MPOX TESTING AND TREATMENT

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VIRGINIA RESPONSE

1. Test

2. Notify close contacts

3. Monitor symptoms

4. Facilitate treatment or vaccine

5. Wastewater Surveillance

[CDC Monitoring and Risk Assessment for Persons Exposed in the Community]

[CDC Mpox Wastewater Surveillance Dashboard]

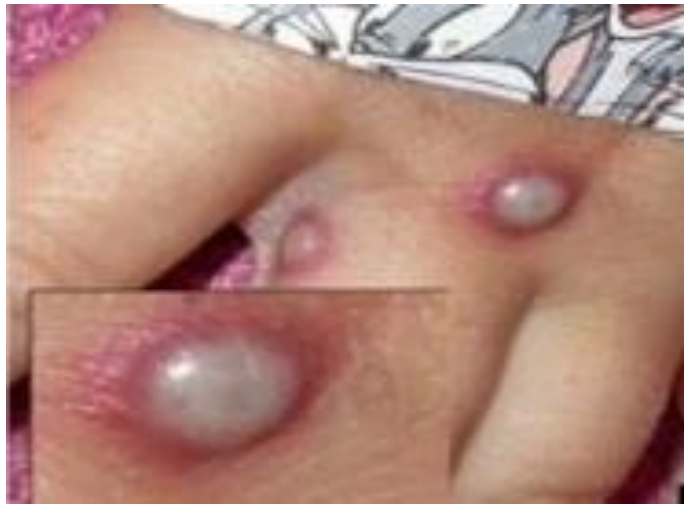
"CLASSICAL" MONKEYPOX

Classic Disseminated Disease

Young children in central Africa
– often with animal contact

Centrifugal distribution

- Rash 2-4 weeks
- Infectious until all lesions have fallen off
- Lesions same age
- Higher mortality rate

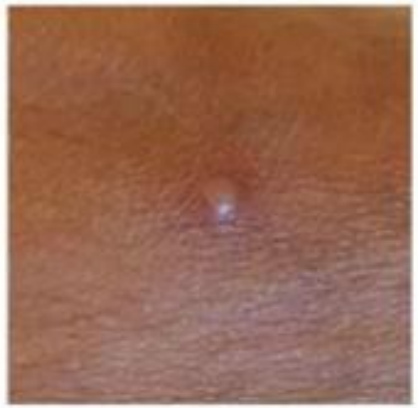


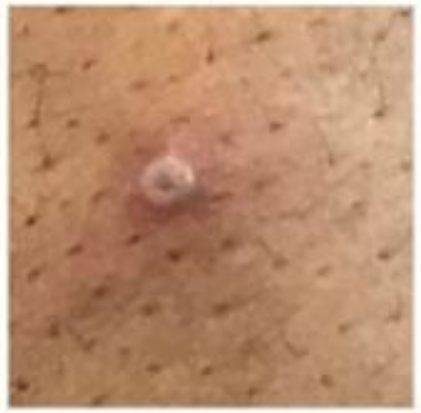
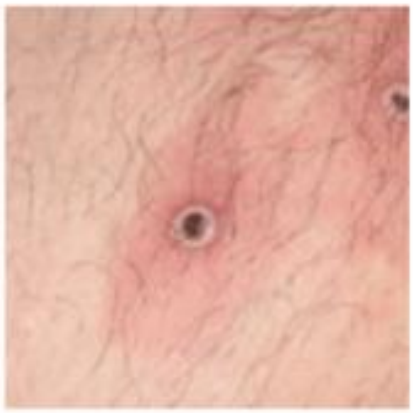
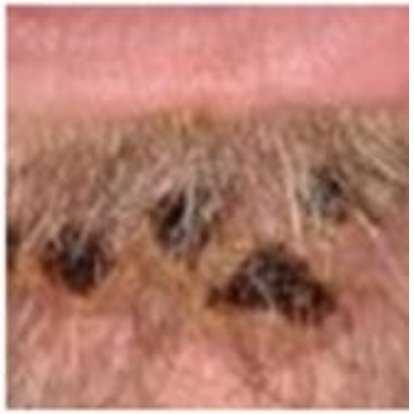
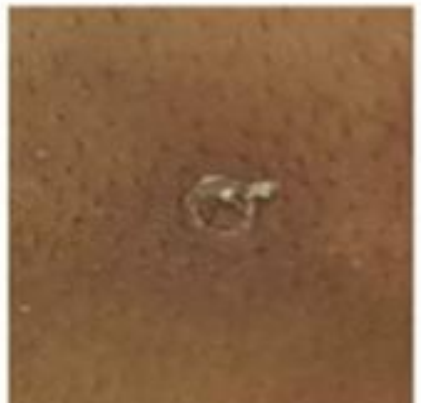
https://www.cdc.gov/poxvirus/monkeypox/clinicians/clinical-recognition.html

CLINICAL FEATURES (CLADE IIB)

- Incubation period about 7-14 days
- Can have prodrome (1-4 days) fever, headache, adenopathy
  - Can present without prodrome, as well
- Eruptive phase (rash) 14-28 days
  - May have a range of lesion evolution
- Usually self limited, often resolving on its own
- Mortality rate in current outbreak: remains low (<0.2%)

