2022 Monkeypox Outbreak
North Carolina’s Response Plan

Update for North Carolina Providers
September 8, 2022
Logistics for Today’s Webinar

Question during the live webinar

Technical assistance

technicalassistanceCOVID19@gmail.com
## Agenda and NC DHHS Members

<table>
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<th>Topic</th>
<th>Members</th>
</tr>
</thead>
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<td>OPENING REMARKS</td>
<td>Elizabeth C. Tilson, MD, MPH State Health Director, Chief Medical Officer</td>
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<td>COVID-19 UPDATE</td>
<td>Susan Kansagra, MD, MBA Assistant Secretary for Public Health, Director, Division of Public Health</td>
</tr>
<tr>
<td>OVERVIEW OF NORTH CAROLINA MONKEY POX RESPONSE</td>
<td>Zack Moore, MD, MPH State Epidemiologist, Epidemiology Section Chief</td>
</tr>
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<td>CLINICAL BACKGROUND AND EPIDEMIOLOGY</td>
<td>Erica Wilson, MD, MPH Medical Director, Vaccine Preventable and Respiratory Diseases</td>
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<tr>
<td>VACCINATION AND TREATMENT</td>
<td>Patrick Brown, PharmD Vaccine Lead, Monkeypox Incident Management Team, NC Division of Public Health</td>
</tr>
<tr>
<td>EQUITY AND COMMUNICATIONS</td>
<td>Tim Davis PharmD, BCNP, PMP Medical Countermeasures Coordinator</td>
</tr>
<tr>
<td>QUESTION AND ANSWER</td>
<td>Amanda Fuller Moore, PharmD Deputy Epidemiology Section Chief, State Pharmacist</td>
</tr>
<tr>
<td></td>
<td>Beth Meadows, RN, MSN Field Services Unit Manager Division of Public Health</td>
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<tr>
<td></td>
<td>Meg Sredl, MPH HAI Epidemiologist, Division of Public Health</td>
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<tr>
<td></td>
<td>Robin Deacle Senior Director, Office of Communications</td>
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</tbody>
</table>
COVID Updates
COVID-19 TRENDS

Early Warning Indicators
Rising levels of these can be an early sign of community spread and illness.

19.3 Million  Previous Week 18.5 Million
COVID-19 Virus Particles Found in Wastewater
COVID-19 virus particles appearing in wastewater can signal how quickly the virus is spreading, even if people don't get tested or have symptoms.

5.0%  Previous Week 5.5%
Emergency Room Visits for COVID Symptoms
The percentage of all emergency department visits that are for COVID-like symptoms can signal how much illness there is in a community.

Average COVID-19 virus copies found per person per week from participating North Carolina wastewater treatment plants.  More Info

Emergency department visits that are for COVID-like illnesses (CLI).  More Info
COVID-19 TRENDS

Health System Capacity
Rising levels of these can indicate strain on the health care system.

19,638  Previous Week 21,288
COVID-19 Reported Cases by Week of Specimen Collection

996  Previous Week 1,103
Hospital Admissions - COVID-19 Patients by Week

Number of new cases reported to the state each week, shown by the date specimen was collected.  More Info
Number of confirmed COVID-19 patients admitted to hospitals each week.  More info
FALL BIVALENT BOOSTER AUTHORIZATION

- The Centers for Disease Control and Prevention (CDC) has officially recommended Pfizer and Moderna bivalent booster doses following FDA emergency use authorization.

- Provides updated protection against original and Omicron strain.

- The monovalent mRNA COVID-19 vaccines are no longer authorized as booster doses for individuals 12 years of age and older. Eligible children 5-11 years old can still receive the original Pfizer booster.

