MONKEYPOX 2022 VACCINE TOOLKIT
<table>
<thead>
<tr>
<th>Name</th>
<th>Indication</th>
<th>Considerations for Vaccination /Treatment</th>
<th>Availability</th>
<th>Packaging/ Storage and Handling</th>
<th>Resources</th>
</tr>
</thead>
</table>
| Jynneos      | FDA Approved for prevention of smallpox & monkeypox in Adults 18+          | • Post exposure prophylaxis (PEP) for individuals up to 14 days after exposure. Best if given within 4 days from exposure.  
• Expanded post exposure prophylaxis (PEP++) for individuals with certain risk factors who are more likely to have been recently exposed to monkeypox  
• Pre-exposure prophylaxis (PrEP) for individuals at high risk of exposure to monkeypox                                                                                                                                   | SNS request  | 20 – Single dose vials of 0.5ml dose  
Keep frozen at -25°C to -15°C (-13°F to +5°F).  
Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks (Updated Storage Info)                                                                                                                   | CDC Monkeypox Vaccine Guidance  
Jynneos Vaccine Information Sheet  
Jynneos Package Insert                                                                                                                     |
|              | Individuals <18 can be treated under expanded access IND.                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SNS Request Only | 3 ml MDV requiring reconstitution  
Prior to reconstitution, store frozen at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months.  
Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F).                                                                                                                                       | ACAM2000 Medication Guide – CDC  
ACAM2000 Package Insert                                                                                                                  |
| ACAM2000     | FDA Approved for Smallpox prevention in adults and peds > 1 yo             | • PEP, PEP++, or PrEP when Jynneos is contraindicated or unavailable. Risk-benefit discussions and review of current medical conditions that could increase risk for serious adverse events should be completed prior to administration. Use should be determined between patient and provider while considering medical history, individual/household profiles, and ability to manage vaccine site lesion to prevent further transmission. | SNS Request Only | Ancillary supplies included in shipment from SNS                                                                                                                                                                                                                                        | ACAM2000 Package Insert                                                                  |
| Vaccine      | Expanded access IND for monkeypox                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SNS Request Only | 200mg capsules in bottles of 42 capsules; stored at room temperature  
IV – requires refrigerated shipping & storage                                                                                                                                                                                                                                      | CDC Guidance for Tecovirimat Use  
Tecovirimat Package Insert  
Tpoxx Fact Sheet                                                                                                                         |
| TPOXX        | FDA approved for treatment of smallpox in adults and pediatric patients weighing at least 3 kg | • Individuals with severe disease (i.e. hemorrhagic disease, sepsis, encephalitis or others requiring hospitalization)  
• Individuals at high risk of severe disease:  
- immunocompromising conditions such as HIV/AIDS  
- pediatrics <8 years old,  
- pregnant/breastfeeding women  
- history of atopic dermatitis  
- ≥1 complication of active infection  
• Aberrant infections involving anatomic areas of monkeypox virus infection that may create hazard (i.e. eyes, mouth, genitals, anus)                                                                 | SNS Request only |                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                 |
<p>| (tecovirimat) | Expanded access IND for monkeypox                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SNS Request only |                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                 |
| Antiviral    |                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SNS Request only |                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                 |
| medication   |                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | SNS Request only |                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                 |</p>
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<tbody>
<tr>
<td><strong>Vistide (cidofovir) Antiviral Medication</strong></td>
<td>FDA approved for treatment of CMV retinitis in AIDS patients</td>
<td>Can be considered as an alternative to or adjunct treatment with TPOXX in certain situations.</td>
<td>SNS request</td>
<td>75 mg/mL in clear glass, single use vial</td>
<td><strong>Vistide package insert</strong></td>
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<td></td>
<td><strong>Expanded access IND for monkeypox</strong></td>
<td></td>
<td>- OR -</td>
<td>Store at controlled room temperature 20-25°C</td>
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<tr>
<td><strong>Vaccinia Immune Globulin (VIGIV)</strong></td>
<td>FDA approved for the treatment of complications associated with vaccinia vaccination</td>
<td>Complications from vaccinia vaccine may include:</td>
<td>SNS request only</td>
<td>Product may be stored frozen at or below 5°F (≤ -15°C)</td>
<td><strong>VIGIV product information</strong></td>
</tr>
<tr>
<td></td>
<td>• Eczema vaccinatum</td>
<td></td>
<td></td>
<td>Once thawed, product may be kept at +2°C to +8°C (+36°F to +46°F) for 60 days</td>
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<tr>
<td></td>
<td>• Progressive vaccinia</td>
<td></td>
<td></td>
<td>Intravenous infusion should begin within 4 hours after entering the vial.</td>
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<td></td>
<td>• Severe generalized vaccinia</td>
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<td></td>
<td>• Vaccinia infections in individuals who have skin conditions</td>
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<td></td>
<td>• Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis)</td>
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<tr>
<td>Name</td>
<td>Indication</td>
<td>Request Criteria/Considerations for Vaccination/Treatment</td>
<td>Availability</td>
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</tbody>
</table>
| **Jynneos Vaccine**      | FDA Approved for prevention of smallpox & monkeypox in **Adults 18+**      | - Post exposure prophylaxis (PEP) for individuals between 4-14 days after exposure  
- Expanded post exposure prophylaxis (PEP++) for individuals with certain risk factors who are more likely to have been recently exposed to monkeypox  
- Pre-exposure prophylaxis (PrEP) for individuals at high risk of exposure to monkeypox | SNS request  
- OR – Push product within NC county jurisdictions  
Ancillary supplies not included                                                                 | 20 – Single dose vials of 0.5ml dose  
Keep frozen at -25°C to -15°C (-13°F to +5°F).  
Once thawed, the vaccine may be kept at +2°C to +8°C (+36°F to +46°F) for 8 weeks **(Updated Storage Info)** | CDC Monkeypox Vaccine Guidance  
Jynneos Vaccine Information Sheet  
Jynneos Package Insert |
| **ACAM2000 Vaccine**     | FDA Approved for Smallpox prevention in adults and peds > 1 yo             | - PEP, PEP++ or PrEP when Jynneos is contraindicated or unavailable. Risk-benefit discussions and review of current medical conditions that could increase risk for serious adverse events should be completed prior to administration. Use should be determined between patient and provider while considering medical history, individual/household profiles and ability to manage vaccine site lesion to prevent further transmission. | SNS Request Only  
Ancillary supplies included in shipment from SNS | 3 ml MDV requiring reconstitution  
Prior to reconstitution, **store frozen** at -15°C to -25°C (5°F to -13°F); may also be stored refrigerated at 2°C to 8°C (36°F to 46°F) for up to 18 months.  
Diluent stored at room temperature of 15°C to 30°C (59°F to 86°F). | ACAM2000 Medication Guide – CDC  
ACAM2000 Package Insert |
| **Tecovirimat (Tpoxx) Antiviral medication** | FDA approved for treatment of smallpox in adults and pediatric patients weighing at least 3 kg  
**Expanded access IND for monkeypox** | - Individuals with severe disease (i.e. hemorrhagic disease, sepsis, encephalitis or others requiring hospitalization)  
- High risk of severe disease:  
  - immunocompromising conditions such as HIV/AIDS  
  - pediatrics <8 years old,  
  - pregnant/breastfeeding women  
  - history of atopic dermatitis  
  - ≥1 complication of active infection  
- Aberrant infections involving anatomic areas of monkeypox virus infection that may create hazard (i.e. eyes, mouth, genitals, anus) | SNS Request only | 200mg capsules in bottles of 42 capsules; stored at room temperature  
IV – requires refrigeration (shipping & storage) | CDC Guidance for Tecovirimat Use  
Tecovirimat Package Insert  
Tpoxx Fact Sheet |
## Monkeypox Medical Countermeasures Request Process - Adults 18+ years old

