

# Maine CDC Clinician Update: Monkeypox Vaccines and Therapeutics

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STATE OF MAINE

Department of

Health and Human Services

*September 13, 2022*

# Next webinar: Tuesday, October 11, at 12pm

## Maine CDC Clinician Update: COVID-19 and Monkeypox

*Please join us to learn more about COVID-19 in Maine and current vaccines and therapies  
(2<sup>nd</sup> Tuesday of the month from 12–1pm)*

<https://mainestate.zoom.us/j/83384535429>

Meeting ID: 833 8453 5429

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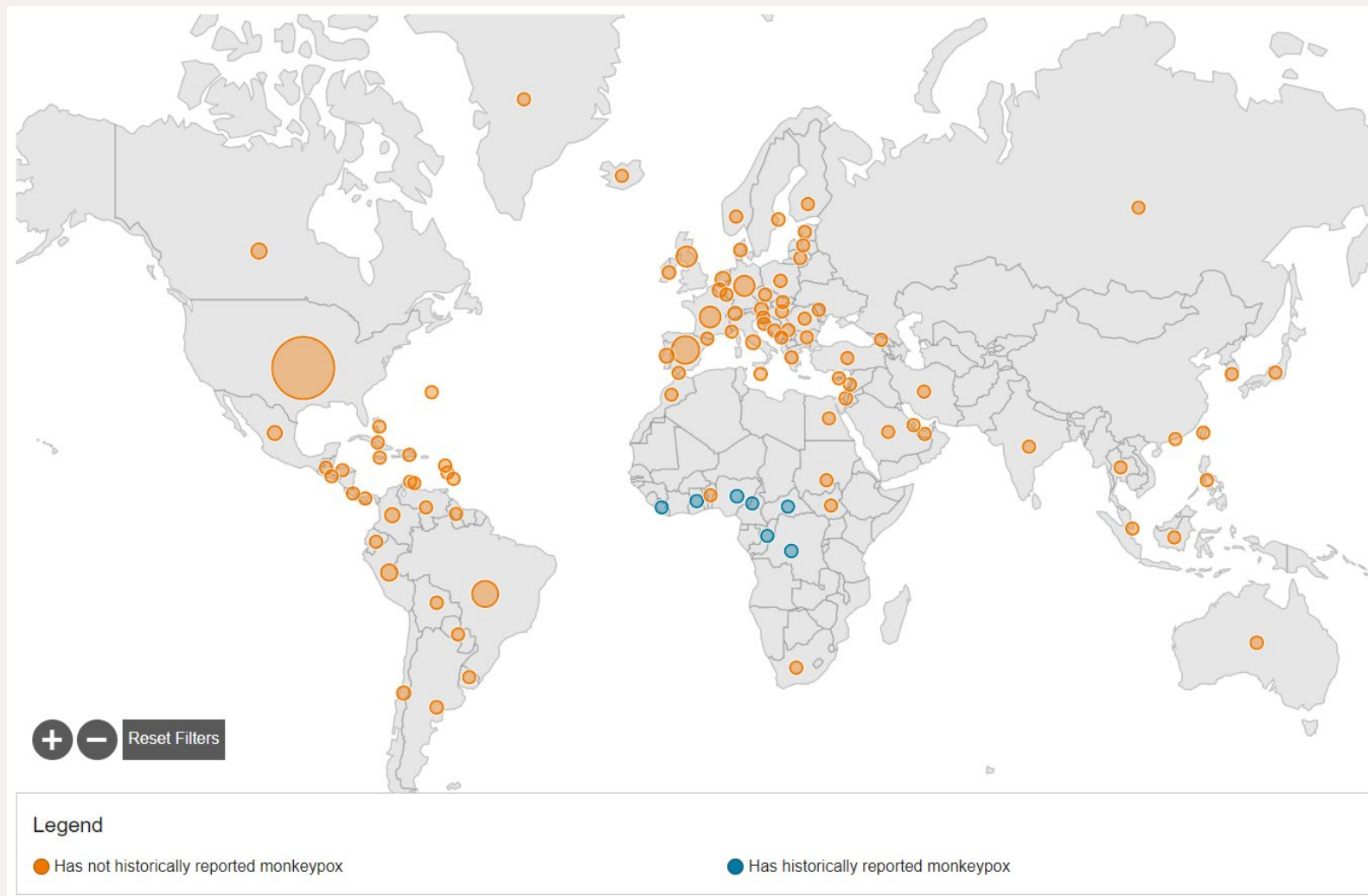
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- +1 312 626 6799 US (Chicago)
- +1 646 876 9923 US (New York)
- +1 669 900 6833 US (San Jose)
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- Meeting ID: 833 8453 5429