**Pfizer-BioNTech COVID-19 Bivalent Booster Dose (12+)**

All individuals 12 and older are recommended to receive a bivalent booster dose if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

**EUA fact sheets:**
- Pfizer 12+ Bivalent Booster Fact Sheet for Healthcare Providers
- Pfizer 12+ Bivalent Booster Fact Sheet Recipients and Caregivers

**Moderna COVID-19 Bivalent Booster Dose (18+)**

All individuals 18 and older are recommended to receive a bivalent booster dose if it has been at least two months since they have completed primary vaccination or have received the most recent booster dose with any authorized or approved monovalent COVID-19 vaccine.

**EUA fact sheets:**
- Moderna 18+ Bivalent Booster Fact Sheet for Healthcare Providers
- Moderna 18+ Bivalent Booster Fact Sheet Recipients and Caregiver
<table>
<thead>
<tr>
<th>Vaccine Type</th>
<th>Which vaccine did you get?</th>
<th>Vaccination Schedule for most people.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech:</td>
<td>Pfizer-BioNTech: 12 years+</td>
<td>1st dose 3-8 weeks 2nd dose 2+ months Bivalent booster dose</td>
</tr>
<tr>
<td>Moderna</td>
<td>Moderna 12 years+ schedule</td>
<td>1st dose 4-8 weeks 2nd dose 2+ months Booster booster dose</td>
</tr>
<tr>
<td>Novavax</td>
<td>Novavax 12 years+ schedule</td>
<td>1st dose 3-8 weeks 2nd dose 2+ months Booster booster dose</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>Johnson &amp; Johnson: 18 years+</td>
<td>1st dose 4+ weeks Addl. dose of Pfizer or Moderna 2+ months Booster booster dose</td>
</tr>
</tbody>
</table>
# IMMUNOCOMPROMISED VACCINE SCHEDULE

## VACCINATION SCHEDULE for moderately or severely immunocompromised people ONLY.

<table>
<thead>
<tr>
<th>Which vaccine did you get?</th>
<th>1st dose</th>
<th>2nd dose</th>
<th>3rd dose</th>
<th>2+ months</th>
<th>Bivalent booster dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pfizer-BioNTech: 12 years+ schedule</td>
<td><strong>3-8 weeks</strong></td>
<td><strong>4+ weeks</strong></td>
<td><strong>2+ months</strong></td>
<td>Bivalent booster dose</td>
<td></td>
</tr>
<tr>
<td>Moderna 12 years+ schedule</td>
<td><strong>4-8 weeks</strong></td>
<td><strong>4+ weeks</strong></td>
<td><strong>2+ months</strong></td>
<td>Bivalent booster dose</td>
<td></td>
</tr>
<tr>
<td>Novavax 12 years+ schedule</td>
<td><strong>3-8 weeks</strong></td>
<td><strong>2+ months</strong></td>
<td>Bivalent booster dose</td>
<td></td>
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<tr>
<td>Johnson &amp; Johnson: 18 years+ schedule</td>
<td><strong>4+ weeks</strong></td>
<td>Addl. dose of Pfizer or Moderna</td>
<td><strong>2+ months</strong></td>
<td>Bivalent booster dose</td>
<td></td>
</tr>
</tbody>
</table>
PFIZER AND MODERNA BIVALENT BOOSTER – WAVE 1 / WAVE 2 / FED PHARMACIES

500K Doses are being delivered to 1,033 providers across all 100 counties

Booster Recap

- All counties are set to receive the new booster products
- Geographic breakdown with an emphasis on equitable distribution for counties with large HMPs and providers serving long-term care facilities
- It will take at least 3 months for everyone who wants a booster to receive it

