Mpox Update: Clinical Management and Outbreaks

Clinician Outreach and Communication Activity (COCA) Call

Thursday, June 27, 2024

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- Instructions for how to earn continuing education will be provided at the end of the call.

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- Content will not include any discussion of the unlabeled use of a product or a product under investigational use with the exception of Dr. Megan Pennini who will discuss using Jynneos for populations who are currently covered under EAU but not on the approved label; and Dr. Yon Yu who will provide an update on the eligibility criteria for using tecovirimat for treating Mpox, which is an unapproved (investigational) use of an approved drug only available in the United States through the USG stockpile.
- CDC did not accept financial or in-kind support from ineligible companies for this continuing education.

Objectives

At the conclusion of today's session, the participant will be able to accomplish the following:

1. Discuss the epidemiology of clade II MPXV and U.S. clinical and vaccine guidance.
2. Describe the JYNNEOS vaccine commercialization.
3. Explain TPOXX EA-IND eligibility criteria for treating mpox.

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Today's Presenters

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- **Meghan Pennini, PhD**
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- **Yon Yu, PharmD**
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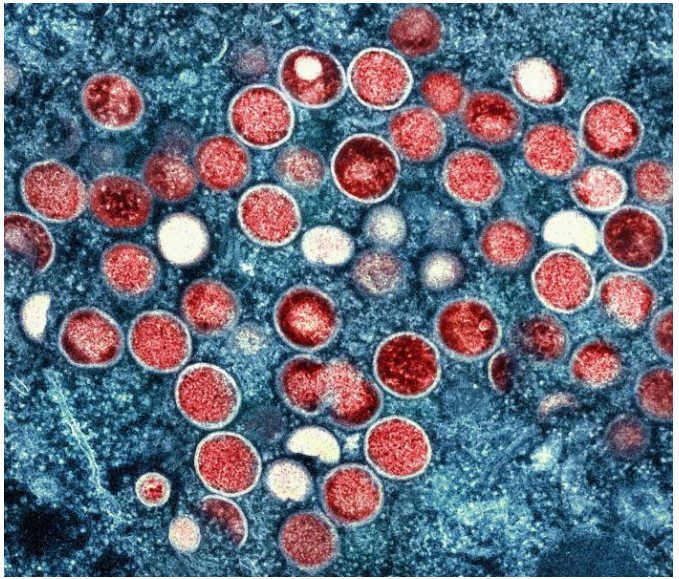
  Office of Readiness and Response
  Centers for Disease Control and Prevention