<table>
<thead>
<tr>
<th>Request Stage</th>
<th>Action Tracker</th>
<th>Notes</th>
</tr>
</thead>
</table>
| Need for MCMs             | Agency identifies need for MCM request for Monkeypox Supplies:  
• Treatment or vaccination needed for confirmed monkeypox case  
• PUI with known close contact(s) in need of PEP  
• Individuals identified who qualify for PEP++  
• Individuals identified who qualify for PrEP  
• Agency/partner interested in receiving vaccine when supplies are more readily available | Time-sensitive or clinical support needs after-hours need to use the Epi On-Call number at 919-733-3419 |
| Submit Request            | Agency will submit the [Monkeypox ReadyOp Request Form](#) with justification, logistics, and MCM items/amount                                                                                               | SNS Inbox will be monitored for ReadyOp requests M-F, 8 am to 5 pm                                |
| Review Process            | Monkeypox Response Team vets the request and makes 1 of 3 decisions:  
• Approved- forward request to CDC for fulfillment  
• Approved- forward request to hub for fulfillment  
• Denied- requesting agency will be provided with a justification for denial of fulfillment |                                                                                                                                                               |
| CDC Fulfillment Option    | • Monkeypox Response Team, CDC, and requesting agency will have a coordination call  
• Distribution details defined                                                                                                                          | • MCMs requested from the SNS have been arriving within 28 hours of the decision to approve the request  
• Shipments include complete course/vaccine regimen  
• Ancillary supplies for Jynneos vaccine are **NOT** included  
• Shipping containers from CDC need to be returned to CDC |
| State Fulfillment Option  | • Monkeypox Response Team will coordinate a call between hub fulfillment site and requesting agency  
• Distribution details defined                                                                                                                                 | • Phase I Distribution includes 444 doses of Jynneos vaccine to NC  
• Current hub sites are Buncombe, Durham, Forsyth, Mecklenburg, New Hanover, Pitt, and Wake LHDs  
• MCMs from local hub sites will be shipped Monday-Thursday |

## Monkeypox Medical Countermeasures Request Process - JYNNEOS for Individuals Aged <18 years old

<table>
<thead>
<tr>
<th>Request Stage</th>
<th>Action Tracker</th>
<th>Notes</th>
</tr>
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<tbody>
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</tbody>
</table>
### Need for MCMs

Agency identifies need for MCM request for Monkeypox Supplies:
- Treatment or vaccination needed for confirmed monkeypox case
- PUI with known close contact(s) in need of PEP
- Individuals identified who qualify for PEP++
- Individuals identified who qualify for PrEP
- Agency/partner interested in receiving vaccine when supplies are more readily available

Time-sensitive or clinical support needs after-hours need to use the Epi On-Call number at 919-733-3419

### Submit Request

Agency will submit request to CDC clinical team at [poxvirus@cdc.gov](mailto:poxvirus@cdc.gov) or by contacting the CDC Emergency Operations Center

Information Required for request:
- Provider willing to administer vaccine and participate in IND protocol
- Justification for why individual needs vaccine

### Next Steps

- CDC provides EA-IND form
- Form submitted to CDC who then seeks approval from FDA

- One form required per patient
- Turnaround time with 1 business day
Entering JYNNEOS in NCIR

Inventory must currently be manually added as private (as opposed to accepting a vaccine transfer). Please follow the steps below to ensure inventory is added correctly prior to vaccine administration.

