

# Provider Webinar

## Monkeypox

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# Objectives

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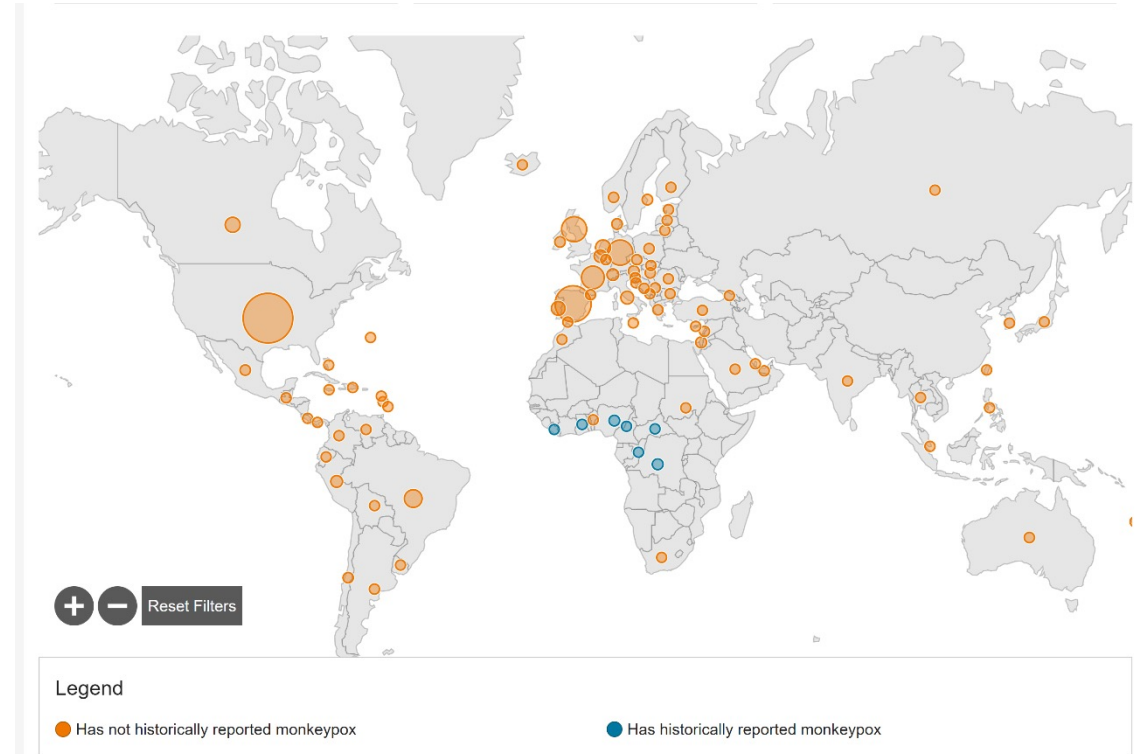
## Review:

- Status of monkeypox in Georgia
- Clinical evaluation and management of monkeypox
- Testing of suspect monkeypox patients
- Reporting of monkeypox cases
- Vaccination requirements and access

# Monkeypox in Georgia

# Situational Update as of August 5, 2022

- Globally there are 81 countries impacted that do not historically report monkeypox, with 27,875 cases confirmed attributed to the 2022 outbreak.
- In the US, there are 7,510 OPX or MPX confirmed cases reported in 52 states or territories



<https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>

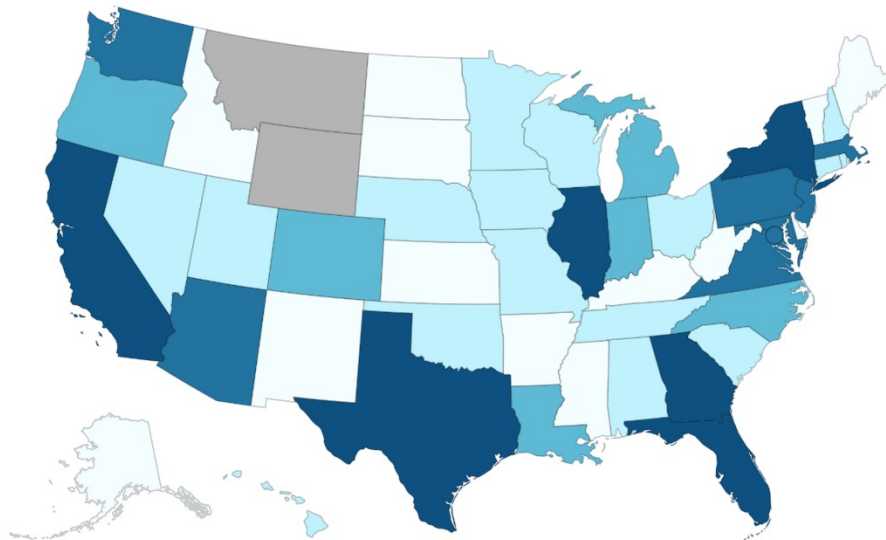
# U.S. Situational Update

## 2022 U.S. Map & Case Count

Updated August 5, 2022 [Print](#)

Total confirmed monkeypox/orthopoxvirus cases: **7,510**

\*One Florida case is listed here but included in the United Kingdom case counts because the individual was tested while in the UK.