Where the Doses are Going

<table>
<thead>
<tr>
<th>Provider Type</th>
<th>Provider #</th>
<th>Moderna</th>
<th>Pfizer</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacy - Federal</td>
<td>604</td>
<td>42,900</td>
<td>189,000</td>
<td>231,900</td>
</tr>
<tr>
<td>Pharmacy - State</td>
<td>147</td>
<td>25,600</td>
<td>68,400</td>
<td>94,000</td>
</tr>
<tr>
<td>LHD</td>
<td>92</td>
<td>27,000</td>
<td>32,400</td>
<td>59,400</td>
</tr>
<tr>
<td>Hospital</td>
<td>40</td>
<td>3,900</td>
<td>37,200</td>
<td>41,100</td>
</tr>
<tr>
<td>PCP</td>
<td>92</td>
<td>3,300</td>
<td>33,900</td>
<td>37,200</td>
</tr>
<tr>
<td>Other</td>
<td>28</td>
<td>6,800</td>
<td>13,200</td>
<td>20,000</td>
</tr>
<tr>
<td>FQHC/RHC</td>
<td>13</td>
<td>1,900</td>
<td>2,400</td>
<td>4,300</td>
</tr>
<tr>
<td>Student Health</td>
<td>4</td>
<td>300</td>
<td>2,700</td>
<td>3,000</td>
</tr>
<tr>
<td>LTC</td>
<td>8</td>
<td>2,500</td>
<td>300</td>
<td>2,800</td>
</tr>
<tr>
<td>Correctional Facility</td>
<td>4</td>
<td>2,000</td>
<td>0</td>
<td>2,000</td>
</tr>
<tr>
<td>Commercial Vax</td>
<td>1</td>
<td>0</td>
<td>1,200</td>
<td>1,200</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>1,033</strong></td>
<td><strong>116,200</strong></td>
<td><strong>380,700</strong></td>
<td><strong>496,900</strong></td>
</tr>
</tbody>
</table>
Overview of North Carolina Monkey Pox Response
Monkeypox: Evolving Public Health Response

• Raising public and clinician awareness

• Testing
  • Wide availability of testing
  • State Laboratory of Public Health, several commercial laboratories, and some academic medical centers
  • Working to increase awareness in the public and among providers

• Case investigation and response
  • All cases required to be reported to your Local Health Department or NCDPH (919-733-3419) within 24 hours per state law and NC State Administrative Code.
  • Local and state public health investigate each case to identify contacts and facilitate access to care and vaccines

• Treatment
  • Medications developed for similar viruses can be used to treat severe cases
  • Tecovirimat (TPOXX) available through Strategic National Stockpile under EA-IND protocol
  • NCDHHS working to streamline access, including pre-positioning doses with providers

• Vaccination
  • JYNNEOS vaccine FDA approved for prevention of monkeypox
  • Can prevent or reduce severity of symptoms if given within 14 days after exposure (post-exposure, PEP)
  • Can be given before exposure to those at higher risk (pre-exposure, PrEP)
Clinical Background
CLINICAL PRESENTATION

- Typically, but not always, begins with flu-like symptoms, lymphadenopathy

- Rash appears within 5 days after prodrome. Lesions may be all over or localized.

- Rash from bumps to vesicles and then pustules before scabbing over and resolving over a period of 2-4 weeks.

- Lesions are usually firm, well circumscribed, and deep seated

- Atypical presentations common in current outbreak
Symptoms of Monkeypox Cases Reported to CDC

- Rash: 97.5%
- Fever: 66.4%
- Malaise (tiredness or not feeling well): 63.7%
- Chills: 61.4%
- Headache: 57.5%
- Enlarged lymph nodes (swollen glands): 57.1%
- Myalgia (muscle aches): 55.8%
- Pruritis (itching): 55.4%
- Rectal pain: 43.3%
- Rectal bleeding: 27.5%
- Tenesmus (pain when wanting to pass stool): 22.1%
- Pus or blood on stools: 21.1%
- Vomiting or nausea: 19.8%
- Abdominal pain (stomach ache): 15.6%
- Proctitis (swelling, soreness in the rectal area): 15.4%
- Conjunctivitis (redness or pain in the eye): 5.5%
How it Spreads

Monkeypox spread through close contact, including:

- Direct skin-to-skin contact with the monkeypox rash, sores, or scabs
- Contact with objects that have been used by someone with monkeypox (e.g., clothes, linens)
- Exposure to respiratory droplets or oral fluids during prolonged face-to-face contact with someone with monkeypox
- From pregnant people to the fetus through the placenta

Individuals are infectious until all scabs have fallen off and a fresh layer of skin has formed
Infection Prevention

• When monkeypox is suspected, healthcare workers should implement contact and enhanced droplet precautions, including wearing gloves, a protective gown, eye protection, and a NIOSH-approved N95 or higher-level respirator.