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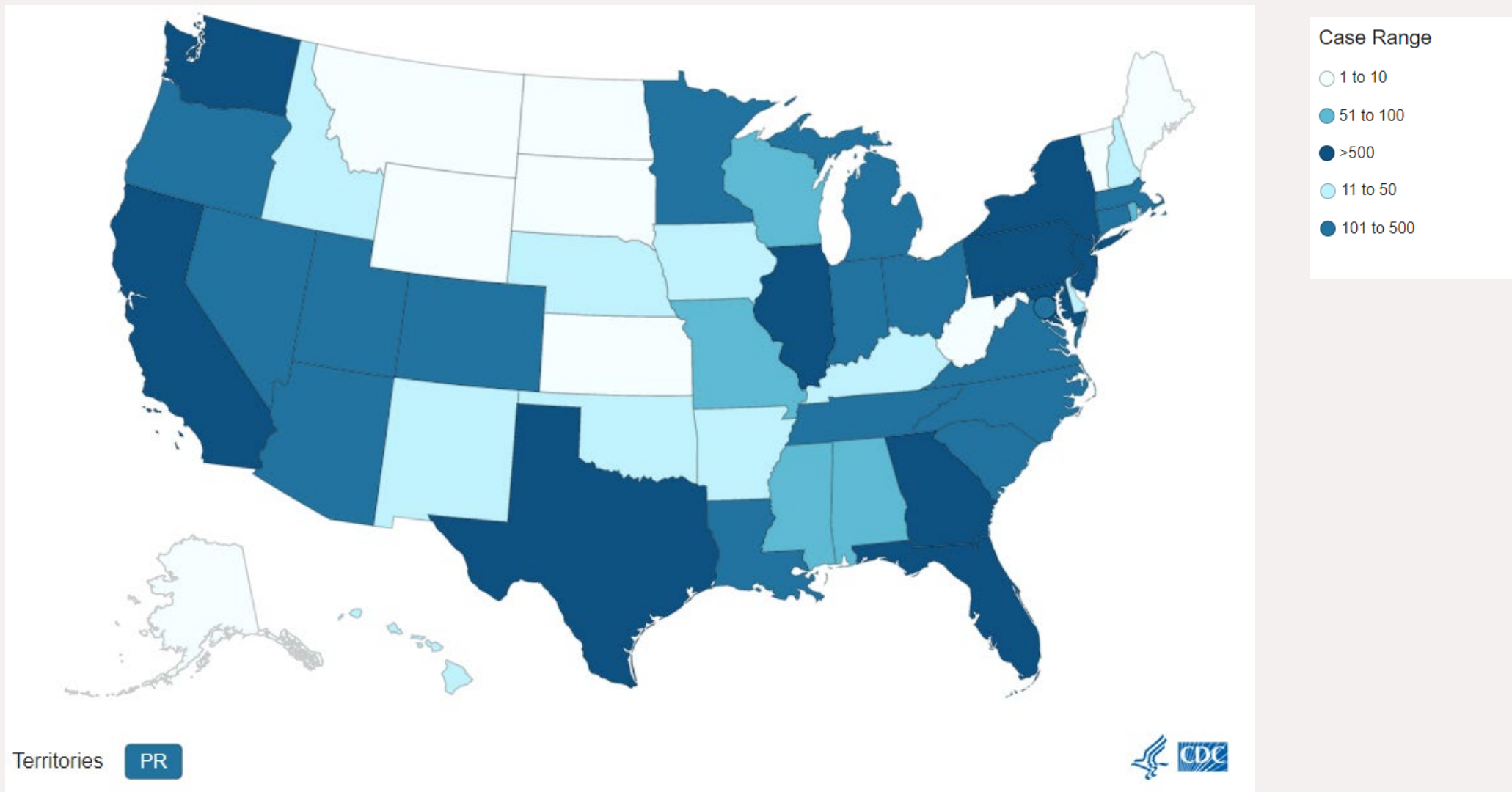
# MONKEYPOX

***Global Case Count: 57,995 (Sept 12, 2022)***



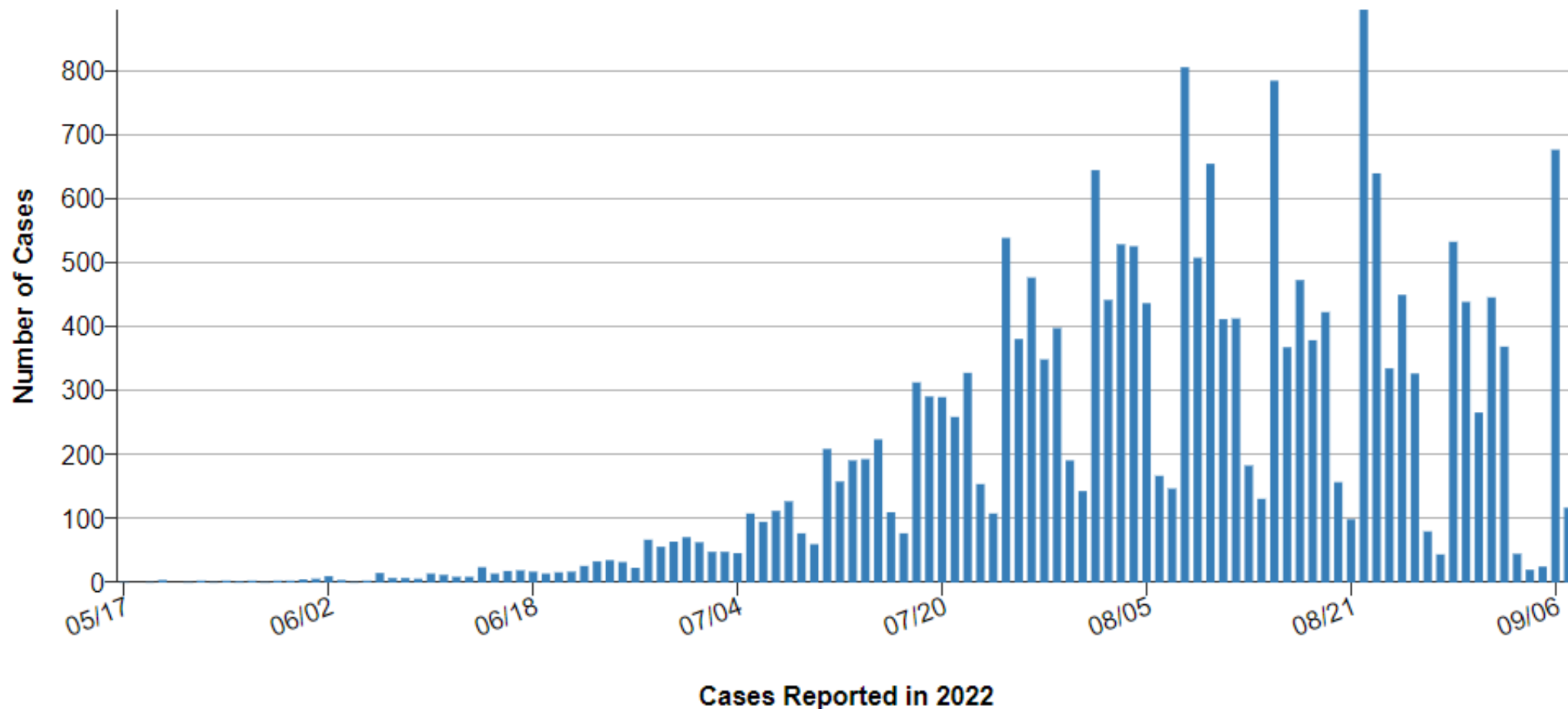
# MONKEYPOX

Total confirmed monkeypox/orthopoxvirus cases: **21,985** (Sept 12, 2022, at 5pm)