Territories [PR](#)



### Case Range



### Data Table

| Location             | Cases |
|----------------------|-------|
| New York             | 1,862 |
| California           | 826   |
| Florida              | 633   |
| Texas                | 606   |
| Illinois             | 602   |
| Georgia              | 596   |
| District Of Columbia | 283   |
| Pennsylvania         | 205   |
| New Jersey           | 188   |

# Georgia Situational Update – August 8

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- In Georgia 402 clinical assessments performed
- 625 Positive Cases identified through GPHL and commercial testing, of which:
  - 619 (99%) are men
  - 6 (1%) are women
    - The majority of cases in GA and in this outbreak nationally are in men who self-report as MSM with sexual or close/intimate contact reported in the 21 days prior to symptom onset. We expect to see cases in close contacts of persons who are infected with MPXV regardless of gender identity or age
  - Age:
    - Range: 18-66
    - Median: 34

# Georgia Situational Update

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- Race (available on 466, 75% of cases)
  - Black or African American: 382 (82%)
  - White: (14%)
  - Other: 9 (2%)
  - Multiracial: 7 (2%)
  - Asian: 3 (1%)
- Ethnicity (available on 444, 71% of cases)
  - Non-Hispanic: 416 (94%)
  - Hispanic: 28 (6%)
- HIV summary statistics have been provided based on our first 452 cases:
  - 303/452 (67%) of cases are in eHARS, indicating they are HIV positive
  - Most are in HIV care and are virally suppressed, most have a CD4 count >200 (<200 being the level where risk of opportunistic infections increases)
    - 92% had last CD4 >200
    - 85% are virally suppressed (VL<200 copies/mL) at last vL

# Clinical Evaluation and Management



# Signs and Symptoms

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- Symptoms of monkeypox can include:
  - Fever
  - Headache
  - Muscle aches and backache
  - Swollen lymph nodes
  - Chills
  - Exhaustion
- A rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body, like the hands, feet, chest, genitals, or anus.
  - The rash goes through different stages before healing completely. The illness typically lasts 2-4 weeks.
  - Sometimes, people get a rash first, followed by other symptoms. Others only experience a rash.

**NOTE:** In this outbreak we are also seeing proctitis, hematochezia, and tenesmus

# Rash

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# Transmission and Duration

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- Spread from person-to-person through direct contact with the infectious rash, scabs, or body fluids
- Spread by respiratory secretions during prolonged, face-to-face contact, or during intimate physical contact, such as kissing, cuddling, or sex
- Monkeypox can spread from the time symptoms start until the rash has fully healed, all scabs have fallen off, and a fresh layer of skin has formed
- The illness typically lasts 2-4 weeks

# Isolation Guidance for Persons with Monkeypox

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- Current data suggests that people can spread monkeypox from the time symptoms start until all symptoms are resolved.
- People with monkeypox should ideally isolate until the rash has fully resolved, the scabs have fallen off, and a fresh layer of intact skin has formed.
- Key points to discuss for isolation:
  - Stay home except to get medical care
  - Separate yourself from other people in your home as much as possible
  - Provide guidance for household cleaning and disinfection
- DPH monkeypox home isolation guidance can be found here:  
<https://dph.georgia.gov/monkeypox>

# Infection Prevention in Healthcare Settings

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- A patient with suspected monkeypox infection should be placed in a single-person room; **special air handling is not required**. The door should be kept closed (if safe to do so).
- If the patient is transported outside of their room, they should use well-fitting source control (e.g., medical mask) and have any exposed skin lesions covered with a sheet or gown.
- PPE used by healthcare personnel should include gown, gloves, eye protection that covers the front and sides of the face, NIOSH-approved particulate respirator equipped with N95 filters or higher
- CDC guidance environmental infection control :  
[https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html#anchor\\_1653508909869](https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html#anchor_1653508909869)