1. Click on Manage Inventory

2. Click on Show Inventory

3. Click on Add Inventory
4. Locate and select the Trade Name JYNNEOS (the manufacturer will auto-populate). Select the NDC, add the correct lot number and expiration date from the vaccine box*. Leave the funding program code as “private” and enter the number of doses received.

*The NDC printed on the carton will differ than the NDC printed on the vial. Expiration dates are printed on the carton, but not the vial. Expiration dates, along with the corresponding lot and NDC numbers can be found at: https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx.

5. Document the administered doses as usual.
Screening Checklist for Contraindications to Vaccines for Adults

For patients: The following questions will help us determine which vaccines you may be given today. If you answer “yes” to any question, it does not necessarily mean you should not be vaccinated. It just means additional questions must be asked. If a question is not clear, please ask your healthcare provider to explain it.

<table>
<thead>
<tr>
<th>Question</th>
<th>yes</th>
<th>no</th>
<th>don't know</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Are you sick today?</td>
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</tr>
<tr>
<td>2. Do you have allergies to medications, food, a vaccine component, or latex?</td>
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<tr>
<td>3. Have you ever had a serious reaction after receiving a vaccination?</td>
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<tr>
<td>4. Do you have a long-term health problem with heart, lung, kidney, or metabolic disease (e.g., diabetes), asthma, a blood disorder, no spleen, complement component deficiency, a cochlear implant, or a spinal fluid leak? Are you on long-term aspirin therapy?</td>
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<tr>
<td>5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem?</td>
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<tr>
<td>6. Do you have a parent, brother, or sister with an immune system problem?</td>
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<tr>
<td>7. In the past 3 months, have you taken medications that affect your immune system, such as prednisone, other steroids, or anticancer drugs; drugs for the treatment of rheumatoid arthritis, Crohn's disease, or psoriasis; or have you had radiation treatments?</td>
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<tr>
<td>8. Have you had a seizure or a brain or other nervous system problem?</td>
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<tr>
<td>9. During the past year, have you received a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug?</td>
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<tr>
<td>10. For women: Are you pregnant or is there a chance you could become pregnant during the next month?</td>
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<tr>
<td>11. Have you received any vaccinations in the past 4 weeks?</td>
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</tr>
</tbody>
</table>

FORM COMPLETED BY ____________________________ DATE ______________

FORM REVIEWED BY ____________________________ DATE ______________

Did you bring your immunization record card with you? yes [ ] no [ ]

It is important for you to have a personal record of your vaccinations. If you don’t have a personal record, ask your healthcare provider to give you one. Keep this record in a safe place and bring it with you every time you seek medical care. Make sure your healthcare provider records all your vaccinations on it.
Information for Healthcare Professionals about the Screening Checklist for Contraindications to Vaccines for Adults

1. Are you sick today? [all vaccines]
   There is no evidence that acute illness reduces vaccine efficacy or increases vaccine adverse events. However, as a precaution with moderate or severe acute illness, all vaccines should be delayed until the illness has improved. Mild illnesses (e.g., upper respiratory infections, diarrhea) are NOT contraindications to vaccination. Do not withhold vaccination if a person is taking antibiotics.

2. Do you have allergies to medications, foods, a vaccine component, or latex? [all vaccines]
   An anaphylactic reaction to latex is a contraindication to vaccines that contain latex as a component or as part of the packaging (e.g., vial stoppers, prefilled syringe plungers, prefilled syringe caps). If a person has anaphylaxis after eating gelatin, do not administer vaccines containing gelatin. A local reaction to a prior vaccine dose or vaccine component, including latex, is NOT a contraindication to a subsequent dose or vaccine containing that component. For information on vaccines supplied in vials or syringes containing latex, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/latest-table-2.pdf; for an extensive list of vaccine components, see www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/explicit-table-2.pdf.
   People with egg allergy of any severity can receive any IV, RIV, or LAIV that is otherwise appropriate for the patient’s age and health status. With the exception of calyV and RIV (which do not contain egg antigen), people with a history of severe allergic reaction to egg involving any symptom other than hives (e.g., angioedema, respiratory distress), or who required epinephrine or another emergency medical intervention, the vaccine should be administered in a medical setting, such as a clinic, health department, or physician office; vaccine administration should be supervised by a healthcare provider who is able to recognize and manage severe allergic conditions.

3. Have you ever had a serious reaction after receiving a vaccination? [all vaccines]
   History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

4. Do you have a long-term health problem with heart, lung, kidney, or metabolic disease? [all vaccines]
   History of anaphylactic reaction (see question 2) to a previous dose of vaccine or vaccine component is a contraindication for subsequent doses. Under normal circumstances, vaccines are deferred when a precaution is present. However, situations may arise when the benefit outweighs the risk (e.g., during a community pertussis outbreak).