• Respirators should not be re-used between patients because fomite transmission is possible.

• Cleaning processes for testing facilities are similar to standard cleaning after a patient visit. See: CDC Infection Control in Healthcare Settings.

• For people with monkeypox who do not require hospitalization, home isolation is required during the infectious period. People are contagious until lesions have scabbed over and a fresh layer of skin has formed underneath.

• People who have had close contact should be monitored and offered post-exposure prophylaxis based on level of exposure.
Epidemiology of Outbreak
Current Outbreak – Global and National

Globally
- 54,400 cases in countries that have not historically reported monkeypox

US
- 20,733 cases
  - 79% in men who report sex with men
  - 33% White non-Hispanic
  - 31% Hispanic
  - 31% Black non-Hispanic
  - 4% Asian
# North Carolina Case Demographics and Coinfection

<table>
<thead>
<tr>
<th>North Carolina Monkeypox Case Demographic Data</th>
<th>Number of Cases (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>387</td>
</tr>
<tr>
<td><strong>Sex/Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>380 (98)</td>
</tr>
<tr>
<td>Female</td>
<td>7 (2)</td>
</tr>
<tr>
<td>Other than sex assigned at birth</td>
<td>0</td>
</tr>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>0-17</td>
<td>2 (1)</td>
</tr>
<tr>
<td>18-29</td>
<td>146 (38)</td>
</tr>
<tr>
<td>30-49</td>
<td>211 (55)</td>
</tr>
<tr>
<td>50+</td>
<td>28 (7)</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
</tr>
<tr>
<td>American Indian/Alaskan Native</td>
<td>3 (1)</td>
</tr>
<tr>
<td>Asian</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Black or African American</td>
<td>261 (67)</td>
</tr>
<tr>
<td>Native Hawaiian or Pacific Islander</td>
<td>0</td>
</tr>
<tr>
<td>White</td>
<td>93 (24)</td>
</tr>
<tr>
<td>Multi-racial</td>
<td>14 (4)</td>
</tr>
<tr>
<td>Other</td>
<td>13 (3)</td>
</tr>
<tr>
<td>Unknown</td>
<td>2 (1)</td>
</tr>
<tr>
<td><strong>Ethnicity</strong></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>43 (11)</td>
</tr>
<tr>
<td>Non-Hispanic</td>
<td>336 (87)</td>
</tr>
<tr>
<td>Unknown</td>
<td>8 (2)</td>
</tr>
<tr>
<td><strong>Coinfection</strong></td>
<td></td>
</tr>
<tr>
<td>Known to be living with HIV</td>
<td>209 (54)</td>
</tr>
</tbody>
</table>

*In the U.S., HIV or recent sexually transmitted infections (STIs)*

are common among people with monkeypox

Among nearly 2,000 people with monkeypox:

- 38% had HIV
- 41% had an STI in the past year
- 61% had either HIV or an STI

It is important to

Prioritize people with HIV and STIs for monkeypox vaccination

Offer HIV and STI screening for people evaluated for monkeypox

https://www.cdc.gov/mmwr/volumes/71/wr/mm7136a1.htm?s_cid=mm7136a1_w
North Carolina Case Trends

North Carolina Monkeypox Cases by Date of Symptom Onset*, 2022

*Symptom onset date is missing for 24 cases. Data will be updated as additional information becomes available.
North Carolina Cases Geographic Trends
Testing
• Testing available at NC SLPH and many commercial and hospital labs
• Prior approval is not needed for monkeypox testing
• Test any patients with clinical symptoms consistent with monkeypox
• Carefully consider testing in patients with no plausible risk of exposure and low suspicion for monkeypox disease. False positive results have been reported and the likelihood is higher when pre-test probability is low
PCR testing of swabs from skin lesions