Epidemiology and Prevention of Monkeypox virus in the United States—An Update



Agam Rao, MD, FIDSA

Chief Medical Officer

Poxvirus and Rabies Branch

Centers for Disease Control and Prevention

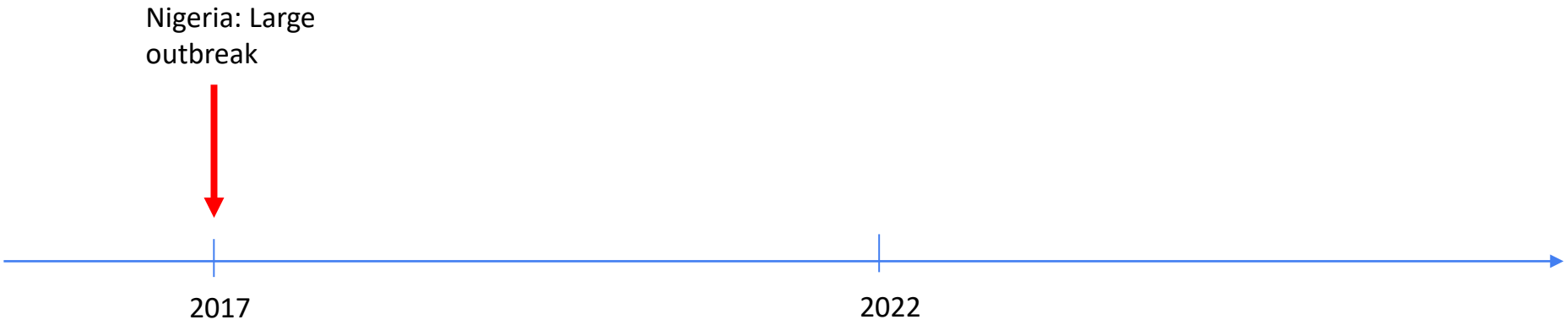
CDC COCA Call

June 27, 2024

Clade II MPXV: Countries historically known as endemic

Nigeria, Sierra Leone, Liberia, Cameroon, Cote D'Ivoire

Historical context: Global clade II Monkeypox virus (MPXV) outbreak



Historical context: Global clade II Monkeypox virus (MPXV) outbreak

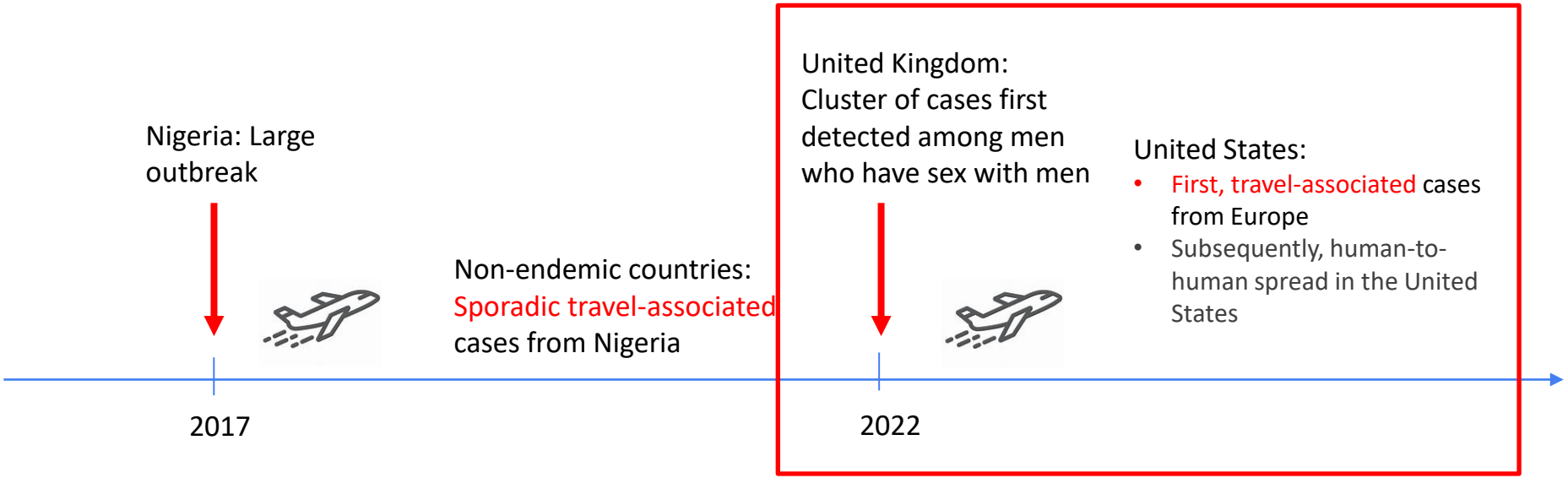
Nigeria: Large outbreak

Non-endemic countries: Sporadic travel-associated cases from Nigeria

2017

2022

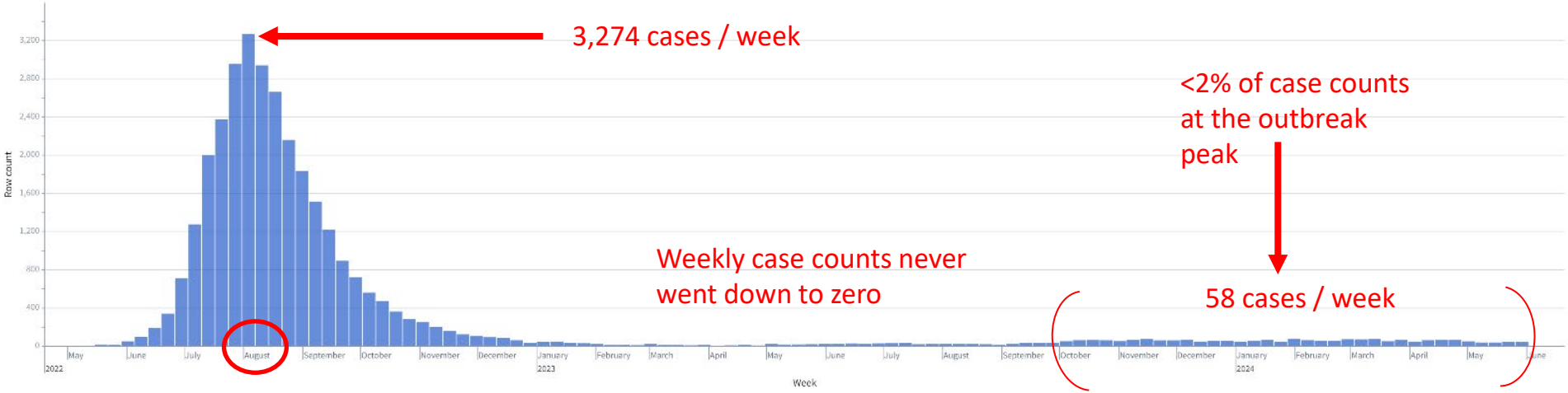
Historical context: Global clade II Monkeypox virus (MPXV) outbreak



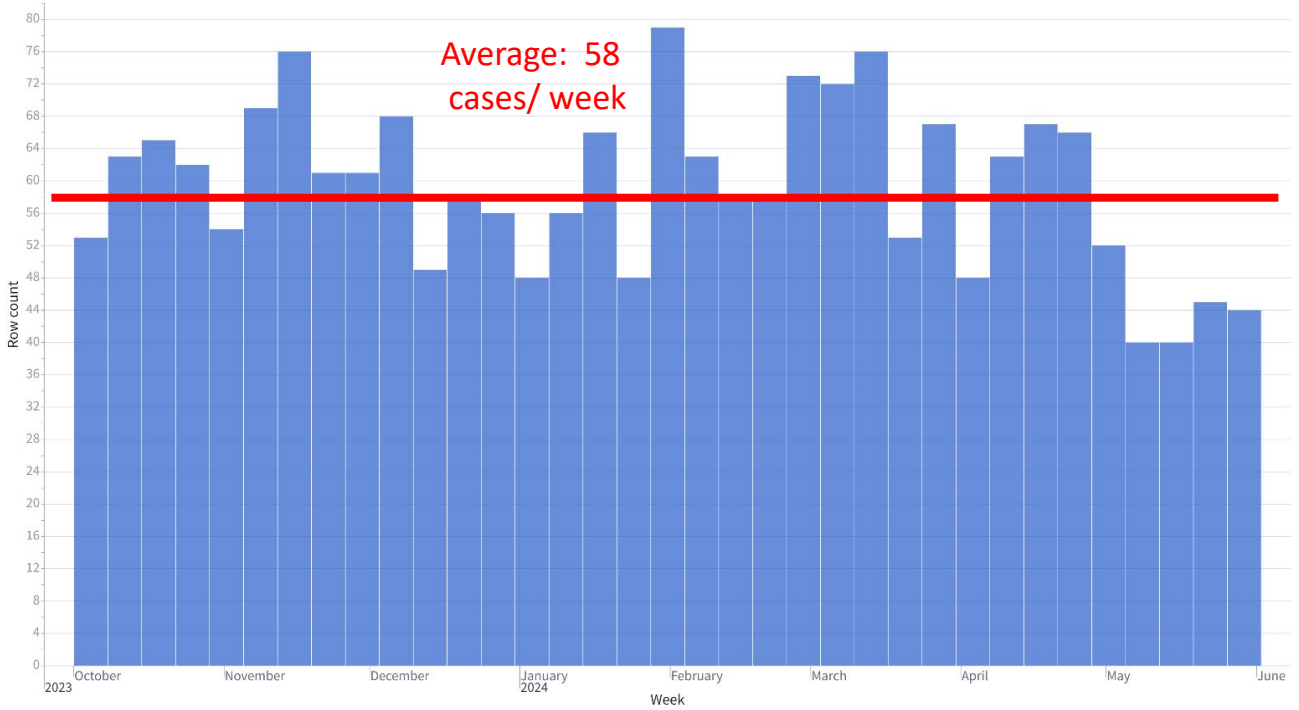
- Sex found to be an effective means of spread
- Men who have sex with men (MSM) most affected

What has happened since May 2022?

Mpox clade II epi-curve—United States, May 1, 2022-June 1, 2024, N= 33,088



U.S. Clade II cases steady during October 1, 2023-June 1, 2024, n= 2,077



- Asynchronous mpox clusters with a cluster in one jurisdiction one week and a cluster in a different jurisdiction the following week
- NYC is exception: Case counts have not fluctuated as much but have remained higher since October 2023; however, these higher case counts are still a fraction (1/20th) of NYC counts at the outbreak peak
- Despite NYC cases, national case counts steady since October

Features of mpox cases across the United States—October 2023–present

- Nationally, demographics unchanged*
- Regionally, demographics and reasons for cases may differ by jurisdiction
  - Low vaccine coverage, particularly in certain racial and ethnic groups?
  - Frequent behaviors associated with mpox transmission (e.g., increased number of sexual partners§)?
  - Other reasons?

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America | hivma hiv medicine association | OXFORD

Investigation of an Mpox Outbreak Affecting Many Vaccinated Persons in Chicago, Illinois—March 2023–June 2023

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*https://www.cdc.gov/mmwr/volumes/73/wr/mm7320a4.htm?s_cid=mm7320a4_w

§https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciae181/7639496?login=true

At this time, vaccine effectiveness is not waning

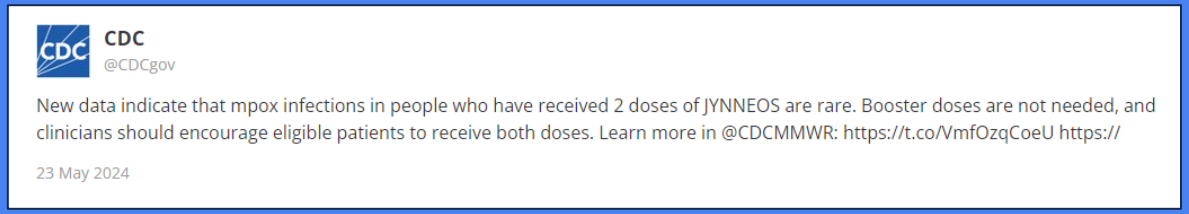
- Serologic studies have shown vaccine titers decrease a few months after vaccination
  - However, levels of circulating titers are not only marker of protection (e.g., cell-mediated immunity, innate immunity not measured)
  - Therefore, clinical significance of decreased titers unknown
- Real world data*§ about infections after 2 JYNNEOS doses has indicated breakthrough infections are rare
  - Occurred in <1% of people fully vaccinated
  - Associated with less severe infections when they occur
  - Occurred at disparate time intervals after vaccination