# MONKEYPOX

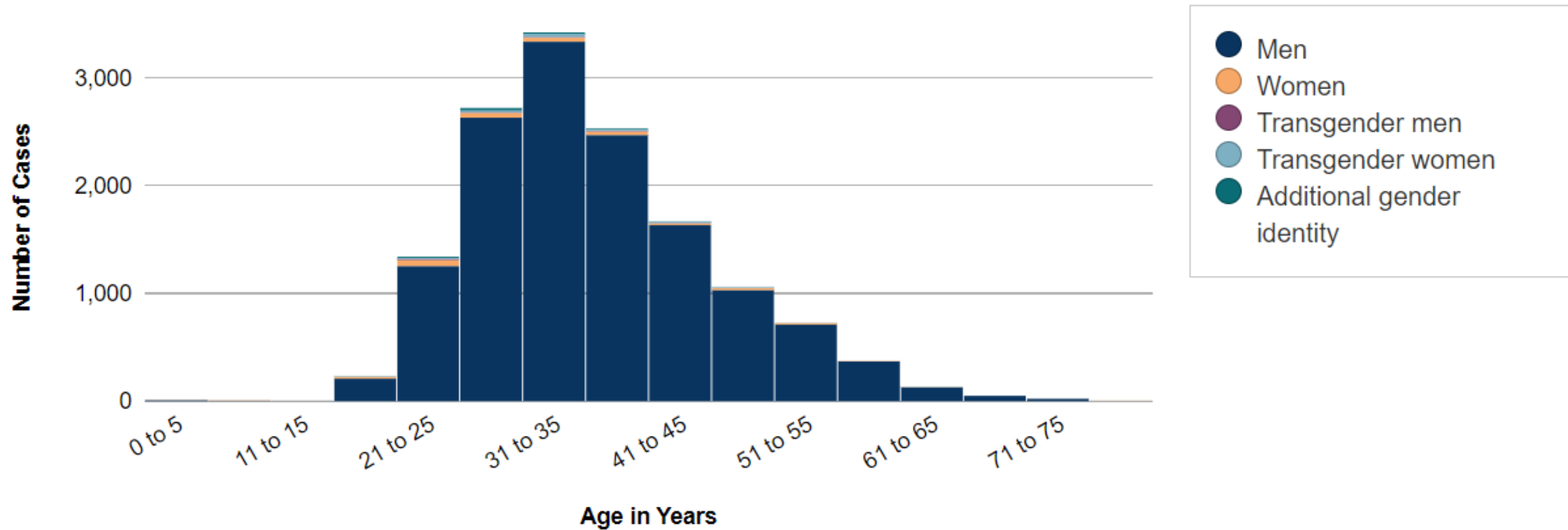
## U.S. Monkeypox Case Trends Reported to CDC



# MONKEYPOX

Data as of 8 Sep 2022 2:00 PM EDT

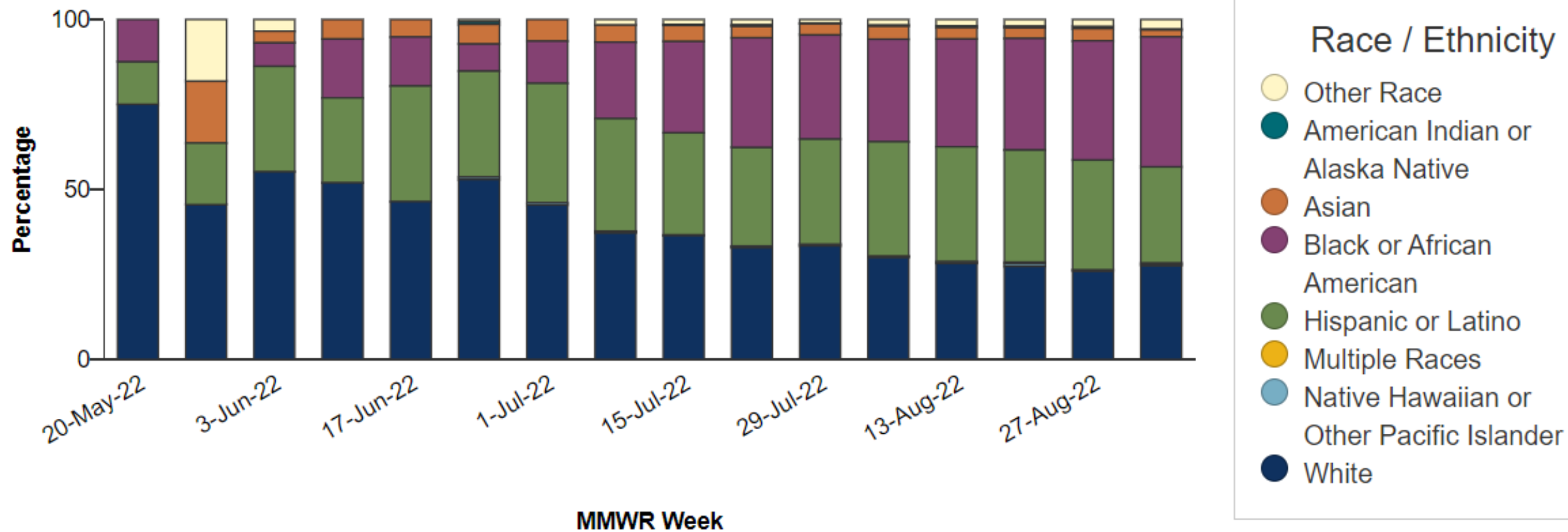
## Monkeypox cases reported to CDC: Age and Gender