- Two **vigorous** swabs from base of each lesion (3 per patient - different body parts or different appearance) using sterile synthetic swabs.
- Place swabs in sterile containers that have a gasket seal and able to be shipped under the required conditions*
- Store refrigerated (2-8°C) or frozen (-20°C or lower) within an hour of collection
- Use of tubes with transport media varies by laboratory*

DO NOT unroof lesions using needles, scalpels, or other sharp instruments

*Adhere closely to the specimen collection and shipping guidance for the specific testing laboratory*
Vaccination
Expanded Vaccine Eligibility - JYNNEOS

- Anyone who had close contact in the past two weeks with someone who has been diagnosed with monkeypox; or
- Gay, bisexual, or other men who have sex with men, or transgender individuals, who are sexually active; or
- People who have had sexual contact with gay, bisexual, or other men who have sex with men, or transgender individuals in the past 90 days; or
- People living with HIV, or taking medication to prevent HIV (PrEP), or who were diagnosed with syphilis in the past 90 days; or
- Certain health care, laboratory, and public health response team members

At this time, most clinicians in the United States and laboratorians not performing the orthopoxvirus generic test to diagnose orthopoxviruses, including monkeypox, are not advised to receive orthopoxvirus PrEP
## VACCINE ADMINISTRATION DATA

<table>
<thead>
<tr>
<th>Sex</th>
<th>Percentage:</th>
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</thead>
<tbody>
<tr>
<td>Female</td>
<td>6%</td>
</tr>
<tr>
<td>Male</td>
<td>85%</td>
</tr>
<tr>
<td>Unknown</td>
<td>9%</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Race</th>
<th>Percentage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>American Indian or Alaska Native</td>
<td>1%</td>
</tr>
<tr>
<td>Asian</td>
<td>3%</td>
</tr>
<tr>
<td>Black or African-American</td>
<td>27%</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander</td>
<td>0%</td>
</tr>
<tr>
<td>Other Race</td>
<td>4%</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3%</td>
</tr>
<tr>
<td>White</td>
<td>62%</td>
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</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Percentage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino</td>
<td>9%</td>
</tr>
<tr>
<td>Not Hispanic or Latino</td>
<td>87%</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>3%</td>
</tr>
<tr>
<td>Unknown</td>
<td>0%</td>
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</table>

<table>
<thead>
<tr>
<th>Age Breakdown</th>
<th>Percentage:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-17</td>
<td>0%</td>
</tr>
<tr>
<td>18-29</td>
<td>26%</td>
</tr>
<tr>
<td>30-49</td>
<td>50%</td>
</tr>
<tr>
<td>50+</td>
<td>24%</td>
</tr>
</tbody>
</table>

- As of Aug. 31, **11,420 vaccine doses** have been administered across the state, and more doses are expected in the coming weeks.

- **Over 2,300 North Carolinians** have been fully vaccinated against Monkeypox during the current vaccine rollout.

- As of 8/29/22 all vaccine providers are required to administer JYNNEOS vaccine **via intradermal route**, barring contraindications.

- **5,000 vials of JYNNEOS** currently on hand in North Carolina.
• **Hub and Spoke Distribution Model**
  • Nine local health departments serving as hubs:
    • Buncombe, Cumberland, Durham, Forsyth, Guilford, Mecklenburg, New Hanover, Pitt, Wake
  • Providing vaccine regardless of county of residence; transferring to other health departments and vaccine providers as needed
  • 61 additional sites identified to pair with LHD hubs to receive vaccine to expand access
    • Vaccines administered in 41 counties across NC
  • Monkeypox vaccine hubs and additional provider locations available at
    • [https://www.ncdhhs.gov/divisions/public-health/monkeypox/monkeypox-vaccine-locations](https://www.ncdhhs.gov/divisions/public-health/monkeypox/monkeypox-vaccine-locations)