# Treatment

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- Many people infected with monkeypox virus have a self-limiting disease course in the absence of specific therapy.
- Although the illness is described as mild, some people particularly those with anogenital and mucosal lesions have experienced severe pain.
- CDC recommends the following:
  - Assess pain in all persons with monkeypox
  - Use topical and systemic strategies including sitz baths, salt-water gargles, topical steroids and lidocaine, OTC pain relievers, and prescription pain relievers such as gabapentin and opioids, and stool softeners for proctitis if indicated
  - Tecovirimat (TPOXX) may indicated for pain control

# Treatment

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- TPOXX was developed to fight smallpox, but the U.S. Food and Drug Administration allows its use to treat monkeypox during the current outbreak
- TPOXX can be considered for treatment for people with monkeypox with
  - Severe disease (e.g. sepsis, encephalitis, conditions leading to hospitalization)
  - Risks for severe disease including immunocompromising conditions
  - Lesions involving eyes, mouth, or other anatomic areas the genitals or anus
  - For more information visit:  
[https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html#anchor\\_1654624161405](https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html#anchor_1654624161405)
- TPOXX must be administered under an Investigational New Drug (IND) protocol

# Required Documents for TPOXX

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3 documents must be completed during the TPOXX treatment process, 2 must be returned to the CDC:

- [FDA Form 1572 \[1MB, 2 pages\]](#) Required to be completed by a physician and submitted to CDC. One Per facility within 3 days of starting treatment.
- [Informed Consent Form \[214KB, 5 pages\]](#) Informed Consent Form must be completed and retained by the client and the treating facility. A copy does not have to be returned to the CDC.
- [Patient Intake Form \[321KB, 3 pages\]](#) complete and submit to CDC within 3 days of TPOXX initiation.
- [Clinical Outcome Form \[279KB, 4 pages\]](#) during treatment at one in-person or telemedicine follow up visit, and at a visit 7-10 days after treatment during the last follow-up in-person or telemedicine visit, document information on the same Clinical Outcome Form and submit to CDC within 3 working days of the last follow-up visit.



# TPOXX Request Process

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- Providers can email [TPOXXorders@dph.ga.gov](mailto:TPOXXorders@dph.ga.gov) to request TPOXX
- Include the provider's phone number and email address
- Dedicated DPH TPOXX on-call staff work with providers to collect required information
- Dedicated DPH TPOXX on-call staff will collect:
  - Patient information
  - Formulation requested
  - Doses needed
  - Shipping information
- TPOXX on-call staff will place order for PO or IV TPOXX

# Information Needed for all TPOXX Orders

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- Relevant clinical summary and clinical eligibility for TPOXX (e.g., suspected monkeypox infection, HIV infected, unable to take oral medication)
- Patient weight (kg)
- Formulation requested (IV or Oral)
- Number of days of therapy requested
- Name of receiving facility
- Shipping address
- Point-of-contact name, phone, and email
- Days/times facility can receive shipment

# Additional Guidance

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- Positive monkeypox test results are NOT required for patients to receive treatment.
- 3 patient visits are required and can be provided via telemedicine: baseline, during treatment, and after completion of treatment.
- IV TPOXX orders take 2-3 days to arrive; Oral TPOXX orders typically take 24 hours to ship when requested on weekdays

# Testing

# Testing Availability

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- The Georgia Department of Public Health (DPH) will continue to support testing at the state public health laboratory but understands that commercial testing provides an expansion of laboratory testing capacity to assist with identifying new cases of monkeypox and stop the spread of disease.
- We know that commercial testing may also fit into the workflow of a facility and facilitate more access to testing in busy settings like emergency departments.
- We encourage providers to utilize commercial testing and the best testing option for their patient.

# Commercial Laboratory Testing

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Commercial Testing is available at the following five labs:

- Labcorp
- Quest
- Mayo
- Aegis
- Sonic
- DPH commercial testing guidance for Georgia providers can be found: <https://dph.georgia.gov/document/document/monkeypox-commercial-testing-guidance-georgia-providers/download>

It is critical to work with commercial laboratories directly to determine:

- Ordering codes
- Specimen requirements
- How results will be returned to you
- To set expectations like turn-around time, billing, etc.

# Testing for all Labs

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- Use CDC recommended PPE (gown, NIOSH-approved N-95 mask, goggles or face shield, and gloves) during assessment and collection of specimens.