*https://www.cdc.gov/mmwr/volumes/73/wr/mm7320a3.htm?s_cid=mm7320a3_w
§Cases for which vaccination data reported to CDC

At this time, vaccine effectiveness is not waning

- Serologic studies have shown vaccine titers decrease a few months after

Booster doses not recommended for people vaccinated during this outbreak



  - Occurred at disparate time intervals after vaccination

*https://www.cdc.gov/mmwr/volumes/73/wr/mm7320a3.htm?s_cid=mm7320a3_w
§Cases for which vaccination data reported to CDC

At this time, vaccine recommendations for people impacted by the ongoing outbreak are unchanged

- Mpox vaccinations not recommended
  - People who have recovered from mpox
  - People who received the recommended 2 dose JYNNEOS series, regardless of how long ago
- Mpox vaccinations recommended
  - People with certain mpox risk factors* who have not been previously vaccinated with both doses and not previously recovered from mpox
  - People who received only one vaccine dose (and never had mpox), should receive the 2nd dose as soon as possible, regardless of the amount of time that has lapsed since the first dose; the series should not be restarted

*Populations with certain mpox risk factors described on next slide

Populations for whom mpox vaccine recommended

ACIP (as of October 2023) recommends vaccination with the 2-dose JYNNEOS vaccine series for persons aged 18 years and older at risk for mpox¶

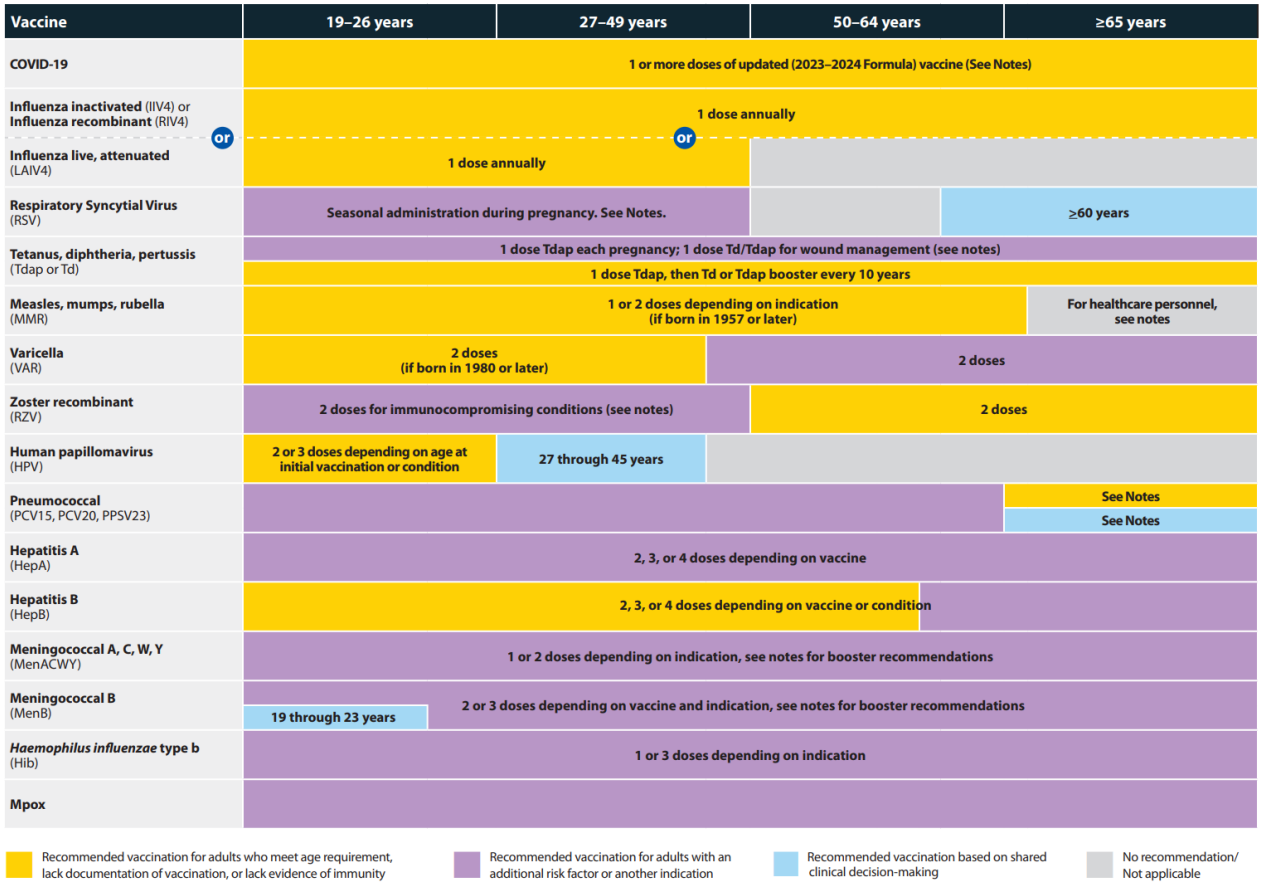
¶Persons at risk

- 1. Gay, bisexual, and other men who have sex with men, 2. transgender people or 3. nonbinary people who, in the past 6 months, have had one of the following
  - New diagnosis of ≥ 1 sexually transmitted disease
  - More than one sex partner
  - Sex at a commercial venue
  - Sex in association with a large public event in a geographic area where mpox transmission is occurring
- Sexual partners of persons with the risks described above
- Persons who anticipate experiencing any of the above

https://www.cdc.gov/poxvirus/mpox/vaccines/vaccine-recommendations.html

Mpox vaccine on routine immunization schedule

Table 1 Recommended Adult Immunization Schedule by Age Group, United States, 2024