• **Going Forward**
  • NC currently has ~2,500 additional vials available in our next order when we have used 85% of our current allocation
  • White House and CDC announced special allocations process for equity-focused community events
    • Up to 100 vials for 5 events
    • Details expected mid-September

*NC VACCINATION RESPONSE - DISTRIBUTION*

*Draft and subject to change based on new information*
1. Patient in need of PEP/PEP++
   - Refer to LHD or clinic with current vaccine supply

2. All providers interested in receiving vaccine supply in the future must complete: NC DHHS Monkeypox Vaccine Enrollment and Capacity Survey
   - Submission of enrollment survey does not guarantee an allocation of vaccine – Current supply very limited
   - Purpose of enrollment
     - Validate vaccine storage capabilities
     - Ensure vaccine accountability
     - Confirm NCIR access for proper documentation
     - Set up HPOP account (federal system used for vaccine ordering)

3. All enrolled providers placed on waitlist until vaccine availability improves

4. Difficulty locating LHD/clinic with vaccine, submit NC DHHS Monkeypox MCM Request Form
   - NC DHHS will review and assist in locating vaccine for transfer

Draft and subject to change based on new information
• Cross functional collaboration
  • We need all providers, local health departments, and community partners working together

• Equity
  • Ensuring our limited resources reach those at highest risk, regardless of their race, ethnicity, or socioeconomic status
  • Collecting the proper data to inform equitable decision making
  • Community-focused events in Mecklenburg County and Durham County have demonstrated ability to close racial gap in vaccine administrations

• Information Sharing
  • Leveraging community partners to help get the word out and support initiatives focused on equity

• Billing and reimbursement
  • Vaccines and therapeutics are provided free from the strategic national stockpile
  • Providers must administer vaccine at no cost to the recipient and regardless of the vaccine recipient’s ability to pay administration fees
  • Providers may seek appropriate reimbursement from a program or plan that covers vaccine administration fees

• Use of the North Carolina Immunization Registry (NCIR)
  • Providers must have NCIR access to be able to receive and administer monkeypox vaccine
  • Provider sites are expected to maintain vaccine inventory and document administrations in NCIR
Treatment
## MEDICAL COUNTERMEASURES: TREATMENT OPTIONS

Currently no proven, safe, and effective treatments for Monkeypox. Animal data suggests smallpox treatments could be used in severe cases.

<table>
<thead>
<tr>
<th>Name</th>
<th>Indication</th>
<th>Dosing &amp; Administration</th>
<th>Availability</th>
<th>Storage and Handling</th>
<th>Notes</th>
</tr>
</thead>
</table>
| **TPOXX** tecovirimat | FDA approved for treatment of smallpox in adults and pediatric patients weighing at least 3kg. | Oral and IV formulations Weight based dosing 14 day course of therapy                   | SNS request  | Oral: 200mg capsules; 42 caps/bottle Stored at controlled room temp (>13kg)  
IV: 200mg/20mL vial Store refrigerated @ 2-8°C (>3kg) | TPOXX IV contraindicated in those with severe renal impairment  
TPOXX oral must be taken within 30 minutes after moderate/high fat meal  
No human data on use in pregnancy; no toxicity in animal reproductive studies |
| **Vistide** cidofovir | FDA approved for treatment of CMV retinitis in AIDS patients                | 5mg/kg IV once weekly x 2 weeks Must be administered with fluids and probenecid        | Commercially & SNS Request | 75 mg/mL in clear glass, single use vial Store at controlled room temperature 20-25°C | Causes severe nephrotoxicity  
Renal function monitored within 48 hours prior to administration  
No human data on use in pregnancy; embryotoxic in rats |
| **Vaccinia Immune Globulin** VIGIV CNJ-016 | FDA approved for the treatment of complications associated with vaccinia vaccination | 6,000 U/kg IV x 1 dose Higher doses can be given if patient does not respond | SNS Request | 15mL vial containing > 50,000 U/vial Product may be stored frozen at or below 5°F (-15°C) or refrigerated at 36 to 46°F (2 to 8°C) | No animal or human pregnancy data; Other immune globulins used in pregnancy w/o negative effects |