# Testing at GPHL

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- For testing at Georgia Public Health Laboratory: Providers should contact **1-866-PUB-HLTH (866-782-4584)** and then proceed with recommendations.
- Collect specimens for monkeypox molecular testing to send to GPHL.
  - For the most up to date information on the types of swabs to use, and how to collect, handle, & transport specimens please visit:  
<https://dph.georgia.gov/monkeypox/information-providers>



# Who to test

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- Persons with a characteristic rash for monkeypox regardless of exposure history **AND/OR**
- Persons with a new rash (even if not characteristic for MPXV) and who within 21 days of illness onset:
  - Reports contact with a person with a similar rash or who received a diagnosis monkeypox **OR**
  - Had close contact with individuals in a social network experiencing monkeypox activity (men who have sex with men (MSM) who meet partners online, or at a social event like a bar or party) **OR**
  - Traveled abroad to a country with confirmed cases of monkeypox.

# Testing and Isolation

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- **Anyone under suspicion of monkeypox should be counseled to isolate while awaiting results**
- Any patient being tested should be given isolation guidance to prevent additional exposures and secondary cases. Test results may take 1-2 business days to receive, they should isolate during that time:  
<https://dph.georgia.gov/document/document/home-isolation-guidance-monkeypox/download>

# Reporting

# Epidemiology Investigation

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Monkeypox cases should be reported to DPH through the traditional notifiable disease reporting system.

District epidemiology staff conduct initial interview with patient to:

- Review and reiterate isolation guidance (to support information already shared up front by testing provider!)
- Identify high risk contacts that could be provided PEP
- Collect information on risk factors
- Complete CDC case report form

# NOTIFIABLE DISEASE CONDITION REPORTING

All Georgia physicians, laboratories, and other health care providers are required by law to report patients with the following conditions.

| REPORT IMMEDIATELY   |  | REPORT WITHIN 7 DAYS   |   |
|--|--|--|---|
| <b>To Report Immediately   Call: District Health Office or 1-866-PUB-HLTH (1-866-782-4584)</b> |  |  |   |
| any cluster of illnesses   | novel influenza A virus infections   | AIDS*  | – anti-HCV(+) or HCV RNA detected children ages <3 years        |
| animal bites   | novel respiratory viruses (COVID-19, SARS, MERS, etc.)<br><small>POSITIVE + NEGATIVE LAB RESULTS, ALL TEST TYPES</small> | acute flaccid myelitis   | hepatitis D (Delta virus present with HBsAg); acute and chronic |
| ▶ anthrax  | ▶ orthopoxviruses (smallpox, monkeypox)  | anaplasmosis   | hepatitis E (acute)   |
| all acute arboviral infections*  | pertussis  | aseptic meningitis   | influenza-associated death (all ages)                           |
| ▶ botulism   | ▶ plague   | babesiosis   | legionellosis   |
| ▶ brucellosis  | poliomyelitis  | blood lead level (all)   | leptospirosis   |
| cholera  |  | campylobacteriosis   | listeriosis***  |
| diphtheria   |  | Carbapenem-resistant Enterobacteriaceae (CRE):<br>Enterobacter species, Escherichia coli, and Klebsiella species | leprosy or Hansen's disease (Mycobacterium leprae)              |
|  |  | chancroid  | Lyme disease  |
|  |  | Chlamydia trachomatis (genital infection)  | lymphogranuloma venereum  |
|  |  | Creutzfeldt-Jakob Disease (CJD), suspected cases, under age 55   | malaria   |
|  |  |  | maternal deaths   |

# Degree of Exposure: High

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## Degree of Exposure: High

### Recommendations

- Monitoring<sup>5</sup>
- PEP<sup>6</sup> – Recommended

### Exposure Characteristics

- Unprotected contact between a person's skin or mucous membranes and the skin, lesions, or bodily fluids from a patient (e.g., any sexual contact, inadvertent splashes of patient saliva to the eyes or oral cavity of a person, ungloved contact with patient), or contaminated materials (e.g., linens, clothing) -OR-
- Being inside the patient's room 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 -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level (i.e., exposure that ordinarily would be considered a lower risk exposure, raised to this risk level because of unique circumstances)

# Degree of Exposure: Intermediate

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## Degree of Exposure: Intermediate

### Recommendations

- Monitoring<sup>§</sup>
- PEP<sup>¶</sup> – Informed clinical decision making recommended on an individual basis to determine whether benefits of PEP outweigh risks <sup>¶¶</sup>

### Exposure Characteristics

- Being within 6 feet for 3 hours or more of an unmasked patient without wearing, at a minimum, a surgical mask -OR-
- Activities resulting in contact between sleeves and other parts of an individual's clothing and the patient's skin lesions or bodily fluids, or their soiled linens or dressings (e.g., turning, bathing, or assisting with transfer) while wearing gloves but not wearing a gown -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level because of unique circumstances (e.g., if the potential for an aerosol exposure is uncertain, public health authorities may choose to decrease risk level from high to intermediate)