5. Do you have cancer, leukemia, HIV/AIDS, or any other immune system problem? [LAIV, MM, VAR]
   Live virus vaccines (e.g., LAIV, MM, VAR) are contraindicated for children and adolescents with CD4+ T-lymphocyte counts of greater than or equal to 200 cells/ml. Immunosuppressed people should not receive LAIV.

6. Do you have a parent, brother, or sister with an immune system problem? [MM, VAR]
   MMR or VAR vaccines should not be administered to persons who have a family history of congenital or hereditary immunodeficiency in first-degree relatives (i.e., parents and siblings), unless the immune competence of the potential vaccine recipient has been substantiated clinically or verified by a laboratory.

7. In the past three months, have you taken medications that affect your immune system, such as corticosteroids, prednisone, other steroids, or anticoagulant drugs? [LAIV, MM, VAR]
   Live virus vaccines (e.g., LAIV, MM, VAR) should be postponed until after chemotherapy or long-term high-dose steroid therapy has ended. For details and length of time to postpone, see references in Notes above. Some immune modulator and immunomodulator drugs (especially the anti-tumor necrosis factor agents adalimumab, infliximab, etanercept, golimumab, and certolizumab pegol) may be immunosuppressive. A comprehensive list of immunosuppressive immunomodulators is available in CDC Health Information for International Travel (the “Yellow Book”) available at www.cdc.gov/travel/yellowbook/2020/travelers-with-additional-considerations/immunosuppressed-travelers.
   The use of live virus vaccines should be avoided in persons taking these drugs. To find specific vaccination schedules for stem cell transplant (bone marrow transplant) patients, see references in Notes above.

8. Have you had a seizure or a brain or other nervous system problem? [LAIV, MM, VAR]
   Seizures that are not related to vaccination, or in people with a personal history of seizures, are not contraindications to vaccination. A history of Guillain-Barre syndrome (GBS) is a contraindication following the following: 1) TD/Tdap, if GBS has occurred within 6 weeks of a tetanus toxoid vaccine and decision is made to continue vaccination, give Tdap instead of TD if no history of prior Td; 2) Influenza vaccine (LAIV/MM, VAR); if GBS has occurred within 6 weeks of a prior influenza vaccine, vaccination should generally be avoided unless the benefit outweighs the risks (for those at higher risk for complications from influenza).

9. During the past week, have you had a transfusion of blood or blood products, or been given immune (gamma) globulin or an antiviral drug? [MM, VAR, LAIV]
   Certain live virus vaccines (e.g., MM, LAIV, VAR) may need to be deferred, depending on several variables. Consult General Best Practice Guidelines for Immunization (referred to in Notes above) for current information on intervals between antiviral drugs, immune globulin or blood product administration and live virus vaccines.

10. For women: Are you pregnant or is there a chance you could become pregnant during the next month? [HPV, IPV, MMR, VAR]
    Live virus vaccines (e.g., MMR, VAR, LAIV) are contraindicated one month before and during pregnancy because of the theoretical risk of virus transmission to the fetus. Sexually active women in their childbearing years who receive live virus vaccines should be instructed to avoid pregnancy for one month following receipt of the vaccine. On theoretical grounds, IPV and MMR should not be given during pregnancy; however, it may be given if there is a risk of exposure. IV and TD are both recommended during pregnancy. HPV vaccine is not recommended during pregnancy.

11. Have you received any vaccinations in the past 4 weeks? [LAIV, MM, VAR, yellow fever]
    People who were given either LAIV or an injectable live virus vaccine (e.g., MM, VAR, yellow fever) should wait 28 days before receiving another vaccination of this type (30 days for yellow fever). Inactivated vaccines may be given at any spacing interval if they are not administered simultaneously.

VACCINE ABBREVIATIONS

- LAIV = Live attenuated influenza vaccine
- IPV = Inactivated Poliovirus vaccine
- MMR = Measles, mumps, and rubella vaccine
- RV = Rotavirus vaccine
- Td = Tetanus, diphtheria, acellular pertussis vaccine
- Var = Varicella vaccine
- HPV = Human papillomavirus vaccine
- Haemophilus influenzae type b vaccine
Storage/Transportation of Vaccine

North Carolina Immunization Program Transportation Guidance for Vaccines
Transportation of vaccines should be rare and expected length of transport should be less than 30 minutes. If conducting an off-site clinic, the total time for transport and workday should be a maximum of 8 hours. A digital data logger with a current and valid certificate of calibration must be used for temperature monitoring during transport. For accountability tracking purposes, transfers must be documented via the North Carolina Immunization Registry (NCIR) when vaccine is transferred from one provider to another. If portable units purpose-built for vaccine transport are not available, the following methods can be used as an acceptable alternative.

Transporting Frozen Vaccines

Guidelines for vaccine transport in emergency situations

1. Hard-sided cooler
2. Frozen cold packs Keep enough frozen cold packs in your freezer to make 2 layers in the transport cooler. NEVER USE DRY ICE.
3. Digital Data Logger [pre-conditioned to frozen temperatures]
4. Packing Materials [bubble wrap, packing foam, or Styrofoam™] to prevent contents from shifting during transport.
5. Temperature Log Record the time and temperature of the vaccine in the cooler before departure, each time the cooler is opened, and upon arrival to the destination. Sample Transport Log: https://www.cdc.gov/vaccines/covid-19/downloads/transport-temperature-log.pdf

Pack vaccines and prepare for transport

Prepare for Transport
- Verify that the destination site has enough room for your vaccine and that someone will be there when the vaccine arrives.
- Verify that you have all the packing supplies on the above list.