Note: CDC is currently developing a expanded access protocol for a fourth treatment; **Tembexa (brincidovofir)**. However, it is currently not available commercially or through SNS request. **Viroptic (trifluridine)** is a commercially available ophthalmic solution that can be considered for monkeypox treatment in patients with ocular lesions.
CDC Recently Revised TPOXX EA-IND Protocol
- Streamlined to make treatment easier, reduce patient visits, and required forms
- All visits can be conducted via **telemedicine**
- All **laboratory testing is optional**
- Required adverse event reporting on **serious adverse events only**
- **No pre-registration is required** to begin providing tecovirimat treatment
- Forms required for EA-IND can all be returned to CDC after treatment begins

**Required As part of EA-IND Process:**
- Obtain informed consent **prior** to treatment
- Conduct a baseline assessment and complete patient intake form
- Document progress once during and once after treatment on the Clinical Outcome Form
- Report life-threatening or serious adverse events with tecovirimat by completing a PDF MedWatch Form and returning to CDC
- Complete FDA Form 1572: **One signed per facility**

For more information: [https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html](https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html)
**HOW TO OBTAIN ACCESS TO TPOXX**

Providers interested in TPOXX can place a request using our [NC DHHS Monkeypox Medical Countermeasures Request Form](#).

**Oral TPOXX Distribution**
- To date more than 747 courses have been shipped to 40 locations in NC for utilization/pre-positioning.
- Current threshold available from CDC has 294 courses remaining.
- CDC currently limiting states to 5 ship to sites per week and need to show 80% utilization to refill threshold.
- Requests are filled based on need utilizing transfers from pre-positioned locations.

**Oral TPOXX Reporting**
- All providers utilizing TPOXX must have a Health Partner Ordering Portal (HPOP) Account
  - This is created as part of the initial request process.
- On-Hand inventory and administrations are required to be reported weekly - every Tuesday by 5pm.
  - Inventory on hand should be reported in bottles.
  - Administrations should be reported in patient courses administered since your last report.

**Provider Attestation**
- Recently provided by CDC, required to attest with each request for TPOXX.
- Attestation includes:
  - Providers utilize TPOXX in accordance with EA-IND and submit all required EA-IND regulatory documentation.
  - Report adverse events via FDA MedWatch within 72 hours.
  - Report inventory and administrations weekly via HPOP.
  - Organization must provide TPOXX to recipients regardless of their ability to pay.
  - Organization must preserve all TPOXX related documents/records for minimum of 3 years.
Equity, Communications, Outreach
Monkeypox Vaccine: Equity Considerations

• Tracking case and vaccination data (including race and ethnicity)
• In North Carolina, 68% of cases were in Black or African American individuals, yet this group has received 27% of vaccines. Nationally, about 10% of vaccine doses have gone to Black or African American individuals.
• Considerations for access to testing, vaccination and treatment:
  • Access to healthcare
  • Transportation
  • Cost
  • Stigma / Anonymity
• NCDHHS is working with all levels of government together in partnership with community organizations to remove disparities in monkeypox cases and vaccinations.
• Extensive communication, town halls and coordination with LGBTQ+ focused CBOs, HBCUs, HIV and other STI care providers, other community partners to ensure awareness, low-barrier access.
• Local events
  • Mecklenburg Public Health and Charlotte Pride events.
  • Triangle Empowerment Center MPX vaccine event in Durham (8/30)
  • NCCU Community Health Fair (9/8)
Communications and Outreach

**LEARN the facts.** Anyone can get monkeypox. It spreads mostly through close skin-to-skin contact.

**LOOK for a rash.** Get new rashes, lesions or sores checked by a health care provider. Talk with your partner about any monkeypox symptoms.

**LOCATE testing and vaccines for yourself or your community.**
- There is no limit on testing. Talk to your doctor or local health department.
- Limited vaccine supply is prioritized for those currently most at risk, and the communities where the virus is spreading.