# Degree of Exposure: Low/Uncertain

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## Degree of Exposure: Low/Uncertain

### Recommendations

- Monitoring<sup>5</sup>
- PEP<sup>6</sup> – None

### Exposure Characteristics

- Entered the patient room without wearing eye protection on one or more occasions, regardless of duration of exposure -OR-
- During all entries in the patient care area or room (except for during any procedures listed above in the high-risk category), wore gown, gloves, eye protection, and at minimum, a surgical mask -OR-
- Being within 6 feet of an unmasked patient for less than 3 hours without wearing at minimum, a surgical mask -OR-
- Exposure that, at the discretion of public health authorities, was recategorized to this risk level based on unique circumstances (e.g., uncertainty about whether Monkeypox virus was present on a surface and/or whether a person touched that surface)



# Degree of Exposure: Healthcare settings

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- Most healthcare provider interactions will fall into Low/Uncertain risk or possibly No Risk
- Recommend awareness, but not daily checks
- Expect CDC updates shortly moving situations where providers are wearing appropriate PPE out of Low/Uncertain Risk category

# Vaccine

# Vaccine

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- Jynneos is an attenuated, live, non-replicating vaccine for use in the prevention of smallpox or monkeypox
- Jynneos is not approved for individuals less than 18 years of age, but can be given through an EA-IND protocol
- People who receive Jynneos are considered to reach maximum immunity 14 days after their second dose (~ 6 weeks from first dose)

# Jynneos Overview

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| Vaccine Virus                               | Replication-deficient Modified Vaccinia Ankara |
|---|--|
| Administration                              | Subcutaneously in 2 doses, 28 days apart       |
| “Take”                                      | No “take” after vaccination                    |
| Inadvertent Inoculation and Autoinoculation | No risk  |
| Cardiac Adverse Events                      | Considered low                                 |
| Contraindications                           | Allergy to vaccine component                   |
| Effectiveness                               | Unknown in current outbreak                    |

# Vaccine Supply and Availability

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- As part of an effort to control MPV in the United States, the federal government has allocated the limited supply of Jynneos vaccine to jurisdictions
- Vaccines are being offered by appointments in all health districts
- Given the currently limited available supply, vaccine is being prioritized for specific indications

# Current Vaccine Priorities

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- Postexposure Prophylaxis (PEP)
  - For high-risk exposure to a confirmed monkeypox case
  - Most beneficial when within 4 days of exposure but some may benefit up to 14 days following exposure
  - If given between 4–14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease.
- Expanded Postexposure Prophylaxis (PEP++)
  - For people with certain risk factors that might make them likely to have had high-risk exposure to monkeypox
  - Used for response to outbreaks in areas where spread is occurring

# Vaccine for Pre-exposure Prophylaxis (PreP)

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- Indicated for people with certain occupations that may place them at high risk for potential exposure such as laboratory staff working with monkeypox specimens
- Due to the limited vaccine supply, vaccine is being prioritized for PEP and PEP++ at this time
- Laboratorians should use appropriate BSL precautions when working with specimens sent for monkeypox evaluation
- Healthcare providers should use standard and recommended isolation precautions when caring for patients with suspected or confirmed monkeypox

# DPH Vaccine Efforts

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- Coordinating with epidemiology and public health districts to ensure that PEP is offered to the eligible individuals
- Coordinating with public health districts to offer PEP++ for populations that may have more likelihood to have exposure to monkeypox cases
- Identifying opportunities to vaccinate at risk individuals with HIV and immunocompromising conditions
- Respond to changes in outbreak epidemiology that may require re-evaluating vaccination priorities in the context of the currently limited supply of vaccine



# Potential FDA Dose Sparing Strategy

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- On August 4, FDA announced it was exploring the feasibility of a Jynneos dose sparing strategy
- The potential dose sparing strategy would change the dose and route of administration for the vaccine and is projected to quintuple vaccine supply
- FDA is evaluating safety and efficacy data to determine if this strategy should be implemented
- The decision is currently pending though we expect an announcement is imminent

# CPT Codes

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The American Medical Association (AMA) has released coding guidance for laboratory testing and vaccine administration (available immediately)

- Laboratory test code 87593: Infectious agent detection by nucleic acid (DNA or RNA); orthopoxvirus (eg, monkeypox virus, cowpox virus, vaccinia virus), amplified probe technique, each
- Vaccine code 90611: Smallpox and monkeypox vaccine, attenuated vaccinia virus, live, non-replicating, preservative free, 0.5 mL dosage, suspension, for subcutaneous use

# Questions

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For more information, please contact:

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