Pack Vaccines

- Spread a layer of frozen ice packs to cover the bottom of the cooler.
- Spread another layer of frozen ice packs to cover the vaccine.
- Stack layers of vaccine boxes directly on top of the frozen ice packs.
- Fill the cooler to the top with insulation material (bubble wrap).
- Place the digital data logger probe with the top layer of the vaccine.
- Close the cooler lid and place the digital data logger’s display on top of the lid with a temperature log.
- Transport the vaccine.

Updated 07/01/2022
Transporting Refrigerated Vaccines

Packing Vaccines for Transport during Emergencies

Be ready BEFORE the emergency
Equipment failures, power outages, natural disasters—these and other emergency situations can compromise vaccine storage conditions and damage your vaccine supply. It’s critical to have an up-to-date emergency plan with steps you should take to protect your vaccine. In any emergency event, activate your emergency plan immediately, and if you can do so safely, follow the emergency packaging procedures for refrigerated vaccines.

1 Gather the Supplies

**Hard-sided coolers or Styrofoam™ vaccine shipping containers**
- Coolers should be large enough for your location’s typical supply of refrigerated vaccines.
- Can use original shipping boxes from manufacturers if available.
- Do NOT use soft-sided collapsible coolers.

**Conditioned frozen water bottles**
- Use 16.9 oz. bottles for medium/large coolers or 8 oz. bottles for small coolers (enough for 2 layers inside cooler).
- Do NOT reuse coolant packs from original vaccine shipping container, as they increase risk of freezing vaccines.
- Freeze water bottles (can help regulate the temperature in your freezer).
- Before use, you must condition the frozen water bottles. Put them in a sink filled with several inches of cool or lukewarm water until you see a layer of water forming near the surface of bottle. The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.

**Insulating material — You will need two of each layer**
- **Insulating cushioning material**: Bubble wrap, packing foam, or Styrofoam™ for a layer above and below the vaccines, at least 1 in thick. Make sure it covers the cardboard completely. Do NOT use packing peanuts or other loose material that might shift during transport.
- **Corrugated cardboard**: Two pieces cut to fit interior dimensions of cooler(s) to be placed between insulating cushioning material and conditioned frozen water bottles.

**Temperature monitoring device**: Digital data logger (DDL) with buffered probe. Accuracy of ±1°F (±0.5°C) with a current and valid certificate of calibration testing. Pre-chill buffered probe for at least 3 hours in refrigerator. Temperature monitoring device currently stored in refrigerator can be used, as long as there is a device to measure temperatures for any remaining vaccines.

**Why do you need cardboard, bubble wrap, and conditioned frozen water bottles?**
Conditioned frozen water bottles and corrugated cardboard used along with one inch of insulating material such as bubble wrap keeps refrigerated vaccines at the right temperature and prevents them from freezing. Reusing vaccine coolant packs from original vaccine shipping containers can freeze and damage refrigerated vaccines.

Visit [www.cdc.gov/vaccines/SxndH](http://www.cdc.gov/vaccines/SxndH) for more information, or your state health department.
Packing Vaccines for **Transport during Emergencies**

### 2 Pack for Transport

#### Conditioning frozen water bottles
- Put frozen water bottles in sink filled with several inches of cool or lukewarm water or under running tap water until you see a layer of water forming near surface of bottle.
- The bottle is properly conditioned if ice block inside spins freely when rotated in your hand.
- If ice “sticks,” put bottle back in water for another minute.
- Dry each bottle.
- Line the bottom and top of cooler with a single layer of conditioned water bottles.
- Do NOT reuse coolant packs from original vaccine shipping container.

**Close lid** — Close the lid and attach DDL display and temperature log to the top of the lid.

**Conditioned frozen water bottles** — Fill the remaining space in the cooler with an additional layer of conditioned frozen water bottles.

**Insulating material** — Another sheet of cardboard may be needed to support top layer of water bottles.

**Insulating material** — Cover vaccines with another 1 in. layer of bubble wrap, packing foam, or Styrofoam™.

**Vaccines** — Add remaining vaccines and diluents to cooler, covering DDL probe.

**Temperature monitoring device** — When cooler is halfway full, place DDL buffered probe in center of vaccines, but keep DDL display outside cooler until finished loading.

**Vaccines** — Stack boxes of vaccines and diluents on top of insulating material.

**Insulating material** — Place a layer of bubble wrap, packing foam, or Styrofoam™ on top (layer must be at least 1 in. thick and must cover cardboard completely).

**Insulating material** — Place 1 sheet of corrugated cardboard over water bottles to cover them completely.

**Conditioned frozen water bottles** — Line bottom of the cooler with a single layer of conditioned water bottles.

### 3 Arrive at Destination

**Before opening cooler** — Record date, time, temperature, and your initials on vaccine temperature log.

**Storage** — Transfer boxes of vaccines quickly to storage refrigerator.

**Troubleshooting** — If there has been a temperature excursion, contact vaccine manufacturer(s) and/or your immunization program before using vaccines. Label vaccines “Do Not Use” and store at appropriate temperatures until a determination can be made.