Mpox vaccination

Special situations

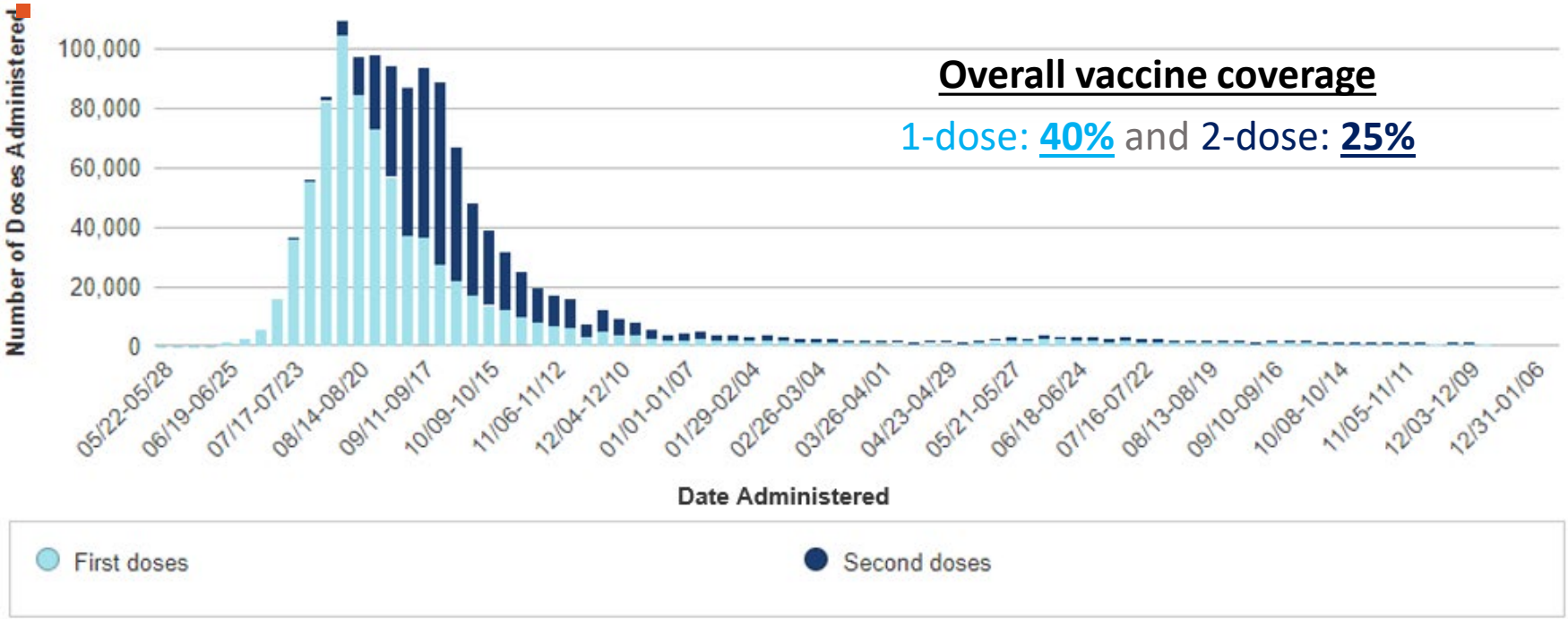
- **Any person at risk for Mpox infection:** 2-dose series, 28 days apart.

Risk factors for Mpox infection include:

- Persons who are gay, bisexual, and other MSM, transgender or nonbinary people who in the past 6 months have had:
  - A new diagnosis of at least 1 sexually transmitted disease
  - More than 1 sex partner
  - Sex at a commercial sex venue
  - Sex in association with a large public event in a geographic area where Mpox transmission is occurring
- Persons who are sexual partners of the persons described above
- Persons who anticipate experiencing any of the situations described above

www.cdc.gov/vaccines/schedules/downloads/adult/adult-combined-schedule.pdf

Vaccinations: U.S. JYNNEOS Administration Data, 2022-2024*



Overall vaccine coverage

1-dose: **40%** and 2-dose: **25%**

*Data reported to CDC between May 22, 2022 and January 9, 2024; however, few requests for JYNNEOS since then

Additional prevention strategies: Counseling patients

- Patients can speak with sex partners about any mpox signs and symptoms and be aware of any unexplained rashes or lesions on a partner’s body
- Avoid close or intimate contact if they or a sex partner become sick with mpox or experience mpox-like rash

Self-knowledge check

Which of the following is true regarding mpox in the United States?

A. Nationally, case counts are increasing exponentially
B. A booster dose of JYNNEOS is recommended for anyone who received both doses of the 2-dose vaccine series during 2022
C. People eligible to be vaccinated who have received only one JYNNEOS dose and have never had mpox should receive the 2nd JYNNEOS dose as soon as possible (i.e., complete the 2-dose series)
D. JYNNEOS vaccine is recommended for all men who have sex with men, including those in a monogamous relationship

Self-knowledge check

The correct answer is: C.

U.S. case counts have been stable since October 2023.

At this time, vaccine immunity is not waning and therefore, booster doses are not recommended.

People who received one dose of the vaccine should receive the 2nd dose as soon as possible (i.e., do not restart the series).

People in monogamous relationships do not have the sexual risk factors for which ACIP recommends vaccination.

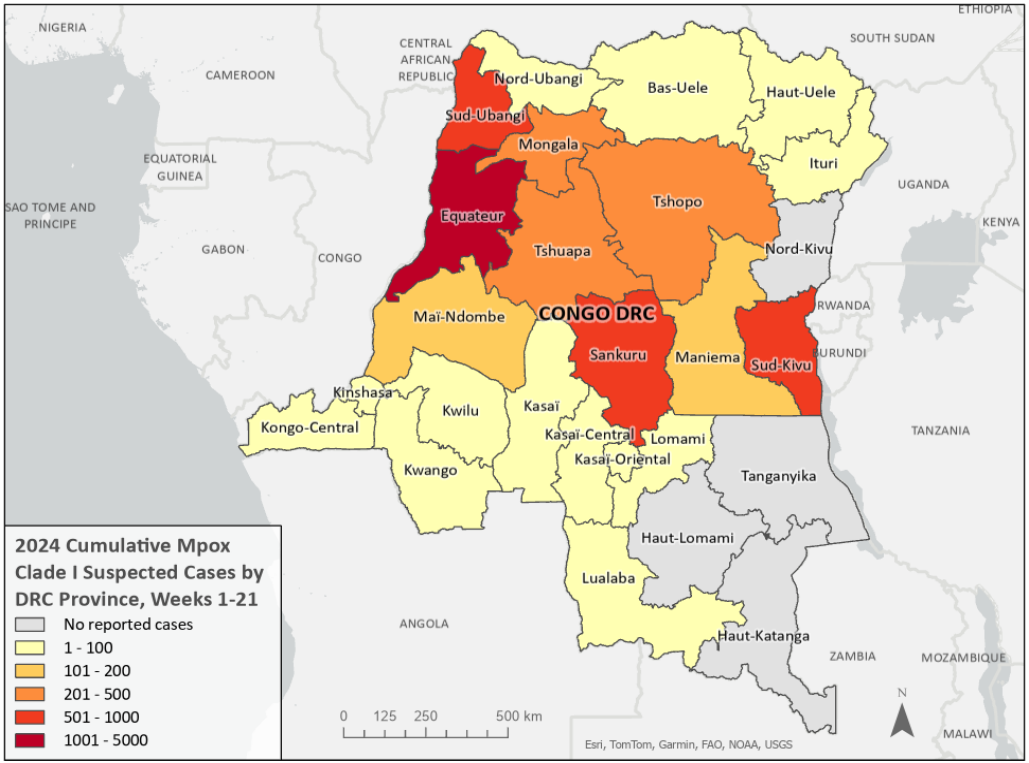
Clade I MPXV

At this time, NO clade I cases identified outside of countries known to be endemic for this MPXV clade

Clade I MPXV: Countries historically known as endemic

Democratic Republic of Congo, Central African Republic, Republic of Congo, Cameroon, Gabon

Geographic distribution of suspected cases* of clade I mpox, DRC, Epi weeks 1-21, 2024



Data source: Ministry of Health, Democratic Republic of Congo – Weekly Mpox Report

- Identified in parts of the country without previous cases
- Some cases associated with sex; however, both genders involved
- Children most affected

*some suspected cases may be diseases other than mpox

Cumulative suspected* and confirmed cases and suspected deaths of clade I mpox, DRC, 2021-2024 (through epi week 21)

	Cases		Suspected Deaths
Year	Suspected	Confirmed	
2021	2,497	N/A	68
2022	5,697	N/A	234
2023	14,626	N/A	654
2024 (Week 21)§	7,864 (+468)	1,134^	383 (+12)

*Most cases are based on clinical suspicion; only a fraction of cases are laboratory-confirmed.

