office Checklist**	
☐	☐	Provide Michigan Vaccine Information Statements (VIS) to vaccine recipients, educate on vaccine, and answer patient questions.
☐	☐	Provide a vaccination record to every person who receives JYNNEOS vaccine.

☐	☐	Report moderate and severe adverse events as well as vaccine administration errors to VAERS. VAERS collects information about reactions and possible side effects that occur (e.g., fever, local reactions, illness, serious reaction, hospitalization, disability, death), after vaccine is administered. Reactions may happen immediately, hours, days, or weeks after vaccination. Report a reaction even if you are not sure that it was caused by a vaccine.
		• Adverse events that occur following monkeypox or smallpox vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reporting is encouraged for any clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Vaccine administration errors can be reported whether or not associated with an adverse event. Information on how to submit a report to VAERS is available at VAERS - Report an Adverse Event (hhs.gov) or by calling 1-800-822-7967.
		• Vaccination providers who are administering JYNNEOS under the EUA are **required** to report the following adverse events that occur after JYNNEOS vaccination:
		  ○ 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.
		• CDC's Clinical Immunization Safety Assessment (CISA) Project is available to provide consultation to U.S. healthcare providers and health departments about complex monkeypox and smallpox vaccine safety questions for their patients. In case of an emergent clinical vaccine safety inquiry, healthcare providers and health department staff can call the CDC Emergency Operations Center (EOC) Watch Desk at (770) 488-7100.

MCIR INVENTORY and DOSE DOCUMENTATION

LHD JYNNEOS Provider Checkoff	**JYNNEOS Provider Office Checklist**	
☐	☐	JYNNEOS vaccine providers must be accountable for JYNNEOS vaccine in MCIR. Currently JYNENOS is through the Strategic National Stockpile (SNS) and MDHHS is placing the order for JYNNEOS vaccine to be delivered to MPV hubs. There is no ordering of JYNNEOS vaccine in MCIR. The LHD will work with the MDHHS VFC team to ensure the "Orthopox 2022" functionality is turned on in the MCIR Outbreak Module for provider access.
☐	☐	When you receive JYNNEOS vaccine the vials must be manually entered into MCIR Outbreak Inventory. For questions on how to manually enter vials into MCIR Outbreak Inventory, please contact your MCIR Regional staff.
☐	☐	Ensure documentation of JYNNEOS vaccine administration is recorded in your clinic's medical record system and MCIR within 24 hours, but no longer than 72 hours. Documentation within 24 hours will help with accountability of doses. Documentation is **required** to include, in order to account for doses administered intradermally (ID): • Route administered. • Dose Volume.
☐	☐	To ensure proper inventory management, JYNNEOS vaccine providers **must** balance the JYNNEOS inventory daily including wastage. For questions regarding balancing inventory, please contact your MCIR Regional staff.

☐	☐	If you are a JYNNEOS vaccine hub and you redistribute JYNNEOS vaccine to another provider, you must manage the inventory and ensure the transfer of the JYNNEOS vaccine to the new provider site. Transfer of vaccine is performed utilizing appropriate inventory transactions in MCIR. Please see section labeled Storage and Handling on page 5 for information on transport guidelines.
☐	☐	For questions regarding MCIR, please contact your MCIR Regional staff.

LHD JYNNEOS Provider Checkoff	JYNNEOS Provider Office Checklist	RESOURCES
☐	☐	MDHHS is committed to monkeypox vaccine equity, which means everyone has fair and just access to vaccination. Many social, geographic, political, economic, and environmental factors create challenges to health equity and vaccination access. Racial and ethnic minorities, including those who are also minority gay, bisexual, and other men who have sex with men (MSM) are often most impacted. Some of these factors include: • Education, income, and wealth gaps. • Job access and working conditions. • Racism, homophobia, and other forms of discrimination. • Gaps in healthcare access. • Transportation and neighborhood conditions. • Lack of trust as a result of past medical racism and experimentation. To learn more about health equity and vaccine equity review these resources: • Monkeypox Vaccine Equity Toolkit | Monkeypox | Poxvirus | CDC • Toolkits for Community, Work, and School | Monkeypox | Poxvirus | CDC • Partnering for Vaccine Equity | CDC • Guides and Resources: Health Equity in Immunization | CDC • Monkeypox Vaccine Equity Pilot Program | Monkeypox | Poxvirus | CDC
☐	☐	• JYNNEOS Vaccine Information Statement • Fact Sheet for Healthcare Providers for JYNNEOS • JYNNEOS MMWR, Erratum for JYNNEOS MMWR • MPV (Monkeypox) MDHHS • Considerations for Monkeypox Vaccine • Monkeypox • CDC COCA call • CDC COCA call from 8-11-22 • Immunization Action Coalition's "Medical Management of Vaccine Reactions in Adults in a Community Setting • JYNNEOS BLA • JYNNEOS Package Insert • FDA Statement

LHD Checklist (For Internal Use Only) – Prior to Approval

This is a quick list of items that need to be done in order to approve the provider to become a JYNNEOS vaccine provider. This list works in conjunction with the JYNNEOS Operational

Guide above. The LHD can check things off the list above when completed or when the provider verbalizes knowledge or location of the resource.

- Schedule onsite visit with provider office.
- Do they have a MCIR User Agreement on file?
- Is the Orthopox 2022 functionality turned on in the Outbreak section in MCIR?
- Have they designated a primary and backup vaccine coordinator?
- Do they have an updated Vaccine Management and Emergency Response Plan?
- Do they have appropriate storage units? Refrigerator and/or Freezer?
- Do they have certified and calibrated DDLs?
- Have they provided one week of temperature logs and graphs with appropriate temperature ranges?
- Do they have Do Not Disconnect posted by the vaccine storage unit outlets?
- Do they have Do Not Disconnect sign posted by the circuit breaker box?
- Do they have emergency transport equipment and packing supplies on hand?
- Do they have standing orders in place to immunize?
- Verify the provider can administer vaccine ID. Do they have supplies on hand for intradermal administration?
- Do they have a protocol for management of anaphylactic reaction/emergency response kit?
- Have they completed their CDC You Call the Shots Storage and Handling, MCIR, and other vaccine administration training?
- Have they reviewed the HHS Monkeypox Vaccination Program Provider Agreement.
- Ensure the provider has reviewed, signed, and submitted a copy of the MDHHS JYNNEOS IIS Program Provider Addendum to the state.
- Provider shall abide by the HHS Monkeypox Vaccination Program Provider Agreement and shall abide by the MDHHS JYNNEOS IIS Program Provider Addendum to become and maintain JYNNEOS provider status.
- Once approved, please email mdhhs-mpv-vaccine@michigan.gov and MDHHS Immunization Field Representative that the site is approved to receive Monkeypox vaccine.
- Coordinate vaccine pick-up or delivery with provider office.