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*Updated 07/01/2022*
JYNNEOS Storage and Handling Guidance

Key Points

- JYNNEOS is shipped at -20°C and can be used through the labeled expiration date when stored between -15°C and -25°C
- The NDC printed on the carton will differ than the NDC printed on the vial
- Expiration dates are printed on the carton, but not the vial
- Expiration dates, along with the corresponding lot and NDC numbers can be found at: https://aspr.hhs.gov/SNS/Pages/Monkeypox.aspx
- When stored at refrigerated temperatures (2°C to 8°C), unopened vials can be used for up to 8 weeks (this differs from the package insert)
- Store the vaccine in the original package to protect from light
- Do not re-freeze a vial once it has been thawed

Temperatures During Transport

➢ If temperatures reach above -15°C during transport (but not warmer than 8°C), place unopened vaccine in a refrigerated unit to be used for up to 8 weeks
➢ If temperatures are maintained between -15°C and -25°C, place unopened vials in a frozen storage unit to be used up to the printed expiration date
➢ If temperatures reach above 8°C, mark the carton “DO NOT USE”, place the unopened vaccine in a refrigerated unit and contact the vaccine manufacturer for a viability assessment. DO NOT USE vaccine that has been exposed to out-of-range temperatures. Document actions taken. Sample Troubleshooting Log: https://www.immunize.org/catg.d/p3041.pdf

Updated 07/01/2022
Coding Guidance for Monkeypox

The following has been identified to use when providing specimen collection and vaccination for Monkeypox. As more information is provided from the Centers for Disease Control (CDC) this guidance will be updated.

May not be reimbursed by third party payors. Can be used in your electronic health record for reporting purposes and billing once payment methods have been established.

Specimen collection:

ICD-10: B04- Monkeypox

A viral disease infecting primates and rodents. Its clinical presentation in humans is similar to smallpox including fever; headache; cough; and a painful rash. It is caused by monkeypox virus and is usually transmitted to humans through bites or via contact with an animal's blood. Interhuman transmission is relatively low (significantly less than smallpox).

CPT: 87798

Infectious agent detection by nucleic acid (DNA or RNA) not otherwise specified

Vaccination with Orthopox approved vaccine;

ICD 10: Z23

Immunization encounter

CPT: 90749

Immunization Vaccine Toxoid

*Note: If applicable, encounter for immunization safety counseling, enter CPT: Z71.85
NC Standing Order Template

JYNNEOS Smallpox Vaccine Administration for 18 years and Older

July xx, 2022

**Purpose**: To reduce morbidity and mortality from Orthopoxvirus (Monkeypox, Smallpox) by vaccinating individuals with JYNNEOS vaccine who are at high risk for exposure or as part of pre and post-exposure prophylaxis who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

**Policy**: Policy note published June 3, 2022. Use of JYNNEOS for Vaccination of Persons at Risk of infection with Orthopoxvirus based on ACIP Recommendations. Under these standing orders, eligible nurses and other health care professionals working within their scope of practice may vaccinate patients who meet the criteria below.

| Condition or Situation in Which the SO Will Be Used | JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in high-risk adults 18 years of age and older. JYNNEOS is recommended to be administered within 4 days from date of exposure to Monkeypox in order to prevent the onset of disease. If given between 4-14 days post exposure, symptoms may be reduced, but disease may not be prevented. JYNNEOS can be administered at the same time as other vaccines.

Patients who present requesting vaccination with Jynneos will receive:

**Primary Series**
2 subcutaneous injections separated by 4 weeks. People who receive JYNNEOS are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose). They should continue to take precautions against monkeypox during this time.

| Pre and Post-Exposure Prophylaxis | Administer Jynneos to persons 18 years of age and older who present requesting vaccination and self-attest to being in a high-risk category based on CDC’s Exposure risk assessment.

**Post-Exposure Prophylaxis (PEP)**
1. PEP is recommended for:
   a. Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
   b. Know that a sexual partner in the past 14 days was diagnosed with monkeypox
   c. Men who have sex with men who have recently had multiple sex partners in a venue where there was known to be monkeypox or in an area where monkeypox is spreading
   d. People who are at risk for severe adverse events with ACAM2000 or severe disease from monkeypox (such as people with HIV or other immunocompromising conditions). This may include:
      i. Known contacts who are identified by public health via case investigation, contact tracing, and risk exposure assessments
      ii. People who are aware that one of their sexual partners from the past 2 weeks has been diagnosed with monkeypox.
      iii. Gay, bisexual, other men who have sex with men, and transgender people who report any of the following in the past 2 weeks:
      iv. Health care workers who were in the same room with or within 6 feet of a patient during any procedures that may create aerosols from oral secretions, skin lesions, or resuspension of dried exudates (e.g., shaking of soiled linens), without wearing an N95 or equivalent respirator (or higher) and eye protection.
2. Persons exposed to monkeypox virus who have not received the smallpox vaccine within the last 3 years should consider getting vaccinated.

3. Vaccine should be given within 4 days from the date of exposure in order to prevent onset of the disease. If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.