# MONKEYPOX

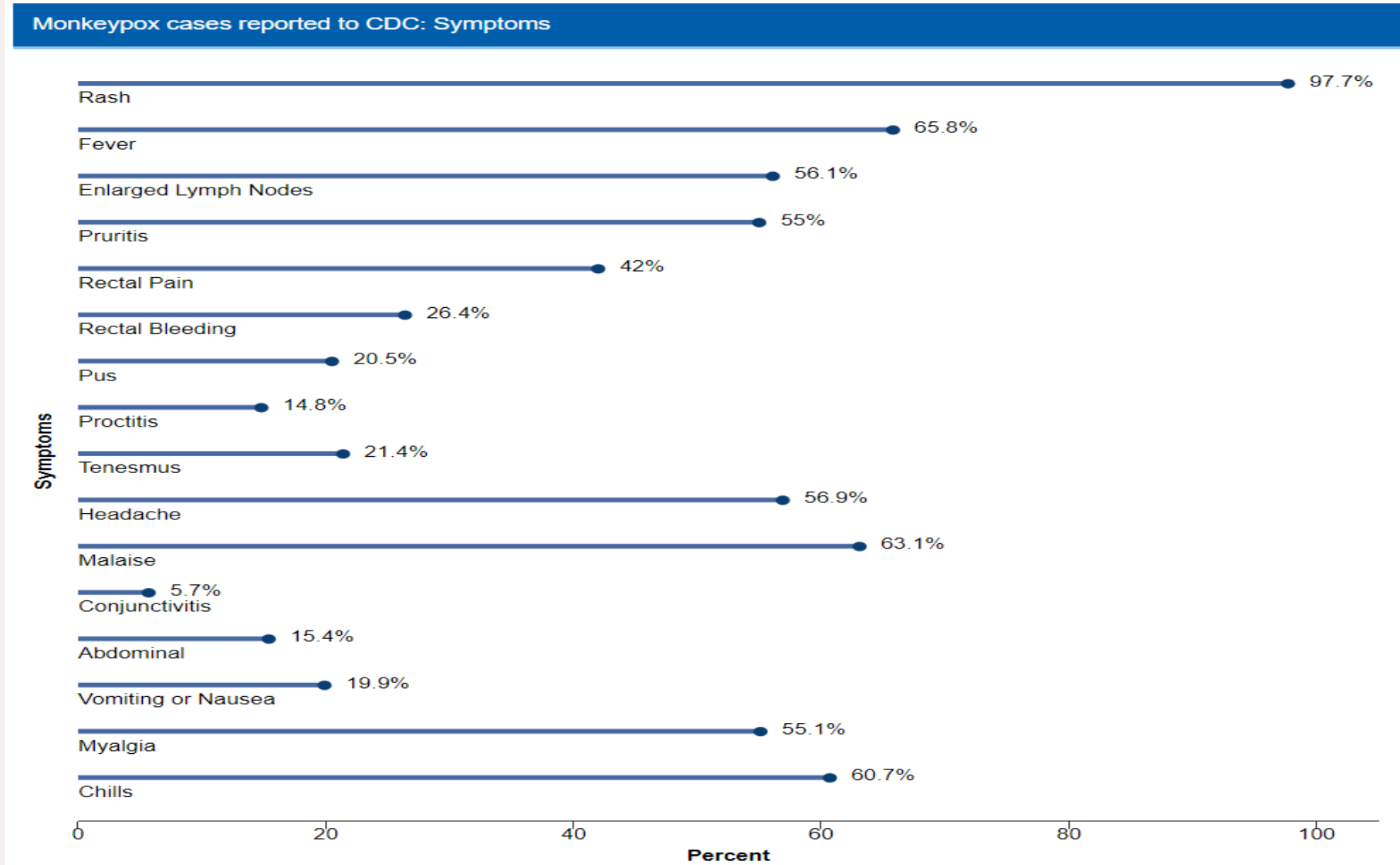
Data as of 8 Sep 2022 2:00 PM EDT

## Monkeypox cases reported to CDC: Race/Ethnicity by Week



# MONKEYPOX

Data as of 8 Sep 2022 2:00 PM EDT





# Maine Case Counts – 10 cases

Confirmed and Probable Monkeypox Cases in Maine (Updated 9/7/2022)	
County	Number of Confirmed and Probable Cases*
Androscoggin	1
Aroostook	2
Cumberland	2
Hancock	1
Sagadahoc	1
York	3
<b>Total</b>	<b>10</b>

\*Cases may be reassigned to other states upon investigation.

Maine CDC currently updates this case count as information becomes available. The schedule for updates may change as cases occur.

# Vaccine Eligibility

- Currently, the group eligible for vaccination for monkeypox in Maine are those individuals of all ages who meet at least one of the criteria below:
  - Gay, bisexual, or other men who have sex with men
  - Transgender, gender non-conforming, or non-binary individuals who have sex with men
  - Individuals exposed to someone with monkeypox in the past 14 days who were notified of the exposure by a:
    - public health agency **OR**
    - person with monkeypox

# Vaccine Allocation and Eligibility

## Monkeypox Vaccine Locations in Maine

County	Healthcare Provider	Address	Phone Number to Schedule
Androscoggin	Maine Family Planning	179 Lisbon St. Lewiston, ME 04240	(207) 922-3222
Cumberland	City of Portland STD Clinic	39 Forest Ave. Portland, ME 04101	(207) 756-8067
Cumberland	Gilman Street Clinic	48 Gilman St. Portland, ME 04102	(207) 661-4400
Cumberland	Greater Portland Health	100 Brickhill Ave. Suite 301 South Portland, ME 04106	(207) 874-2141
Kennebec	Maine Family Planning	43 Gabriel Dr. Augusta, ME 04330	(207) 922-3222
Penobscot	Maine Family Planning	68 Mount Hope Ave. Bangor, ME 04401	(207) 922-3222
York	Local Roots Health Care	12 Depot St. Kennebunk, ME 04043	(207) 569-2021 <a href="#">Schedule your appointment here</a>
York	York County EMA's Sanford Vaccine Clinic	1364 Main Street, Suite 7, Sanford, ME 04073 (at Shaw's Plaza)	Walk-in appointments available Tuesdays and Thursdays 1 pm to 6 pm AND Saturdays 10am to 3:30 pm

# Monkeypox Vaccine Distribution

- Vaccine Distribution as of 9/7/22:
  - 1,215 immunizations given
  - 1,958 doses on hand (390 complete vials)

# Monkeypox Treatment

- Maine CDC is sharing clinical information with healthcare providers via health advisories, clinician webinars, and the Maine CDC website, including:

- Recognition
- Testing
- Reporting
- Vaccination
- Treatment
- Infection control
- Patient resources



# Monkeypox Treatment

- Antivirals, like tecovirimat (TPOXX), are recommended for people who are more likely to get severely ill. This includes:
  - People who are hospitalized for severe monkeypox symptoms
  - People who have a weakened immune system
  - People with certain skin conditions
  - People who are pregnant or breastfeeding
  - People with certain complications
- A positive test is **NOT** needed prior to initiating treatment
- Maine is working with various provider groups and pharmacies across the state to make TPOXX available.