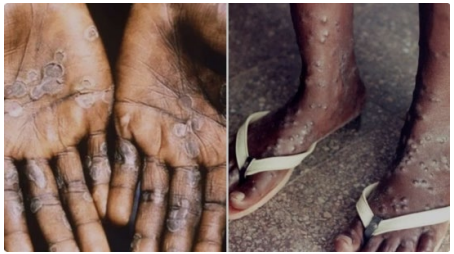
§ Preliminary data for epi weeks 1-21 and subject to change. Note cases numbers reported in previous epi weeks may increase or decrease in the current week's data. This can result in changes in the cumulative number of cases reported. Additional investigation is underway.

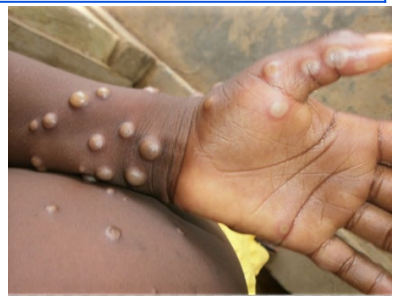
	Ways in which both clades are similar
Clinical presentation	Firm, deep-seated, sometimes umbilicated lesions; presents along a clinical continuum (mild to severe)
Transmission of virus	Contact with skin lesions, fomites, respiratory secretions (e.g., via kissing); contact with animals in endemic settings
Diagnostic testing	FDA cleared non-variola orthopoxvirus (NVO) test used by many laboratories
Hospital waste management	Category B*
IPC for healthcare providers	Gown, gloves, eye protection, N95; in addition to standard precautions, suspected mpox infections have additional IPC precautions
Patient management	Dependent on severity of illness or potential for severe illness
Use of JYNNEOS vaccine and therapeutics	Expected to be effective regardless of clade

*https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2024-03/PHMSA%20Safety%20Advisory%20Notice%20%20Classification%20of%20MPXV%20Diagnostic%20Samples%20and%20Waste.pdf

§ https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html

	Ways in which Clade I cases differ from Clade II
Populations impacted	Might not affect predominantly MSM; uncertain if other populations could be impacted but sexual contact known to be effective
Transmissibility	Clade I MPXV associated with more viral shedding and for that reason, may lead to more secondary cases
Clinical presentation	More of the severe cases could occur disseminated lesions, prodromal symptoms, hospitalization
Diagnostic testing	Clade II specific testing available in some labs but not others
IPC for healthcare providers	Patients may shed more virus; adherence to IPC practices* particularly important



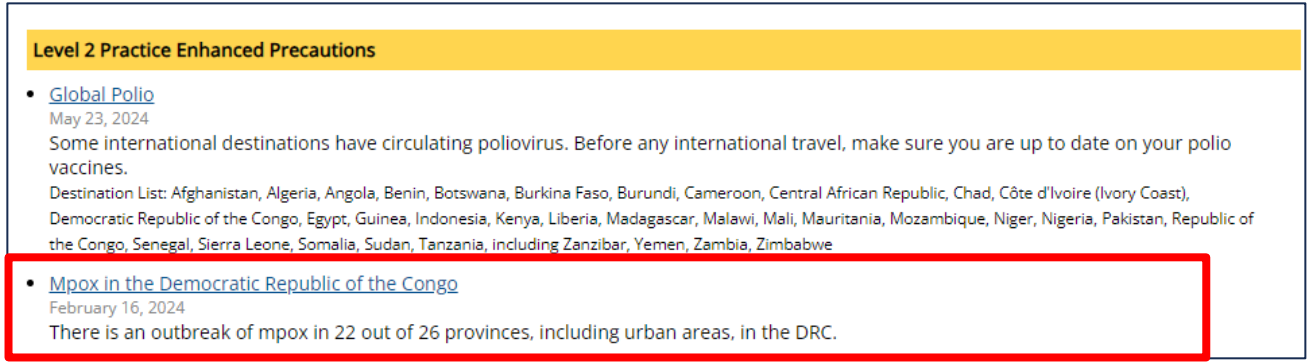


*https://www.cdc.gov/poxvirus/mpox/clinicians/infection-control-healthcare.html

If clade I cases were to occur in the United States…

- Similar to clade IIb spread, travel from other countries could be source of earliest infections
- Similar to clade II, clade I requires close/sustained contact for transmission
- Global outbreak showed that sexual exposures were efficient means of spread, particularly among men who have sex with men
- If clade I cases occurred in the U.S., further specific guidance would be issued

https://wwwnc.cdc.gov/travel/destinations/traveler/none/democratic-republic-of-congo#:~:text=Malaria-,Recommendations,during%20and%20after%20your%20trip.



Level 2 Practice Enhanced Precautions

- Global Polio
  May 23, 2024
  Some international destinations have circulating poliovirus. Before any international travel, make sure you are up to date on your polio vaccines.
  Destination List: Afghanistan, Algeria, Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Chad, Côte d'Ivoire (Ivory Coast), Democratic Republic of the Congo, Egypt, Guinea, Indonesia, Kenya, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Niger, Nigeria, Pakistan, Republic of the Congo, Senegal, Sierra Leone, Somalia, Sudan, Tanzania, including Zanzibar, Yemen, Zambia, Zimbabwe
- Mpox in the Democratic Republic of the Congo
  February 16, 2024
  There is an outbreak of mpox in 22 out of 26 provinces, including urban areas, in the DRC.

CDC activities and guidance for clade I MPXV

- Clade specific testing is occurring for positive specimens in the United States; some commercial laboratory tests can rule out clade I and CDC is collaborating with many private and public health laboratories
- For patients with suspected mpox and a history of recent travel to DRC, contact public health authorities as soon as possible so that clade specific testing can be expedited
- Vaccinate people who are at-risk because of the ongoing clade II outbreak
- CDC is assisting public health authorities in DRC [§]
- At this time, no recommendation for vaccination before travel to DRC

*https://www.idsociety.org/globalassets/idsa/multimedia/clinician-call-slides--qa/3-14-2024-clinician-call.pdf
§https://www.cdc.gov/mmwr/volumes/73/wr/mm7319a3.htm?s_cid=mm7319a3_w

Take-home messages

- Clade II
  - Continues to circulate
  - Nationally, clade II MPXV case counts stable since October 2023
  - Regionally, clusters have occurred; differing reasons may explain these cases but waning immunity is an unlikely reason
  - Increasing 2-dose vaccination coverage and counseling patients about other prevention strategies are best ways for clinicians to prevent cases
- Clade I
  - At this time, no clade I mpox cases have occurred outside of endemic countries
  - Clinicians should contact public health authorities if they suspect clade I in a patient with recent travel to DRC
  - CDC is engaged in the clade I response in DRC and preparing in the event of spread to the United States

Thank you

poxvirus@cdc.gov

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

ASPR Administration for Strategic Preparedness & Response

Jynneos
Transition to Commercial Availability

U.S. Department of Health and Human Services (HHS)

Meghan Pennini, PhD
Chief Science Officer
HHS Coordination Operations and Response Element (H-CORE)
Administration for Strategic Preparedness & Response (ASPR)

05 June 2024

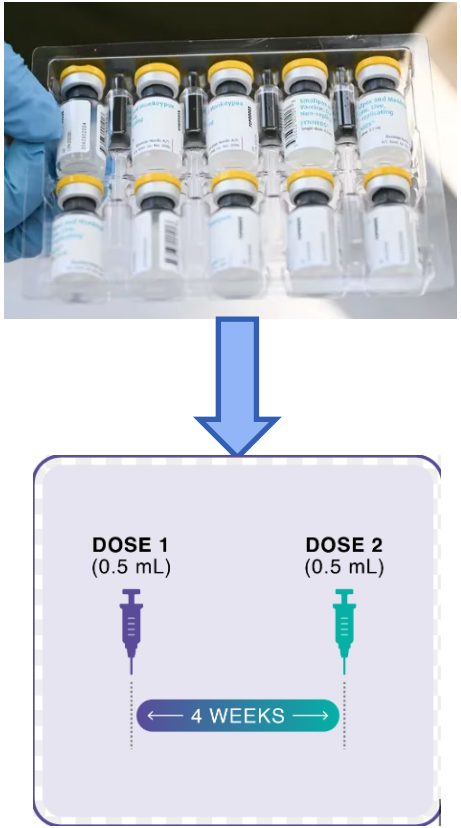
Mpox in the United States – Where are We?