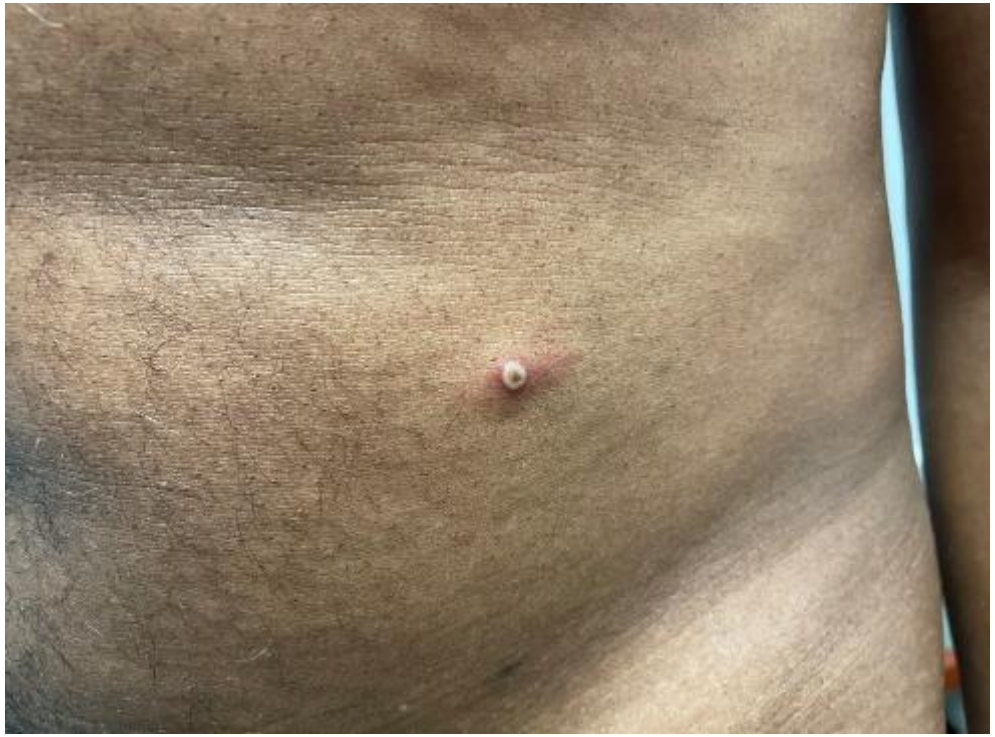
KEY CHARACTERISTICS OF RASH

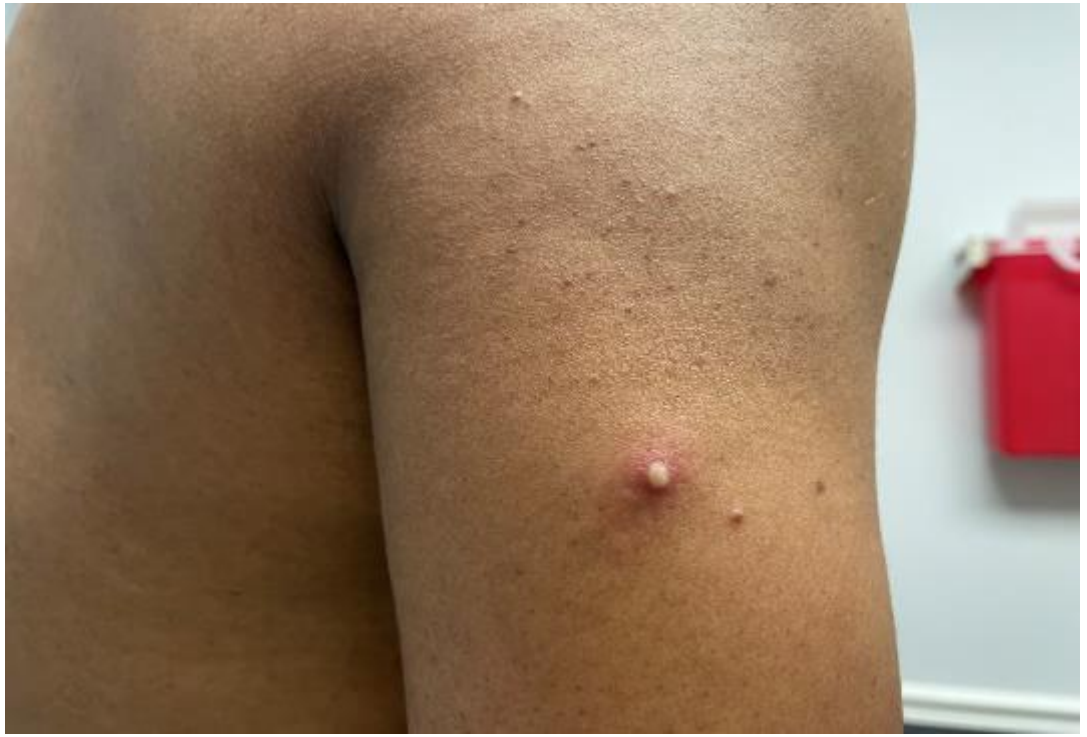


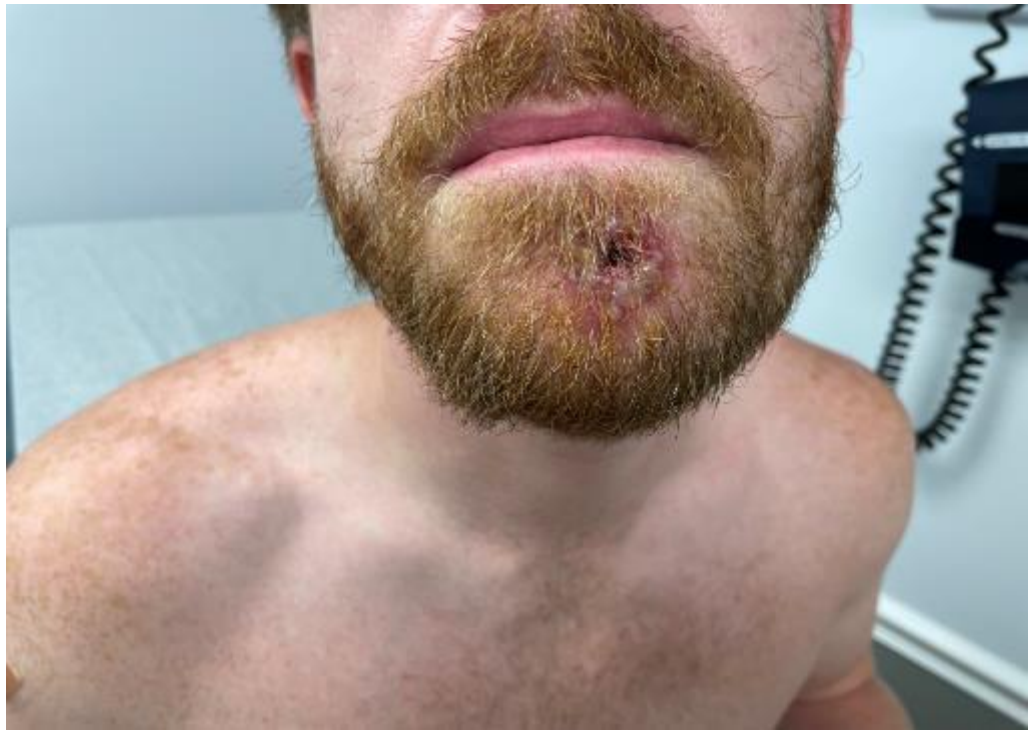
[CDC Mpox Signs and Symptoms]