# Tecovirimat (TPOXX) Locations

- Tecovirimat (TPOXX) is available in 35 locations in the State, including hospitals, walk-in clinics, urgent care clinics, and pharmacies
- [Locations](#) include Androscoggin, Aroostook, Cumberland, Hancock, Kennebec, Oxford, Penobscot, and York counties
  - Northern Light Health Virtual Walk-In Care is available in all counties
- Any healthcare provider can prescribe TPOXX to outpatients, after completion of regulatory paperwork, to fill at certain pharmacies

# Medical Countermeasures Stockpiled for Orthopoxviruses

## ■ Vaccines

- JYNNEOS
- ACAM2000

## ■ Treatment

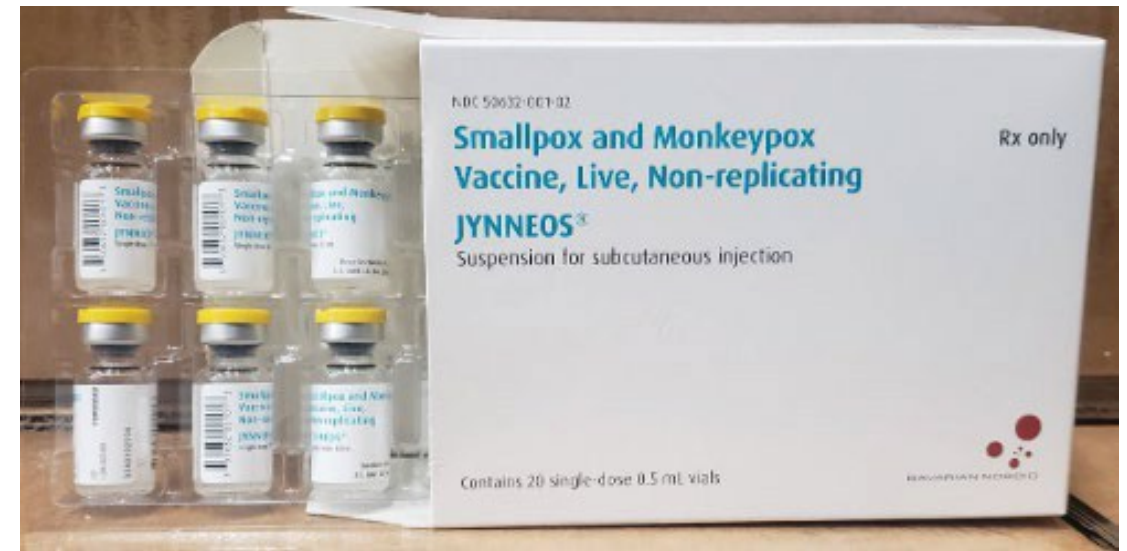
- Tecovirimat
- Vaccinia Immune Globulin Intravenous (VIGIV)
- Cidofovir



# JYNNEOS vaccine

- Vaccination with JYNNEOS **can be considered** for people who are at high risk for infection to prevent monkeypox disease
- Third-generation smallpox vaccine based on a live attenuated **non-replicating** orthopoxvirus, Modified Vaccinia Ankara (MVA)
- Licensed for prevention of smallpox and monkeypox disease
- Distributed to jurisdictions from the Strategic National Stockpile
- Global supply is currently limited
- Mild side effect profile compared with ACAM2000 vaccine

<https://www.cdc.gov/poxvirus/monkeypox/considerations-for-monkeypox-vaccination/jynneos-vaccine.html>



# Vaccination Strategies

Strategy	Definition
Post-Exposure Prophylaxis ( <b>PEP</b> )	Vaccination <b>after known</b> exposure to monkeypox
Expanded Post-Exposure Prophylaxis ( <b>PEP++</b> )	Vaccination <b>after known or presumed</b> exposure to monkeypox
Pre-Exposure Prophylaxis ( <b>PrEP</b> )	Vaccination <b>before</b> exposure to monkeypox

# CDC Interim Guidance

## Interim Clinical Considerations for Use of JYNNEOS and ACAM2000 Vaccines during the 2022 U.S. Monkeypox Outbreak

Updated August 9, 2022 [Print](#)

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# JYNNEOS vaccine

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# Monkeypox Vaccine (JYNNEOS)

- JYNNEOS is the only FDA-licensed vaccine in the US to prevent monkeypox disease in individuals 18 years of age and older
  - Also licensed to prevent smallpox disease in this age group
  - Requires two doses (days 1 and 28)
- Non-replicating viral vectored vaccine using Modified Vaccinia Ankara (MVA-BN) originally developed as alternative to ACAM2000 (live replicating vaccinia virus-based smallpox vaccine)
  - For use in the event of a bioterrorist attack in immunocompromised individuals in whom such a live replicating virus vaccine was relatively or absolutely contraindicated

# Intradermal Dosing Regimen

- Early on during its development in the 1970's, MVA was given intradermally in Germany to thousands of people
- Intradermal MVA has also sometimes been given as a boost in combination with other vaccines; redness at inoculation site noted
- Clinical trial conducted in accordance with GCP by NIAID indicates 1/5 of the dose (0.1 mL) given intradermally (ID) on the same schedule (day 1 and 28) produces similar efficacy to subcutaneous (SC) with more local redness and itching, less local pain
  - Frey SE et al, Vaccine 2015; 33: 5225-5234

# Immunogenicity

Assay	SC peak titer	ID peak titer	Difference	97.5% CI
SLU PRNT	8.37	8.36	0.005	0.43, 0.44
BN PRNT	5.63	5.90	-0.27	-0.77, 0.23
SLU ELISA	9.66	9.52	0.14	-0.21, 0.49
BN ELISA	9.59	9.57	0.02	-0.31, 0.35

# Reactogenicity

Reactogenicity event	SC (%) N=166	ID (%) N=190
Feeling Tired	49.7	<b>51.3</b>
Muscle Aches	41.3	30.4
Headache	43.1	41.4
Nausea	21.6	23.0
Change in Appetite	15.0	20.4
Chills	12.6	14.7
Joint Pain	9.0	17.8
Pain at injection site	<b>91.0</b>	<b>65.4</b>
Erythema at injection site	<b>81.4</b>	<b>99.5</b>
Induration at injection site	<b>69.5</b>	<b>99.5</b>
Itchiness	48.5	<b>89.0</b>
Underarm pain	18.0	20.9
Underarm swelling	6.0	10.5



# Summary

- 1/5 of the dose (0.1 mL) given ID on the same schedule produces similar efficacy to SC, albeit with more local redness
- Could facilitate vaccination of entire current target population and allow for additional supply in the event of further spread
- Information on management issues
  - Education on administration by ID route
  - Use of single dose vial to draw up multiple doses within a few hours
  - Management of side effects

# Vaccination Schedule

JYNNEOS vaccine regimen	Route of administration	Injection volume	Recommended number of doses	Recommended interval between 1st and 2nd dose
<b>Alternative regimen</b>				
People age $\geq 18$ years	ID	0.1 mL	2	28 days
<b>Standard regimen</b>				
<u>People age &lt;18 years</u>	Subcut	0.5 mL	2	28 days
People of any age who have a history of developing keloid scars	Subcut	0.5 mL	2	28 days

# Interchangeability

- A person aged 18 years or older who received one JYNNEOS vaccine dose with the standard (subcutaneous) regimen may receive a second dose with the alternative (intradermal) regimen to complete the vaccination series.
- For example, a person who received only one dose of the standard regimen before August 9 may receive one dose with the alternative regimen to complete the series.
- Also, a person whose 18<sup>th</sup> birthday occurs between their first and second dose may complete the series with the alternative regimen.