- As of 3/24, weekly case counts remain low

CDC. 2022-2023 outbreak cases and data. Accessed January 10, 2024. https://www.cdc.gov/poxvirus/mpox/response/2022/index.html

Jynneos Commercialization Transition

- Jynneos is FDA-approved for prevention of smallpox and mpox disease in adults 18 years and older at high risk for infection
  - Currently on the ACIP routine immunization schedule for certain individuals
- Jynneos has an EUA for active immunization by subcutaneous injection for prevention of mpox disease in individuals younger than 18 years of age determined to be at high risk for mpox infection
- Jynneos should be administered as two injections (two-dose series)
  - The two doses should be given 28 days apart (range 24-35 days) or as soon as possible if more time has elapsed



Jynneos Transition Timeline

- Beginning in May 2022, HHS has made Jynneos available from the Strategic National Stockpile under the National Mpox Vaccination Strategy
- **February 2023**: ACIP recommendation for at risk adults during an outbreak
- **October 2023**: ACIP recommendation for routine vaccination of adults at risk of mpox infection
- **April 1, 2024**: Bavarian Nordic made Jynneos available for commercial purchase
- **April 30, 2024**: Distribution of HHS supplied Jynneos transitioned to request only as commercial market ramped up
  - Providers should use any remaining HHS-supplied inventory that was previously distributed, especially to support access for under or uninsured
  - Additional ordering is only to support access in circumstances where commercial supply is not yet accessible
- **On or near August 1, 2024**: Full transition of Jynneos to usual commercial workflow

Sustained Access through Commercial Availability

- Medicaid & Medicare
  - Full coverage for all beneficiaries within ACIP recommended populations
- Commercial Insurance
  - Expect private insurance plans to fully cover within ACIP recommendations
  - Plans obligated to cover first plan year that begins one year after the ACIP recommendation
- CDC 317 & Vaccine For Children (VFC) Programs
  - Access for under/uninsured individuals within ACIP recommendation (currently 18+, high risk)
    - 18 years: VFC provides vaccines for uninsured (and underinsured when served in FQHCs/RHCs)
    - 19+ years: 317 program used by jurisdictional partners to serve some adults
  - Ordering expected to open on or near August 1, 2024
- Ryan White & other HRSA-supported clinics
  - Access for under and uninsured populations
  - HRSA grant and Ryan White HIV/AIDS Program (RWHAP) funding may be used to purchase and administer Jynneos vaccine www.hrsa.gov/mpox-faqs
  - 340B Prime Vendor Program offers reduced price to eligible provider sites (e.g., FQHCs)
- Retail Pharmacies
  - Appointments now available at several pharmacy chains (e.g., CVS, Rite Aid, Walgreens) in states that allow pharmacist administration

Self-knowledge Check

Which statement best describes insurance coverage for the commercially available JYNNEOS vaccine?

A. Since the product is only available under Emergency Use Authorization, there is currently no insurance coverage expected.

B. As an FDA-approved and ACIP-recommended vaccine, both Medicare and Medicaid provide full coverage for at risk beneficiaries aged 18 years and older.

C. The product is not expected to be covered by commercial insurance plans for any age group.

D. Insurance plans are expected to cover only one dose of the 2-dose series with additional doses paid out-of-pocket.

Self-knowledge Check

The correct answer is: B.

Medicaid and Medicare fully cover JYNNEOS to those individuals within the JYNNEOS ACIP recommendation. Private insurance plans are also expected to fully cover this vaccine.

Update on Tecovirimat Expanded Access Investigational New Drug Protocol Eligibility Criteria for Treatment of Mpox

Clinician Outreach and Communication Activity (COCA) Call

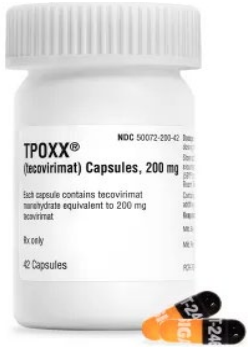
June 27, 2024

CAPT Yon Yu, PharmD

Medical Countermeasures Regulatory Support Team

Office of Readiness and Response

Background on Tecovirimat



- Tecovirimat (TPOXX), an antiviral drug developed and stockpiled for smallpox preparedness, is FDA-approved only for treatment of smallpox based on animal efficacy data and safety data in 359 healthy adults
- Efficacy and safety of tecovirimat in treating any human orthopoxvirus infections not yet determined
- Ongoing clinical trials to evaluate efficacy and safety in people with Monkeypox virus (MPXV) infection
- Because Tecovirimat is not FDA-approved for mpox, access is through NIH's Study of Tecovirimat for Mpox (STOMP) clinical trial or CDC's expanded access Investigational New Drug (EA-IND) protocol
- Stockpiled tecovirimat made available under the EA-IND protocol at the start of the 2022 mpox outbreak, including prepositioned supplies
- NIH's STOMP launched in Sept 2022 and continues to recruit patients with mpox for voluntary participation

Background on Tecovirimat, continued

- Per FDA regulations, EA-IND use
  - must be for treatment of **serious** or **life-threatening** disease or condition and when there is no comparable or satisfactory alternative therapy
  - **cannot interfere** with the conduct or completion of **clinical investigations** that could **support marketing approval** of the expanded access use
- More than 7,900 patients prescribed tecovirimat under the EA-IND
  - most treated as outpatients for mild to moderate illness
  - most commonly reported reasons for tecovirimat were lesions in sensitive anatomic areas and pain, including pain as the only reported reason for some patients
  - EA-IND use is not designed or adequate to determine efficacy
- Tecovirimat remains available for treatment of mpox
- Oral tecovirimat access is primarily through enrollment in NIH's STOMP (randomized and open-label arms) with remote enrollment available Monday-Friday
- Oral and intravenous tecovirimat available under the CDC's EA-IND for patients who meet EA-IND eligibility

Revised Tecovirimat EA-IND Protocol (v 6.4 dated June 5, 2024)

Updated to specify the patients with mpox who are eligible for treatment under the protocol:

1. Patients with severely immunocompromised condition(s) defined as:

- HIV with CD4 < 200 cells/mm^3
- Leukemia or lymphoma
- Generalized malignancy
- Solid organ transplantation
- Therapy with alkylating agents within 180 days prior to mpox illness onset
- Antimetabolites within 180 days prior to mpox illness onset
- Radiation therapy within 180 days prior to mpox illness onset
- Tumor necrosis factor inhibitors within 180 days prior to mpox illness onset
- High-dose corticosteroids (equivalent of 20 mg or greater of prednisone for at least 14 days) within 90 days prior to mpox illness onset
- 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
- Other comparable severe immunocompromising condition