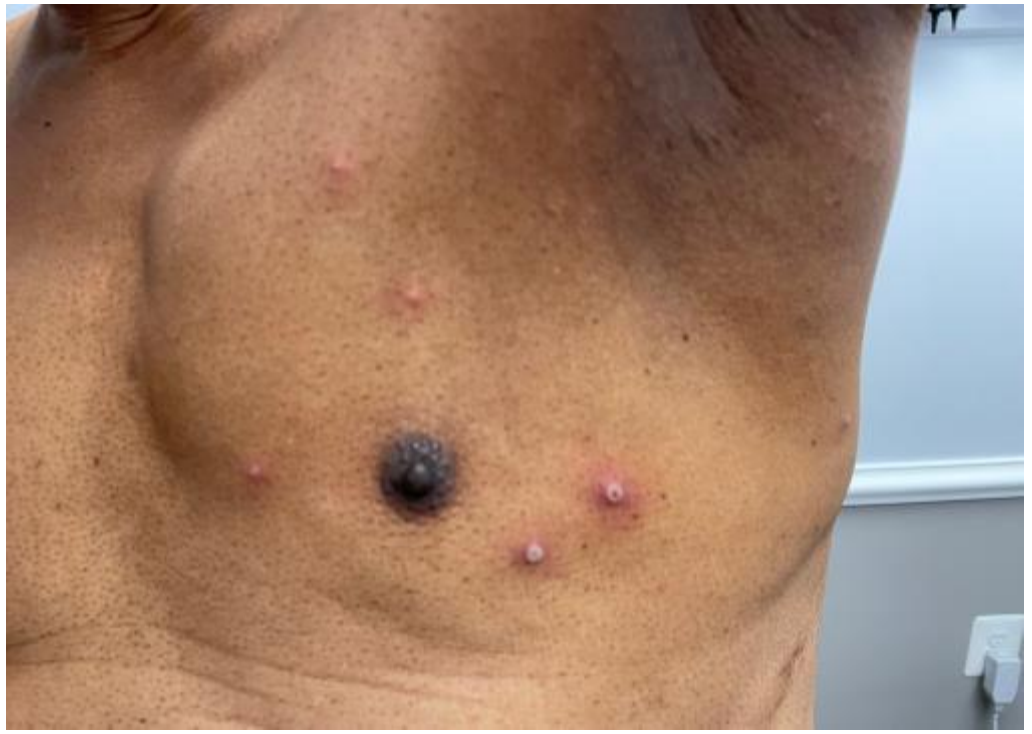
DISCRETE PUSTULAR LESIONS



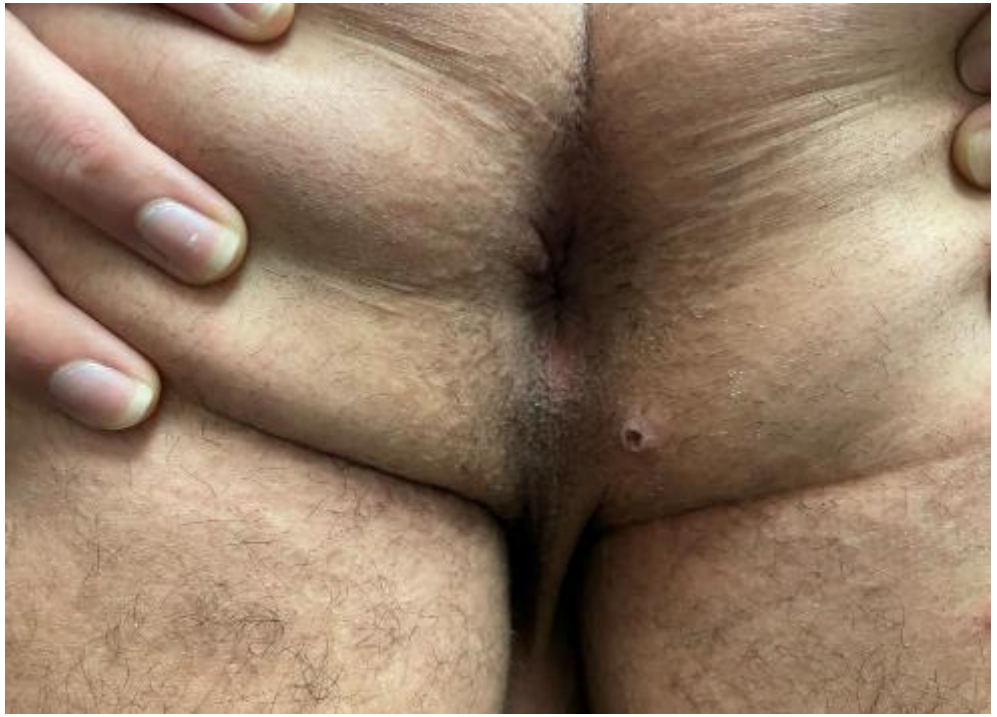


CROPS, "IMPETIGO-LIKE", ESCHAR FORMATION





AFFINITY FOR GENITAL AND ANAL AREAS



LOCAL GENITAL EDEMA AND RISK FOR STRICTURES

SEVERE MPOX IN IMMUNOCOMPROMISED PATIENTS WITH HIV OR OTHER CONDITIONS

- Most severe cases were in people with untreated HIV
- Providers should:
  - **Test all sexually active adults and adolescents for HIV and other STIs, assess for other immunocompromising conditions**