# Duration of Immunity and Dosing Intervals

- Peak immunity is expected 14 days after the second dose
- Duration of immunity after two doses of JYNNEOS is unknown
- *Recommended interval: 28 days (or up to 35 days)*
  - If the second dose is not administered during the recommended interval, it should be administered as soon as possible.
  - There is no need to restart or add doses to the series if there is an extended interval between doses.
- *Minimum interval: 24 days*
  - 4-day grace period applies

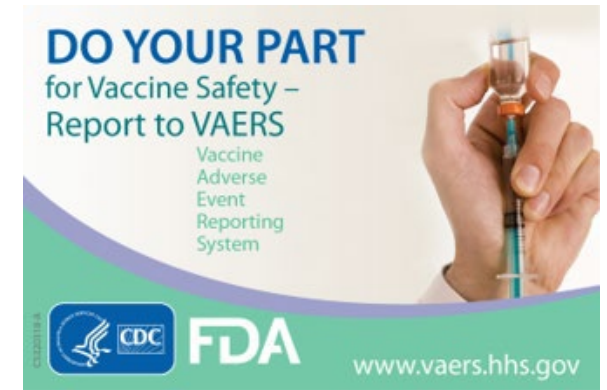
# Safe Injection Practices

- Every year, unsafe injection practices by U.S. healthcare providers—like syringe reuse and misuse of medications vials—can cause outbreaks.
- It is the responsibility of every provider who prepares and administers injections, or supervises those that prepare and administer injections, to make sure that patients receive the correct medication and are not exposed to life-threatening infections.
- Providers should adhere to Standard Precautions and the principles of Safe Injection Practices, including the use of a sterile, single-use, disposable needle and syringe for each injection given, and prevention of contamination of injection equipment and medication.



# Adverse Event Reporting

- Vaccination providers who are administering JYNNEOS under the EUA are required to report the following adverse events that occur after JYNNEOS vaccination:
  - Vaccine administration errors
  - Serious adverse events
  - Cases of cardiac events, including myocarditis and pericarditis
  - Cases of thromboembolic events and neurovascular events
- Information on how to submit a report to the Vaccine Adverse Event Reporting System (VAERS) is available at <https://vaers.hhs.gov> or by calling 1-800-822-7967.



# MONKEYPOX

## **Treatment Considerations for Monkeypox**

- Many individuals infected with monkeypox virus have a mild, self-limiting disease course in the absence of specific therapy
- The prognosis for monkeypox depends on multiple factors such as previous vaccination status, initial health status, and concurrent illnesses or comorbidities

# Treatment Considerations for Monkeypox

Patients who should be considered for treatment following consultation with CDC might include:

- People with severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, or other conditions requiring hospitalization)
- People who may be at high risk of severe disease:
  - People with immunocompromise (e.g., human immunodeficiency virus/acquired immune deficiency syndrome infection, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)<sup>1</sup>
  - Pediatric populations, particularly patients younger than 8 years of age<sup>2</sup>
  - People with a history or presence of atopic dermatitis, persons with other active exfoliative skin conditions (e.g., eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease [keratosis follicularis])
  - Pregnant or breastfeeding women<sup>3</sup>
  - People with one or more complications (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)<sup>4</sup>
- People with monkeypox virus aberrant infections that include accidental implantation in eyes, mouth, or other anatomical areas where monkeypox virus infection might constitute a special hazard (e.g., the genitals or anus)



# MONKEYPOX

## **Clinical Considerations for Treatment and Prophylaxis in People with HIV**

- People with advanced HIV or who are not virologically suppressed with antiretroviral therapy can be at increased risk of severe disease related to monkeypox virus infection
- Post-exposure prophylaxis and antiviral treatments are available for persons exposed to monkeypox or with monkeypox virus infection
- Antiviral treatments have few interactions with antiretroviral therapy
- Vaccination with JYNNEOS is considered safe for people with HIV

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>

# MONKEYPOX

## Tecovirimat

- Tecovirimat (TPOXX or ST-246) is an antiviral medication developed for smallpox and is available from the Strategic National Stockpile
- **Oral capsule and IV formulations** approved by FDA for the treatment of human smallpox disease in adults and pediatric patients under Animal Rule
  - Efficacy based on studies of non-human primates infected with monkeypox and rabbits infected with rabbitpox
  - Safety evaluation in 359 healthy adults (18-79 years)
- Tecovirimat use for unapproved indications (i.e., uses not covered by the FDA-approved labeling) requires an alternative regulatory mechanism (e.g., Expanded Access Investigational New Drug (EA-IND) or Emergency Use Authorization)



# MONKEYPOX

## Dosing: oral

<13 kg: Safety and efficacy not established

13 kg to <25 kg: 200 mg PO BID for 14 days

25 kg to <40 kg: 400 mg PO BID for 14 days

40 kg to <120 kg: **600 mg PO BID for 14 days**

≥120 kg: 600 mg PO TID for 14 days

**Take within 30 minutes after eating a full meal**

# MONKEYPOX

## Dosing: IV

Use for patients weighing <13 kg OR if unable to take PO

If IV treatment is necessary, conversion from IV to oral is recommended as soon as oral treatment can be tolerated

In patients receiving an IV infusion, give the first oral dose at the next scheduled IV dosing

<3 kg: Safety and efficacy not established

3 kg to <35 kg: 6 mg/kg IV over 6 hr q12hr for 14 days; patients weighing  $\geq 13$  kg should switch to capsules to complete 14-day treatment as soon as oral therapy can be tolerated

35 kg to <120 kg: **200 mg IV over 6 hr q12hr for 14 days**

$\geq 120$  kg: 300 mg IV over 6 hr q12hr for 14 days

# MONKEYPOX

## Other Treatment Options

- VIGIV is licensed by FDA for the treatment of complications due to vaccinia vaccination
- Cidofovir (also known as Vistide) is an antiviral medication that is approved by the FDA for the treatment of cytomegalovirus (CMV) retinitis in patients with Acquired Immunodeficiency Syndrome (AIDS)
- CDC-held Expanded Access Investigational New Drug Protocol allows use of VIGIV and Cidofovir for Non-Variola Orthopoxvirus Infection (e.g., monkeypox)