2. Patients in the following categories:

- Those with active skin conditions placing them at higher risk for disseminated infection, defined as: atopic dermatitis; active exfoliative skin condition(s) such as eczema, burns, impetigo, active varicella zoster virus infection, psoriasis, or Darier disease (keratosis follicularis)
- Pregnant or lactating individuals, regardless of illness severity or underlying comorbidities at presentation
- Children (< 18 years), regardless of illness severity or underlying comorbidities at presentation

3. Patients with protracted or life -threatening manifestations of mpox at presentation as defined by one of the following:

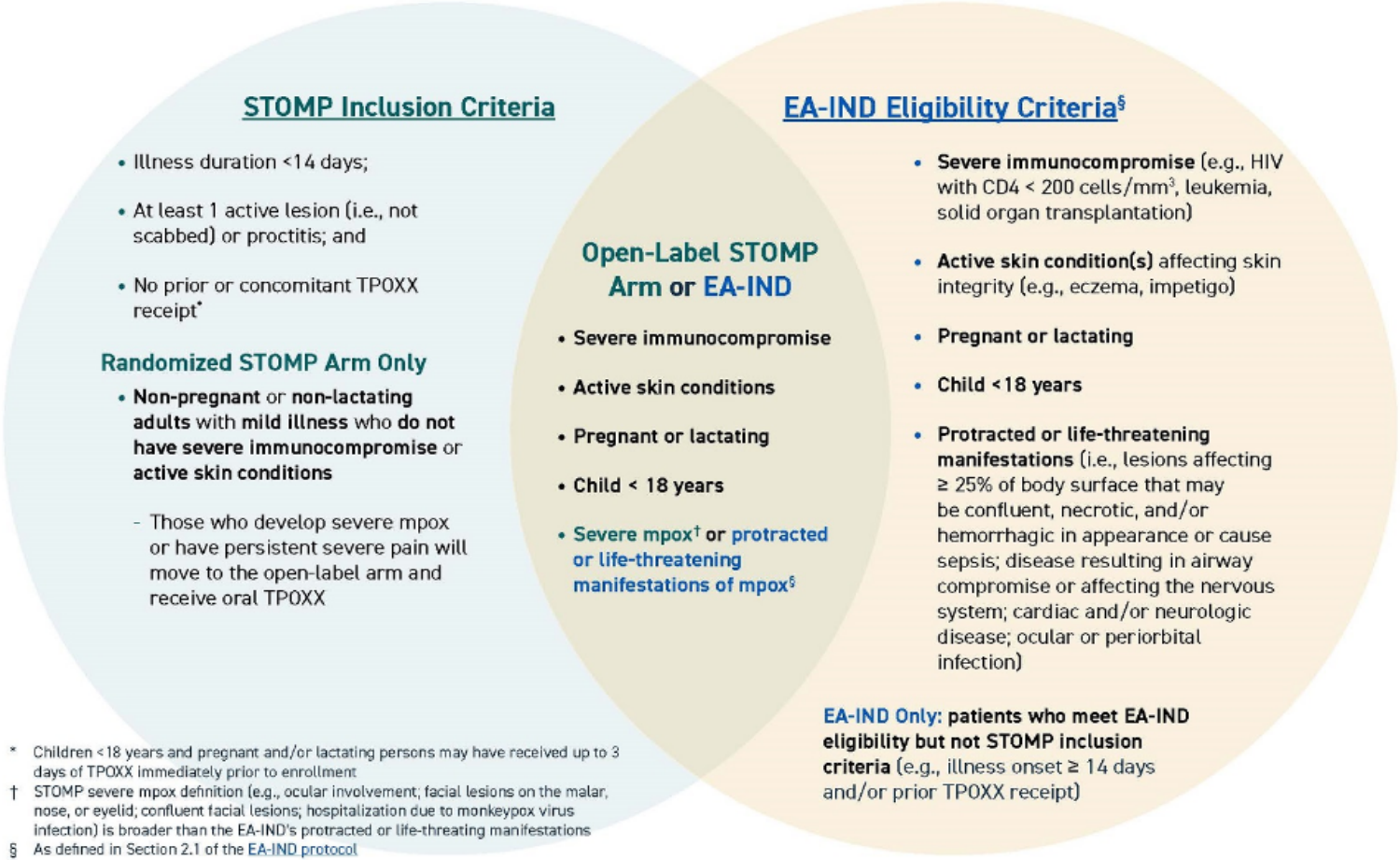
- Lesions affecting ≥ 25% of body surface that may be confluent, necrotic, and/or hemorrhagic in appearance or cause sepsis
- Disease resulting in airway compromise or affecting the nervous system
- Cardiac (e.g., myocarditis) and/or neurologic disease (e.g., encephalitis) which might occur in a small number of patients with mpox
- Ocular or periorbital infection, regardless of the time since infection onset

Reasons for Revised EA-IND Eligibility Criteria

- To ensure tecovirimat access for patients with mpox through STOMP and EA-IND that facilitates appropriate use of tecovirimat and allows for evaluating efficacy through STOMP
  - Generate data to inform policy, clinical, and regulatory decisions
- Known risk of tecovirimat resistance
  - FDA posted notice[1] for judicious use of tecovirimat given tecovirimat's low barrier to viral resistance
  - Resistance in > 50 patients with mpox, including those who received tecovirimat during illness[2] and a new cluster of MPXV variant with resistance detected in 18 patients from 5 U.S. states (October 2023-February 2024)
  - A cluster of tecovirimat-resistant MPXV infections among 11 tecovirimat-naïve individuals[3]