**Pre-Exposure Prophylaxis (PrEP)**

*At this time, most clinicians in the United States and laboratorians not performing the orthopox virus generic test to diagnose orthopox viruses, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP. However, the Federal Department of Health and Human Services is considering a broader PrEP strategy as supply allows and based on evolving need.*

1. Clinical laboratory personnel who perform testing to diagnose orthopox viruses, including those who use polymerase chain reaction (PCR) assays for diagnosis of orthopox viruses, including Monkeypox virus

2. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopox viruses that infect humans, including Monkeypox virus, replication-competent Vaccinia virus, or recombinant Vaccinia viruses derived from replication-competent Vaccinia virus strains

3. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes

4. People who can get PrEP if they want to receive it include healthcare personnel who administer ACAM2000 or anticipate caring for many patients with monkeypox.

**Assessment**

<table>
<thead>
<tr>
<th>Assessment Criteria</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objective</strong></td>
<td>JYNNEOS is not licensed for persons for persons under 18 years of age</td>
</tr>
<tr>
<td></td>
<td>1. Immunization record reveals client has not previously completed a smallpox vaccine series with either ACAM2000 (smallpox) or JYNNEOS vaccine within the last two years for pre-exposure prophylaxis or within the last three years for post-exposure prophylaxis.</td>
</tr>
<tr>
<td></td>
<td>2. Immunization record indicates receipt of 1 dose of Jynneos at least 4 weeks ago, and patient is presenting for second dose of the primary series.</td>
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<tr>
<td></td>
<td>3. Jynneos is safe for administration to people with HIV and atopic dermatitis</td>
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</tbody>
</table>

**Subjective**

1. Client 18 years and older presents requesting smallpox vaccine (JYNNEOS) and is at high risk for exposure (pre-exposure prophylaxis) or has experienced a high risk exposure to monkeypox within the past 14 days (post-exposure prophylaxis).

2. Client 18 years and older presents requesting 2nd dose of Jynneos
   a. People with minor illnesses, such as a cold, may be vaccinated. People who are moderately or severely ill should usually wait until they recover before getting any dose of JYNNEOS™.
   b. Persons recommended to receive JYNNEOS™ due to an exposure to monkeypox virus should be vaccinated regardless of concurrent illnesses, pregnancy, breastfeeding, or weakened immune system.

**Nursing Plan of Care**

Assess patient’s risk level using the [CDC’s Exposure risk assessment guidance](https://www.cdc.gov/healthrievezmonkeypox/index.html). Patients 18 years and older determined to be at high risk for exposure (criteria for Pre-exposure prophylaxis above) shall be vaccinated with JYNNEOS. Patients who have experienced a high-risk exposure or expanded PEP criteria above shall be vaccinated with JYNNEOS within 14 days of the date of exposure. Vaccination is most effective when given within 4 days of the date of exposure. Vaccine given between 4–14 days after the date of exposure may reduce symptoms of disease but may not prevent the disease.
### Contraindications and Precautions

4. Screen all adults 18 years and older for contraindications and precautions to JYNNEOS vaccine. Note that **pregnancy and breastfeeding are not contraindications**. Because JYNNEOS is non-replicating, it can be administered regardless of timing to previous live virus vaccine administration (e.g., MMR, Varicella). Consult with medical staff if the following contraindications or precautions are present:

#### Contraindications:
- People with a severe allergy to any component of the vaccine (gentamicin, ciprofloxacin, egg protein) should not receive this vaccine. (Note: JYNNEOS is formulated without preservatives. The vial stoppers are not made with natural rubber latex). More information on Jynneos cell line [here](#).
- Patient is currently taking Deflazacort (Calcort)

#### Precautions:
- Moderate to severe acute illness with or without fever.
- Patient is currently taking one of the following medications:
  - SAPHNELORTM (Anifrolumab-fnia)
  - ILARIS® (Canakinumab)
  - DUPIXENT® (Dupilumab)
  - GILENYA® (Fingolimod)
  - TALTZ® (Ixekizumab)
  - ZEPOSIA® (Ozanimod)
  - PONVORY™ (Ponesimod)
  - COSENTYX® (Secukinumab)
  - MAYZENT® (Siponimod)
  - ADBRY™ (Tralokinumab-lدرم)
  - LUPKYNISTM (Voclosporin)

### Nursing Actions

Implement the following vaccine regimen if above criteria are met and no precautions or contraindications are identified:

1. Provide patient with a copy of the most current federal Vaccine Information Statement (VIS) for Smallpox/Monkeypox. The VIS can be found at [https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html](https://www.cdc.gov/vaccines/hcp/vis/vis-statements/smallpox-monkeypox.html). You must document in the patient’s medical record or office log, the publication date of the VIS and date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred; these can be found at [https://www.immunize.org/vis/vis_smallpox_monkeypox.asp](https://www.immunize.org/vis/vis_smallpox_monkeypox.asp).

2. Written consent is not required under federal or state law for JYNNEOS administration. However, administering agencies may obtain consent following internal guidelines/policies.

3. Inform patient/caregiver of possible side effects and reactions. Persons with a history of immunocompromising conditions should be counseled on the possibility of a reduced response to the vaccine.

4. Counsel patients that we do not know if JYNNEOS will fully protect against monkeypox virus infection in this outbreak. Individuals wanting to minimize their risk of infection should take additional preventive measures and immediately self-isolate should symptoms occur, such as a rash.