# MONKEYPOX

## **Tecovirimat EA-IND (also known as compassionate use)**

- CDC holds an EA-IND to provide an umbrella regulatory coverage
  - Allow use of tecovirimat for non-variola orthopoxvirus infection (e.g., monkeypox, complications from replication-competent vaccinia virus vaccine)
  - CDC IRB serves as central IRB for review and approval
    - ❖ Non-research determination and that federal-wide assurance requirements do not apply
    - ❖ CDC IRB will provide a reliance agreement for facilities that elect to rely on CDC IRB approval
  - Clinicians and facilities do not need to request and obtain their own INDs
  - Provides liability coverage under the Public Readiness and Emergency Preparedness (PREP) Act for healthcare providers prescribing, administering, or dispensing the drug and for patients to seek compensation if they are seriously injured by the medication via the Countermeasure Injury Compensation Program

# MONKEYPOX

## Revised Tecovirimat EA-IND Protocol

### Required

- Obtain [Informed Consent](#) prior to treatment
- Conduct a baseline assessment and complete the [Patient Intake Form](#)
- Document progress once during and once after treatment on the [Clinical Outcome Form](#)
- Report life-threatening or serious adverse events associated with tecovirimat by completing a [PDF MedWatch Form](#) and returning it to CDC
- [FDA Form 1572](#): One signed 1572 per facility

### Optional

- Photos of lesions
- Pharmacokinetic samples for testing
- Clinical laboratory parameters (hematology, chemistry, and urinalysis parameters)
- Lesion samples for resistance testing, if feasible, on new onset of lesions during and after completion of treatment
- [Patient Diary](#), if feasible, give the form for patient to complete and voluntarily return it directly to CDC

<https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>

## Summary of Revised Tecovirimat EA-IND Protocol

- Recently updated to make it easier for providing tecovirimat treatment
- Streamlined and substantially reduces the number of patient visits and required forms
  - All patient visits can be conducted via **telemedicine**
  - All laboratory testing is **optional**
  - Required safety reporting on **serious adverse events only**
  - No pre-registration is required for clinicians and healthcare facilities to begin providing tecovirimat treatment
  - Forms required under the EA-IND can all be returned to CDC after treatment begins



# MONKEYPOX

## Revised Tecovirimat EA-IND Protocol – additional clarification

- Primary tecovirimat use under the IND remains for **treatment** of laboratory confirmed or suspected OPXV infection based on known exposure and compatible clinical symptoms
  - Post-exposure prophylaxis (PEP) on **individual case-by-case basis** for certain individuals for whom an alternative to PEP vaccination may be clinically necessary
    - Added in anticipation of potential PEP considerations for certain individuals while keeping the IND protocol evergreen
    - Any PEP use must be in clinical consultation with CDC
  - Refer to CDC's Interim Clinical Considerations for the treatment of monkeypox for most up to date guidance regarding patients who should be considered for treatment
  - No lower weight cap for use of IV tecovirimat. Allowed use in neonates under the IND protocol
  - Includes explanation on IV administration over 6 hours and administration through syringe pumps
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>

# Modeling the Impact of Sexual Networks in the Transmission of Monkeypox virus Among Gay, Bisexual, and Other Men Who Have Sex With Men — United States, 2022

Weekly / September 2, 2022 / 71(35);1131-1135

- “Modeling of sexual infection transmission between men indicates that one-time partnerships, which account for 3% of daily sexual partnerships and 16% of daily sex acts, account for approximately 50% of daily Monkeypox virus (MPXV) transmission. A 40% reduction in one-time partnerships might delay the spread of monkeypox and reduce the percentage of persons infected by 20% to 31%.”
- “Reductions in one-time partnerships, already being reported by MSM, might significantly reduce MPXV transmission.”

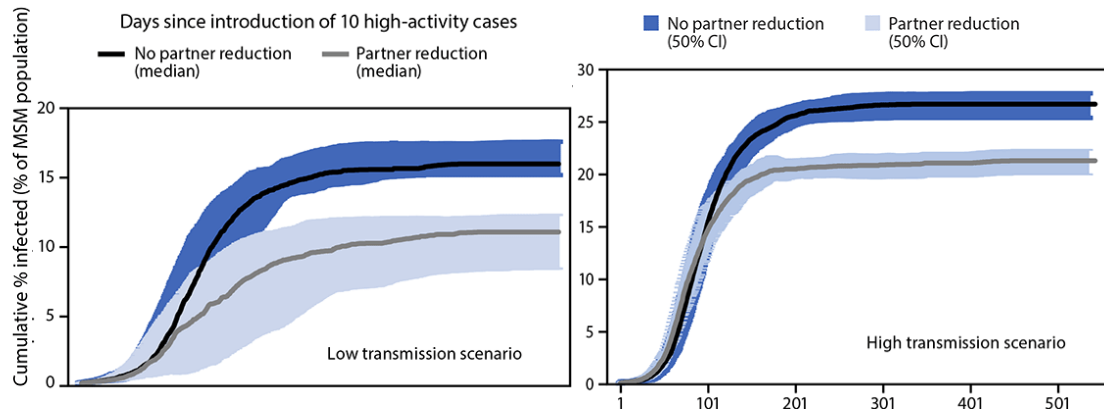


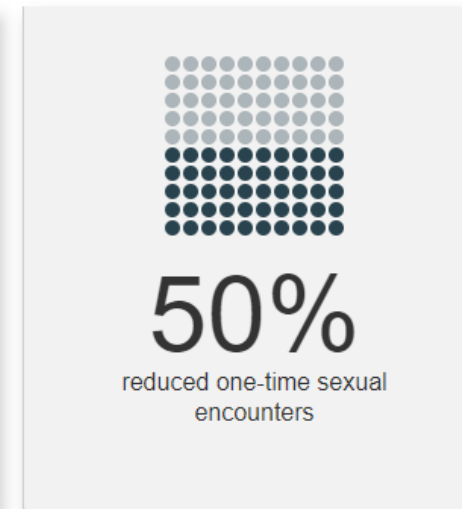
TABLE. Modeled mean number of partners, population size, and risk ratio for acquiring monkeypox among gay, bisexual, and other men who have sex with men, by level of sexual activity — United States, 2022\*

Sexual activity stratum <sup>†</sup>	Mean no. and types <sup>§</sup> of partners during time interval			% of population	RR (by transmission scenario)	
	Past yr	Past 3 wks			Lower	Higher
	All types	All types	One-time only			
1 (lowest)	1.8	0.8	0.0	19	0.6	0.5
2	1.8	0.8	0.0	19	0.7	0.5
3	4.0	0.9	0.1	19	0.9	0.9
4	4.0	1.0	0.2	19	1.0 <sup>¶</sup>	1.0 <sup>¶</sup>
5	14.7	1.5	0.7	19	1.8	2.3
6 (highest)	124.7	6.6	5.8	5	3.6	6.9

# Strategies Adopted by Gay, Bisexual, and Other Men Who Have Sex with Men to Prevent Monkeypox virus Transmission — United States, August 2022

Weekly / September 2, 2022 / 71(35);1126-1130

- “In a recent survey of gay, bisexual, and other men who have sex with men, approximately one half reported reducing their number of sex partners, one-time sexual encounters, and use of dating apps because of the monkeypox outbreak. Receipt of vaccine to protect against monkeypox varied by race, ethnicity, and geography.”
- “It is essential that public health programs continue to deliver tailored, respectful harm reduction messages that do not create stigma to diverse communities of men who have sex with men. Vaccine programs should prioritize efforts to maximize equitable access.”