  - Be aware of risk factors for severe manifestations

CDC Severe Manifestations of Monkeypox among People who are Immunocompromised Due to HIV or Other Conditions

CDC Severe Monkeypox in Hospitalized Patients — United States, August 10–October 10, 2022

COMMON MIS-DIAGNOSES

- Varicella
- Dermatomal zoster
- Herpes simplex

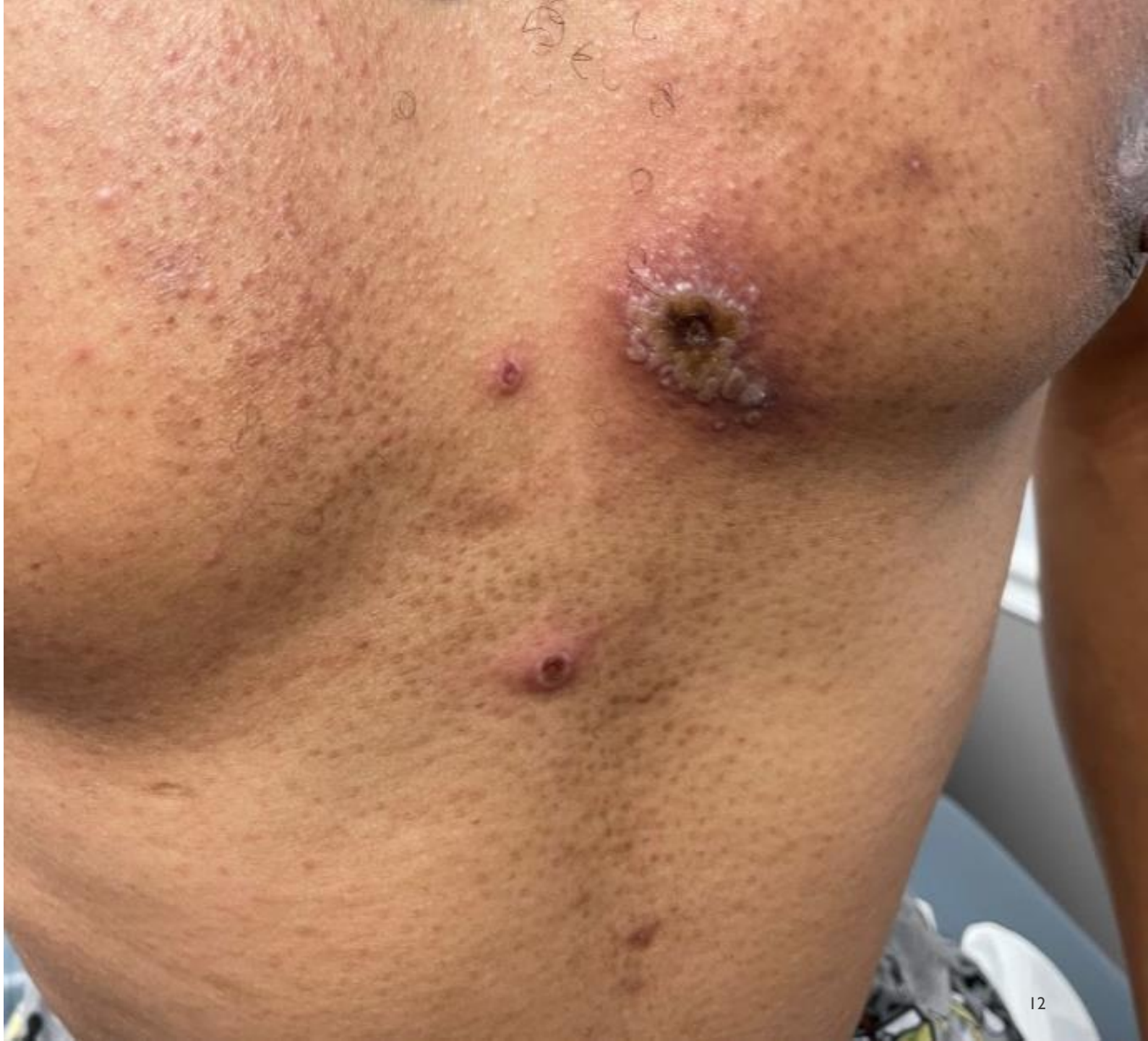
- Other ulcerative or pustular infections
  - MRSA folliculitis
  - Syphilis