5. Specific Groups:
   a. Pregnancy and breast feeding are not contraindications to vaccination.
   b. Pediatric and Geriatric populations: there have not been adequate studies to determine safety and efficacy in those under 18* or over the age of 65. (*JYNNEOS is not licensed for administration to individuals under the age of 18). Due to an unknown risk for myocarditis after JYNNEOS,
persons might consider waiting 4 weeks after receipt of vaccination before receiving an mRNA COVID-19 vaccine. If post-exposure prophylaxis is recommended, vaccination with JYNNEOS should not be delayed because of recent receipt of an mRNA COVID-19 vaccine.

6. Health care personnel should follow routine infection control procedures when administering vaccines. Follow strict aseptic medication preparation practices. Perform hand hygiene before preparing vaccines. Use a designated, clean medication area that is not adjacent to areas where potentially contaminated items are placed. Avoid distractions. Some facilities have a no-interruption zone, where health care professionals can prepare medications without interruptions. Prepare medications for one patient at a time. Always follow the vaccine manufacturer’s directions, located in the package inserts.

7. Allow the vaccine to thaw and reach room temperature before use.

8. Swirl the vial gently before use for at least 30 seconds. Withdraw a dose of 0.5 mL into a sterile syringe for injection.

9. Administer 0.5ml JYNNEOS via subcutaneous injection in the fatty tissue over triceps in adults. Use a 23-25g, 5/8” needle. Inject at a 45° angle.

10. Document each patient’s vaccine administration information and follow up in the following locations: Electronic medical record/North Carolina Immunization Registry (NCIR)- record the date the vaccine was administered, manufacturer and lot number, the vaccination site and route, the name and title of the person administering the vaccine. Race and ethnicity are now required fields in NCIR and should be reviewed and updated to ensure accurate documentation for the JYNNEOS recipient. For tracking purposes, ensure doses are documented from live inventory in NCIR (do not enter historically).

11. If the vaccine was not administered, record reason (s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal).

12. Inform patient/caregiver to go to the Emergency Department of the nearest hospital if an adverse reaction occurs.

13. Advise vaccine recipient to report any adverse events to their healthcare provider or to the Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 and www.vaers.hhs.gov.

14. Instruct patient to call clinic, or their health care provider with any questions and/or problems.

15. Inform vaccine recipient of the importance of completing the two dose vaccination series (at least 28 days apart) for first time vaccine recipients.

Follow-up

**VAERS Reporting:** Healthcare providers are required to report to VAERS adverse events found in the Reportable Events Table (RET) at https://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf. For events not included in the RET, healthcare providers are encouraged to report any additional clinically significant adverse events after vaccination to VAERS even if it is uncertain whether the vaccine caused the event.

**Anaphylaxis Management:** Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis.

**Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.

Criteria for Notifying the physician/APP

<table>
<thead>
<tr>
<th>Criteria for Notifying the physician/APP</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Allergic reaction: Call 911, implement medical protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service.</td>
<td></td>
</tr>
<tr>
<td>2. Consult with physician/ advanced practice provider if the patient reports any contraindications or precautions to the vaccine prior to administration.</td>
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</tbody>
</table>
JYNNEOS Standing Order Template Original 06/2022

**Monkeypox Vaccination – Eligibility – Phase I**

JYNNEOS is a safe and effective vaccine that can prevent monkeypox in people who have been exposed to the virus if given within 4 days of exposure and reduce the risk of severe illness if given within 14 days of exposure. The number of JYNNEOS doses is currently limited, therefore the vaccine is currently available to be given to people with known or suspected exposure to monkeypox virus.

Please let me know if any of the following apply to you:

1. People who have been in close physical contact in the past 14 days with someone diagnosed with monkeypox, or
2. People who know their sexual partner was diagnosed with monkeypox, or
3. Men who have sex with men, or transgender individuals, who have had multiple or anonymous sex partners in the last 14 days in either a venue where monkeypox was present or in an area where the virus is spreading.[1]

[1] Currently, this includes several locations in Europe and parts of the following U.S. jurisdictions: California, District of Columbia, Florida, Illinois, Massachusetts, New York, and Texas. Updated global and U.S. case numbers are posted on the CDC site [here](https://www.cdc.gov/).

7/7/2022
To whom it may concern,

For operational flexibility, drug product may be shipped either frozen at -20°C (-4°F) or refrigerated at 2-8°C (36-46°F) during an event depending on freezer capacity at the receiving site(s). Upon receipt the vaccine can be stored as follows:

If vaccine is shipped frozen at -20°C and requires storage before use, maintain:

- Frozen ( -20°C ), if freezer capacity is available,
  OR
- Refrigerated (2-8°C). Do not refreeze.

If vaccine is shipped at 2-8°C and requires storage before use, maintain:

- Refrigerated at 2-8°C. Do not refreeze.

Unopened vials of drug product may be stored at 2-8°C up to 8 weeks from thawing. This information has been provided by the vaccine manufacturer based on available supportive stability data.

Please be aware that this differs from the storage and use by period of 12 hours once thawed that is found in the JYNNEOS package insert (Sections 2.2. Preparation and Administration and 16.2 Storage Conditions).

If stored frozen (-20°C), the vaccine should be used within the printed expiration date on the carton. Please note that the expiration date is not shown on the individual vial.”

Best Regards,

Rehana Mukhtar
Snr. Director CMC Regulatory Affairs
Bavarian Nordic A/S