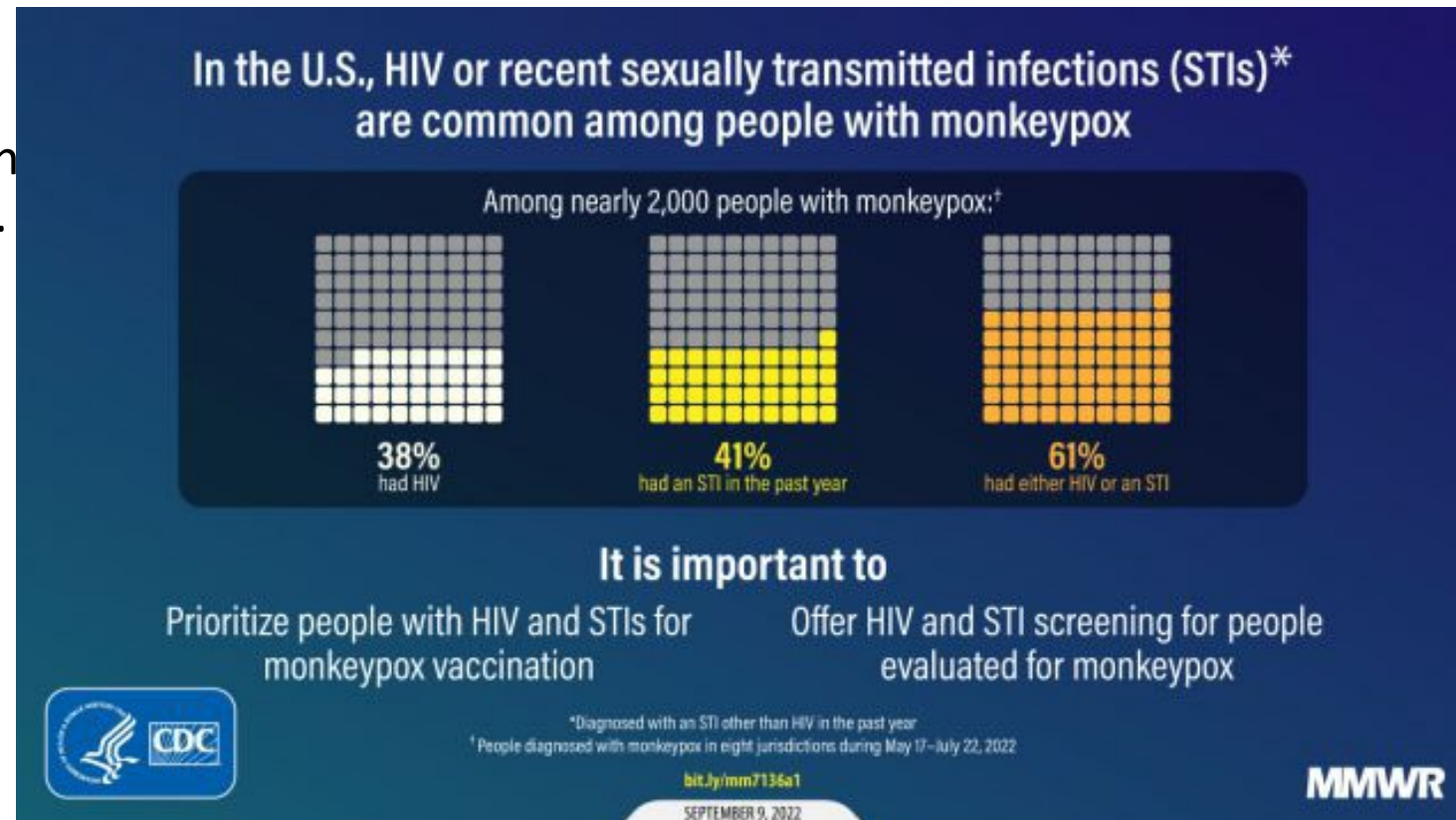


Gay, bisexual, and other men who have sex with men are taking steps to protect themselves and their partners from monkeypox.

# HIV and Sexually Transmitted Infections Among Persons with Monkeypox — Eight U.S. Jurisdictions, May 17–July 22, 2022

Weekly / September 9, 2022 / 71(36);1141–1147

- “Among 1,969 persons with monkeypox in eight U.S. jurisdictions, 38% had HIV infection, and 41% had an STI in the preceding year. Among persons with monkeypox, hospitalization was more common among persons with HIV infection than persons without HIV infection.”
- “It is important to leverage systems for delivering HIV and STI care and prevention and prioritize persons with HIV infection and STIs for vaccination. Screening for HIV and other STIs and other preventive care should be considered for persons evaluated for monkeypox, with HIV care and HIV preexposure prophylaxis offered to eligible persons.”



# Resources

## US CDC Resources

- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/infection-control-healthcare.html>
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/monitoring.html>
- <https://www.cdc.gov/poxvirus/monkeypox/transmission.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/world-map.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/us-map.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/mpx-trends.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/demographics.html>
- <https://www.cdc.gov/poxvirus/monkeypox/response/2022/2022-lab-test.html>
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html>
- <https://www.cdc.gov/poxvirus/monkeypox/interim-considerations/jynneos-vaccine.html>
- <https://www.cdc.gov/std/treatment-guidelines/default.htm>
- <https://www.cdc.gov/poxvirus/monkeypox/clinicians/people-with-HIV.html>

## Maine CDC Resources

- <https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/monkeypox.shtml>
- <https://www.maine.gov/dhhs/mecdc/infectious-disease/epi/zoonotic/monkeypox-providers.shtml>