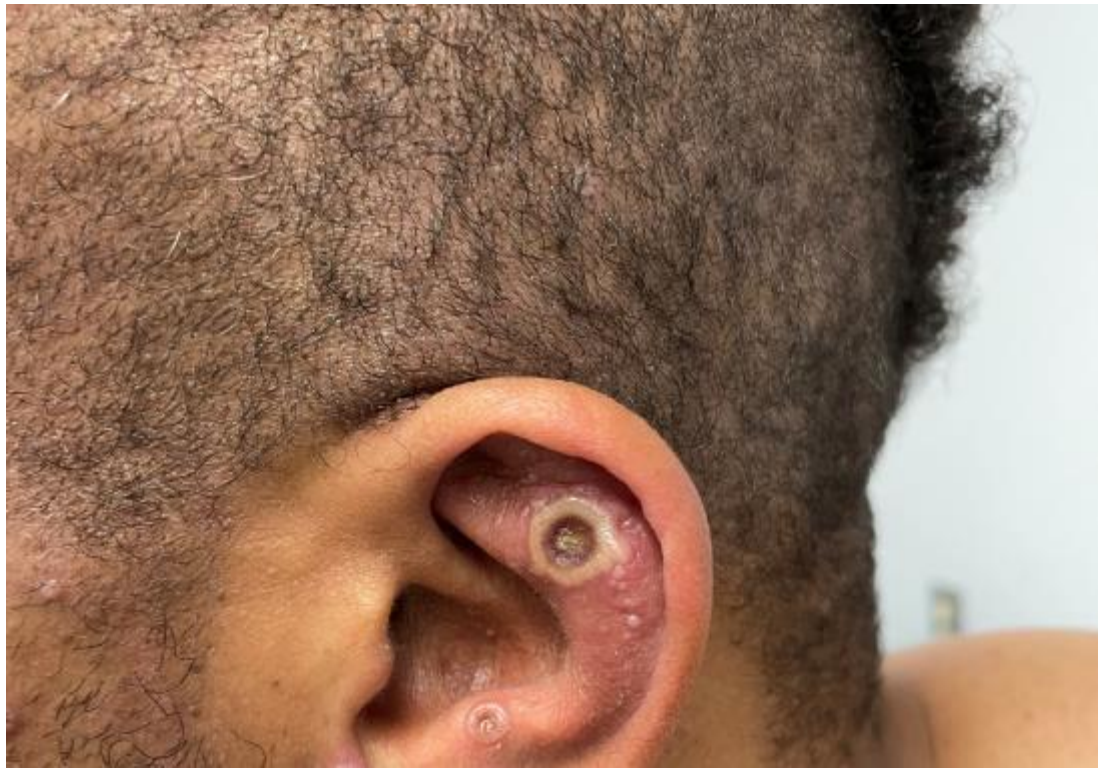
- Avoid withholding treatment for other conditions