For more info, testing and vaccine locations: ncdhhs.gov/monkeypox

https://epi.dph.ncdhhs.gov/cd/diseases/monkeypox.html#
Communications and Outreach

LEARN the facts: Anyone can get monkeypox. It spreads mostly through close skin-to-skin contact.

Examples of Monkeypox Exposure by contact with someone who has the virus

HIGHEST EXPOSURE:
• Bare skin-to-skin contact with infectious rash, scabs or bodily fluids
• Sexual contact
• Other intimate skin-to-skin contact such as kissing, massage or cuddling

SOME EXPOSURE:
• Crowds where people aren’t wearing much clothing with a lot of skin-to-skin contact
• Sharing drinks, utensils, cigarettes, vapes, pipes, etc.
• Sharing towels, bed linens, or other personal items
• Exposure to respiratory droplets through prolonged face-to-face contact with no mask use

UNLIKELY EXPOSURE:
• Crowds where people are mostly clothed, not much skin-to-skin contact
• Shaking hands with someone with no visible rash
• Shopping at the grocery store or mall
• Traveling by bus, train or plane or using public restrooms
• Trying on clothing at a store

LOOK for a rash: Get new rashes, lesions or sores checked by a health care provider. Talk with your partner about any monkeypox symptoms and be aware of any new or unexplained rash or lesion on either of your bodies, including the mouth, genitals and anus.

LOCATE testing and vaccines for yourself, or your community: There is no limit on testing. Talk to your doctor or local health department: ncdhhs.gov/monkeypox

Vaccine is available at local health departments and clinics. Find out if you are eligible: ncdhhs.gov/monkeypox

Everyone can do their part to control the spread: We are in this together. Learn more: ncdhhs.gov/monkeypox

*Photos used with permission.

https://epi.dph.ncdhhs.gov/cd/diseases/monkeypox/toolkit.html
MONKEYPOX VACCINE AND TREATMENT RESOURCES

CDC:
- U.S. Monkeypox Outbreak 2022: Situation Summary
- Monkeypox and Smallpox Vaccine Guidance
- Interim Clinical Guidance for the Treatment of Monkeypox

NC DHHS:
- NC DHHS Monkeypox Website: Vaccine Locations
- Monkeypox Communication Toolkit
- Provider Memo (July 14th)
- Vaccine Toolkit
- Interim Guidance for NC Healthcare Providers: Tecovirimat in Treatment of Monkeypox
- Communicable Disease Manual for LHDs

Draft and subject to change based on new information
Questions
Additional information
Many rashes can have similar appearances.

Yearly in the US:

- 7-10,000 chickenpox cases
- 39,000 syphilis cases
- 572,000 genital herpes infections
- 1,000,000 shingles cases
- Unknown number of arthropod bites/stings, molluscum, hand-foot-mouth disease, and more
## Typical Characteristics of Rash Illnesses

<table>
<thead>
<tr>
<th>Disease</th>
<th>Prodrome</th>
<th>Rash Appearance</th>
<th>Direction of Rash Spread</th>
<th>P/S</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Macular</td>
<td>Papular</td>
<td>Vesicular</td>
</tr>
<tr>
<td>Monkeypox</td>
<td>YES</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Molluscum contagiosum</td>
<td>NO</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Syphilis</td>
<td>+/-</td>
<td>X</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Chickenpox</td>
<td>+/-</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Shingles</td>
<td>+/-</td>
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<tr>
<td>Measles</td>
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<tr>
<td>Herpes</td>
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<td>X</td>
<td></td>
</tr>
<tr>
<td>Hand-foot mouth</td>
<td>YES</td>
<td>X</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>RMSF</td>
<td>YES</td>
<td>X</td>
<td></td>
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</tr>
</tbody>
</table>

**Webinar May 24, 2022 - What Clinicians Need to Know about Monkeypox in the United States and Other Countries (cdc.gov)**