[1] FDA Mpox Response | FDA; [2] Smith et al., 2023; [3] Garrigues et al., 2023

Oral Tecovirimat via NIH's STOMP vs. CDC's EA-IND Protocol

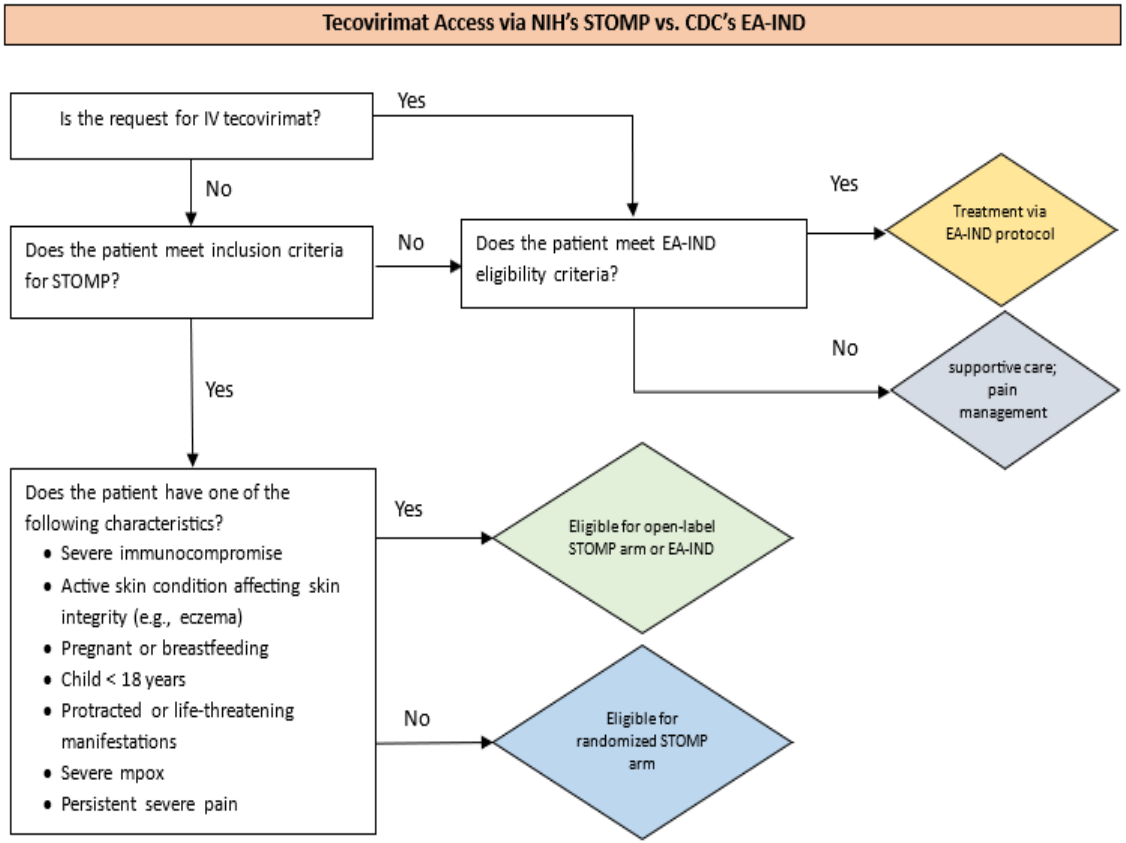


* Children <18 years and pregnant and/or lactating persons may have received up to 3 days of TPOXX immediately prior to enrollment

† STOMP severe mpox definition (e.g., ocular involvement; facial lesions on the malar, nose, or eyelid; confluent facial lesions; hospitalization due to monkeypox virus infection) is broader than the EA-IND's protracted or life-threating manifestations

§ As defined in Section 2.1 of the EA-IND protocol

Determining STOMP vs. EA-IND for Tecovirimat Access



- For STOMP-eligible patients, contact the STOMP Call Center (855-876-9997).
- Patients eligible for STOMP's open-label arm and EA-IND protocol can choose treatment under either option.
- For patients not eligible for STOMP (e.g., illness onset > 14 days or prior TPOXX receipt) but meet EA-IND eligibility (e.g., severe immunocompromise), contact their jurisdictional health department for any remaining tecovirimat supply.
- If no local supply, health departments should contact the CDC Emergency Operations Center at (770) 488-7100 to request tecovirimat on behalf of the providers.

Additional Stockpiled Therapeutics for Treatment of Mpox

- Brincidofovir (Tembexa) available from the Strategic National Stockpile based on FDA-authorization for single-patient emergency use (eIND)
- On June 14, 2024, FDA updated its criteria for brincidofovir eIND treatment of human mpox
  - Have severe* disease **OR** are at high risk for progression to severe* disease,
  - **AND meet any of the following:**
    - experience clinically significant disease progression while receiving tecovirimat or who develop recrudescence (initial improvement followed by worsening) of disease after an initial period of improvement on tecovirimat, *OR*
    - are otherwise ineligible or have a contraindication for oral or intravenous tecovirimat, OR
    - Are enrolled in the open-label treatment arm (Arm C) of the STOMP trial, OR
    - Are severely immunodeficient (e.g., uncontrolled HIV infection – CD4 < 200). Severely immunodeficient patients without prior tecovirimat use can simultaneously initiate combination therapy with brincidofovir and tecovirimat (Note: For these cases, FDA will encourage STOMP enrollment and provide link to trial information: https://www.stomptpoxx.org)

(*Severe – consider severe disease when a patient has conditions such as hemorrhagic disease; a large number of lesions such that they are confluent; necrotic lesions; severe lymphadenopathy that can be necrotizing or obstructing (such as in airways); involvement of multiple organ systems and associated comorbidities (for example, pulmonary involvement with nodular lesions; sepsis; encephalitis; myocarditis; ocular or periorbital infections); or other conditions requiring hospitalization; FDA Mpox Response | FDA)

Additional Stockpiled Therapeutics for Treatment of Mpox

- Vaccinia Immune Globulin Intravenous (VIGIV) available under CDC's VIGIV EA-IND protocol for
  - Patients with protracted or life-threatening manifestations of mpox
  - Patients with clinically significant disease progression while receiving tecovirimat or who have recrudescence (initial improvement followed by worsening) of disease after an initial period of improvement on tecovirimat
  - Patients for whom there is concern that the virus is resistant to tecovirimat
  - Patients allergic to or otherwise unable to receive tecovirimat
- To request VIGIV, contact the CDC Clinical Consultation Team by email (poxvirus@cdc.gov) during business hours, or the CDC Emergency Operations Center (770-488-7100).

References

- STOMP (stomptpoxx.org)
- Tecovirimat (TPOXX) IND Information (cdc.gov)
- Mpox Treatment Information for Healthcare Professionals | Mpox | Poxvirus | CDC
- FDA Mpox Response | FDA
- SNS Products: Vaccines and Treatment Available for Use in the Mpox Response (hhs.gov)

Self-knowledge Check

Which statement regarding tecovirimat for treatment of mpox is **FALSE:**

A. Tecovirimat is not FDA-approved for treatment of mpox.

B. Oral tecovirimat for treatment of mpox is primarily available through the NIH's Study of Tecovirimat for Mpox (STOMP) clinical study.

C. Tecovirimat for treatment of mpox under the CDC's expanded access Investigational New Drug (EA-IND) protocol must be for those who meet eligibility as defined in the current version of the EA-IND protocol.

D. Those who are EA-IND eligible for oral tecovirimat can also receive drug through enrollment in the open-label arm of STOMP.

E. A patient with HIV (CD4 = 400) who has proctitis and pain due to mpox for the last 2 days can be treated with tecovirimat under the CDC's EA-IND protocol.

The correct answer is E.

This patient does not meet the EA-IND eligibility for tecovirimat treatment. However, the patient has the option of enrolling in the placebo-controlled randomized arm of STOMP where two-thirds of participants are randomized to tecovirimat treatment arm. Those who have persistent severe pain will be moved to the open-label arm of STOMP.

Thank you

For more information, contact CDC
1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

To Ask a Question

- Using the Zoom Webinar System
  - Click on the “Q&A” button
  - Type your question in the “Q&A” box
  - Submit your question

- If you are a patient, please refer your question to your healthcare provider.

- If you are a member of the media, please direct your questions to CDC Media Relations at 404-639-3286 or email media@cdc.gov.

Joining the Q&A Session

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Centers for Disease Control and Prevention

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National Center for HIV, Viral Hepatitis, STD, and TB Prevention
Centers for Disease Control and Prevention

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- **Transcripts & Certificates**: You can access and download CE transcripts and certificates in TCEO through the end of 2025.

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- Those who will participate in the on-demand activity and wish to receive continuing education should complete the online evaluation between **July 30, 2024,** and **July 30, 2026,** and use **course code WD4520-062724.**

Today's COCA Call will be Available to View On-Demand

- **When:** A few hours after the live call ends*
- **What:** Video recording
- **Where:** On the COCA Call webpage
  - https://emergency.cdc.gov/coca/calls/2024/callinfo_062724.asp

**A transcript and closed-captioned video will be available about one week after the live session*

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The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.