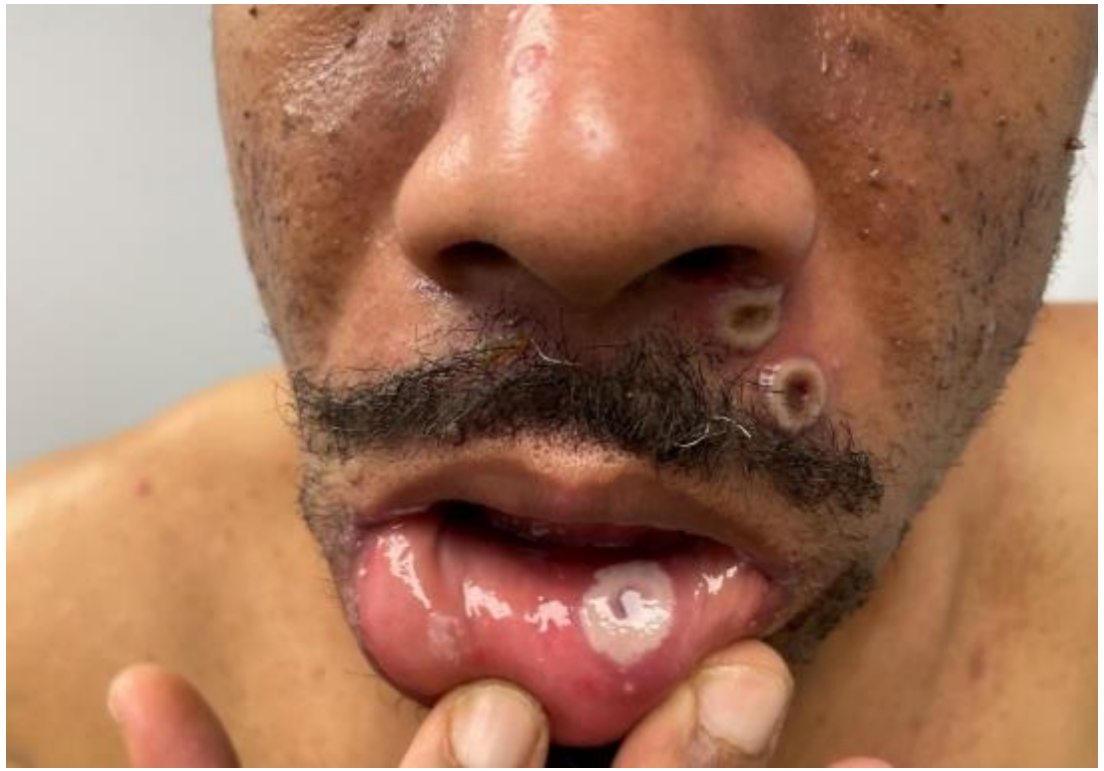
IMMUNO-COMPROMISED HOSTS

38 year old man

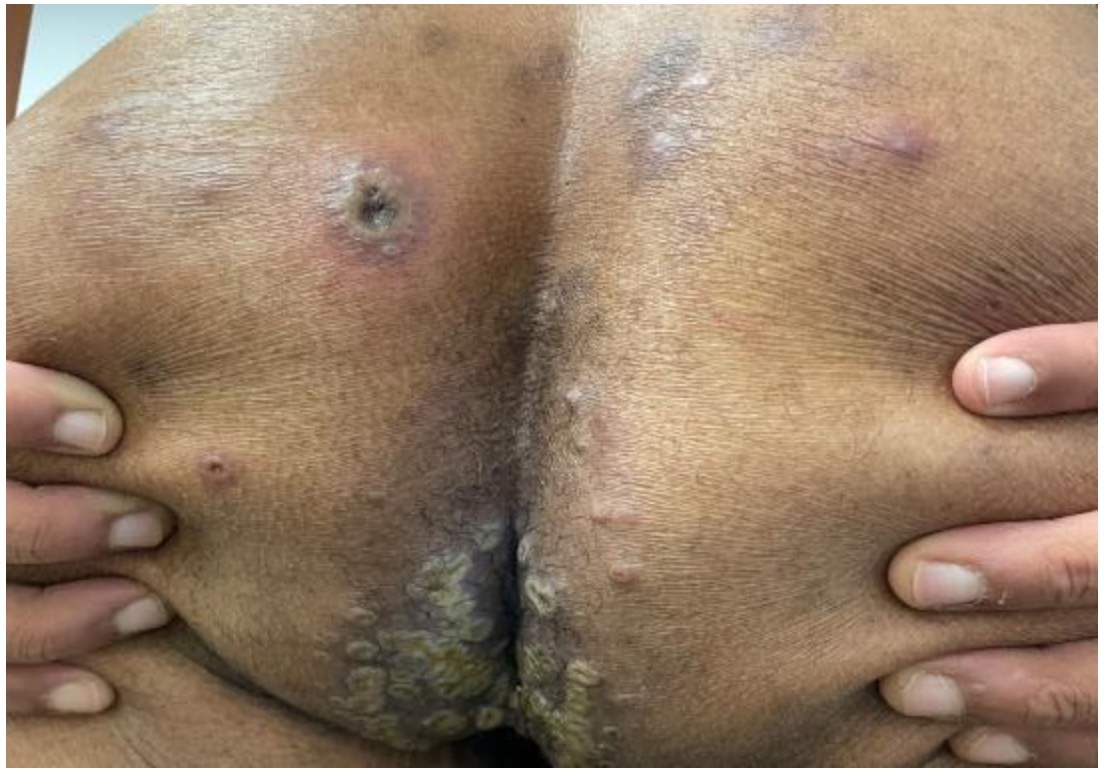
- Little PMH
- 3 weeks of rash
- Seen in urgent care x 2
- “allergic dermatitis”
- 2 rounds of prednisone
- Brief improvement then return with intensity
- Significant anal pain
- ER & HD: refer to ID (stat)





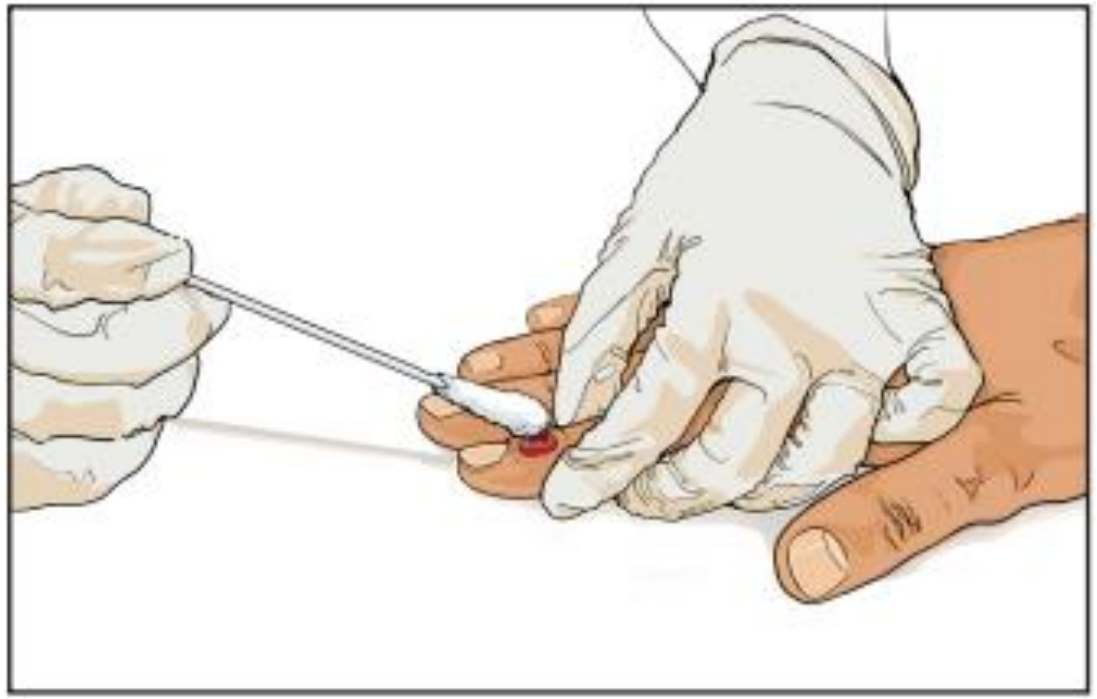


ADVANCED HIV: PREVIOUSLY UNRECOGNIZED



TESTING

- PCR test for non-variola orthopox viruses
- Initially thru the CDC and health departments
- Now thru commercial labs (Quest, LabCorp)
- Available thru health dept for eligible patients
- Variety of swabs
  - Dry, culture media
- Results in 48 hours



LABCORP

- Mpox (Orthopoxvirus) DNA, PCR
- Test 140230, CPT: 87593
- 3-4 day turn-around

- Universal transport media (UTM) or viral transport media (VTM)
  - The pink liquid
- Rayon, Dacron or polyester swab
- Refrigerate

VDH TREATMENT STRATEGIES

SUPPORTIVE CARE FOR ALL PATIENTS

- Assess and provide supportive care for pain management, skin and oral lesions, proctitis, gastrointestinal symptoms

- Examples include:
  - Over-the-counter or prescription pain medications
  - Oral antihistamines for pruritic skin lesions
  - Rehydration for fluid losses
  - Anti-emetics for nausea and vomiting
  - Sitz baths for proctitis or painful lesions

- Encouragement and guidance

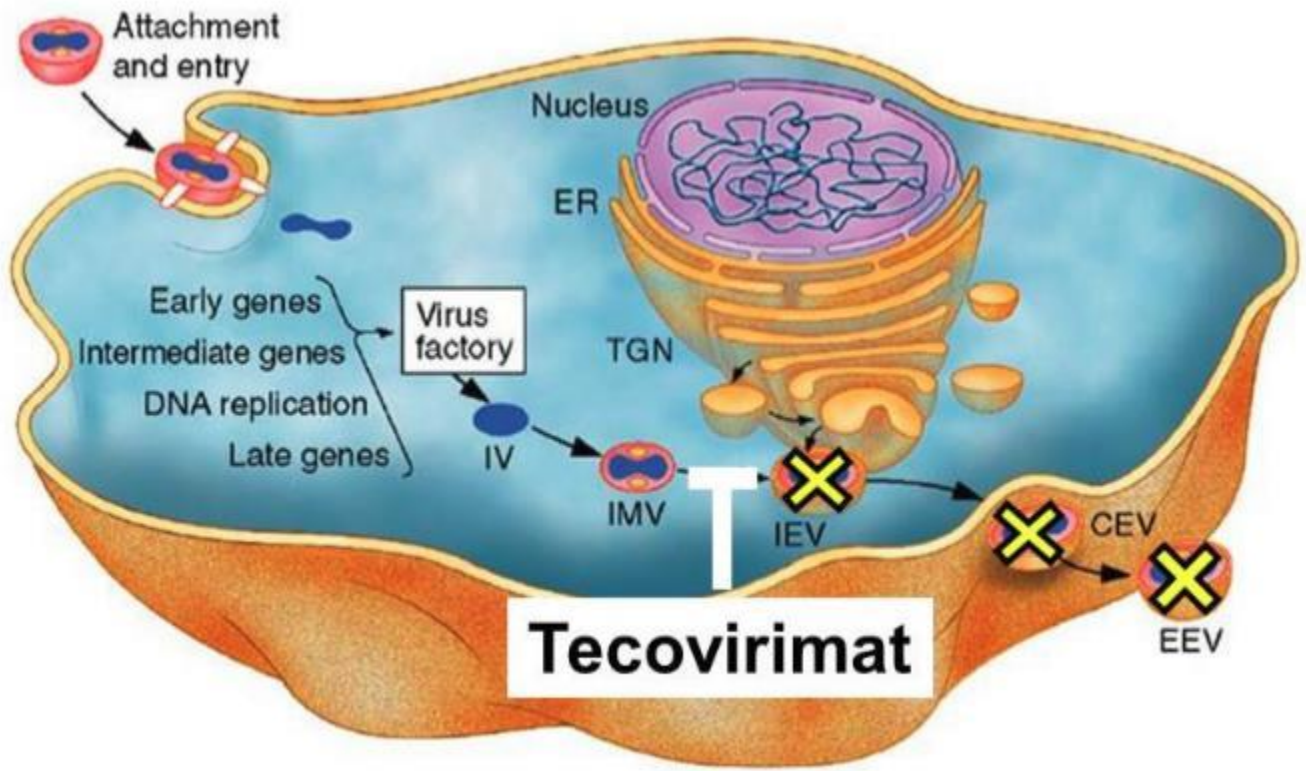
TREATMENT OPTIONS

Treatment Option	Indication	Formulations Available
Tecovirimat (TPOXX or ST-246) *Antiviral	Per EA-IND, for patients with laboratory confirmed non-variola orthopoxvirus infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease	Oral (200 mg capsule)* Injection for intravenous administration *ability to mix with semi-solid food for pediatrics < 13 kg
Cidofovir (Vistide) *antiviral	FDA approved for treatment of cytomegalovirus retinitis in patients with AIDS	Intravenous infusion single-unit vial
Vaccinia Immune Globulin Intravenous (VIGIV)	FDA licensed for treatment of complications due to vaccinia vaccination	Intravenous infusion single-dose vial
Brincidofovir (Tembexa) *antiviral	FDA approved for the treatment of smallpox in adults and pediatrics, including neonates *As of 10/31/22, available from SNS through an e-IND request to FDA.	Oral (100 mg tablet or 10 mg/mL suspension)

TREATMENT

- Most people do not need antiviral therapy
- Tecovirimat 200 mg
  - Developed for smallpox in 2018
  - Animal and PK data
  - No clear data on monkeypox
- Brincidofovir, cidofovir
  - Excessive toxicity

TECOVIRIMAT INHIBITS THE MEMBRANE WRAP



CONSIDERATIONS WITH TPOXX

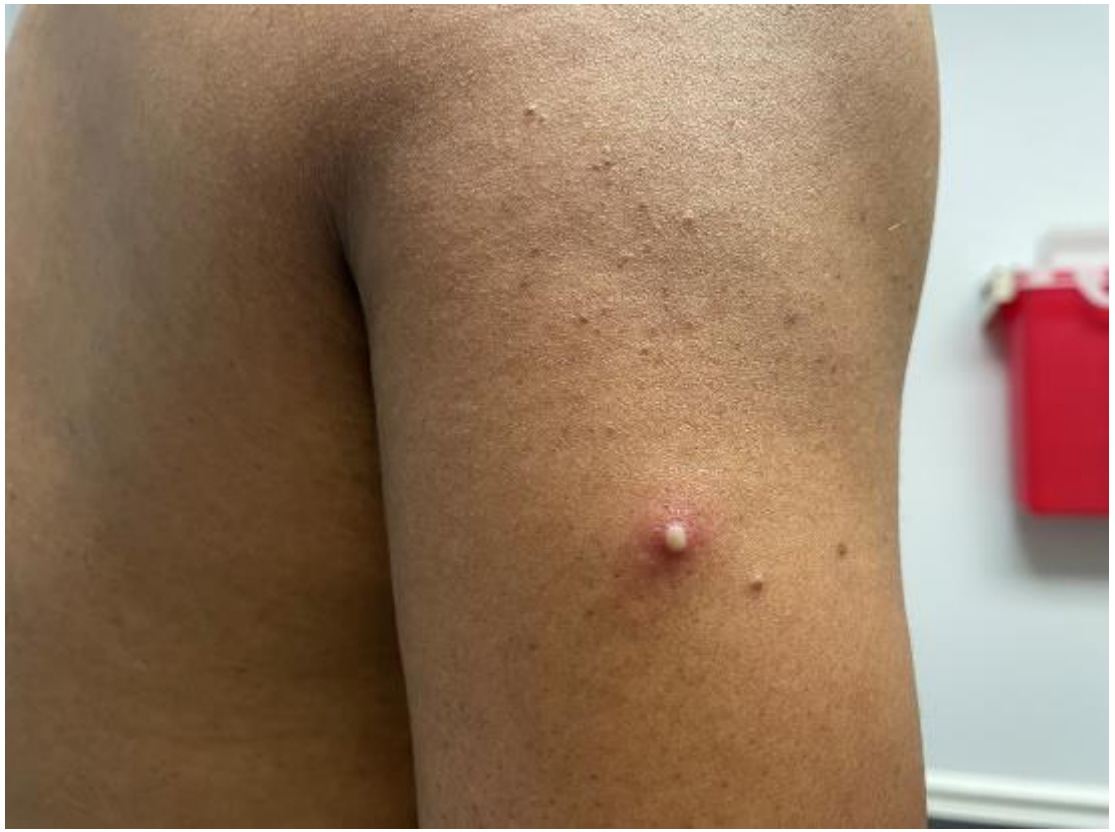
- For adults and adolescents 40-120 kg
  - 3 capsules twice a day for 14 days

- Clinicians and patients should understand
  - Limited tecovirimat effectiveness data in people with mpox
  - Lack of data indicating which patients might benefit the most
  - Concern for development of resistance that could render the drug ineffective for any treated patients

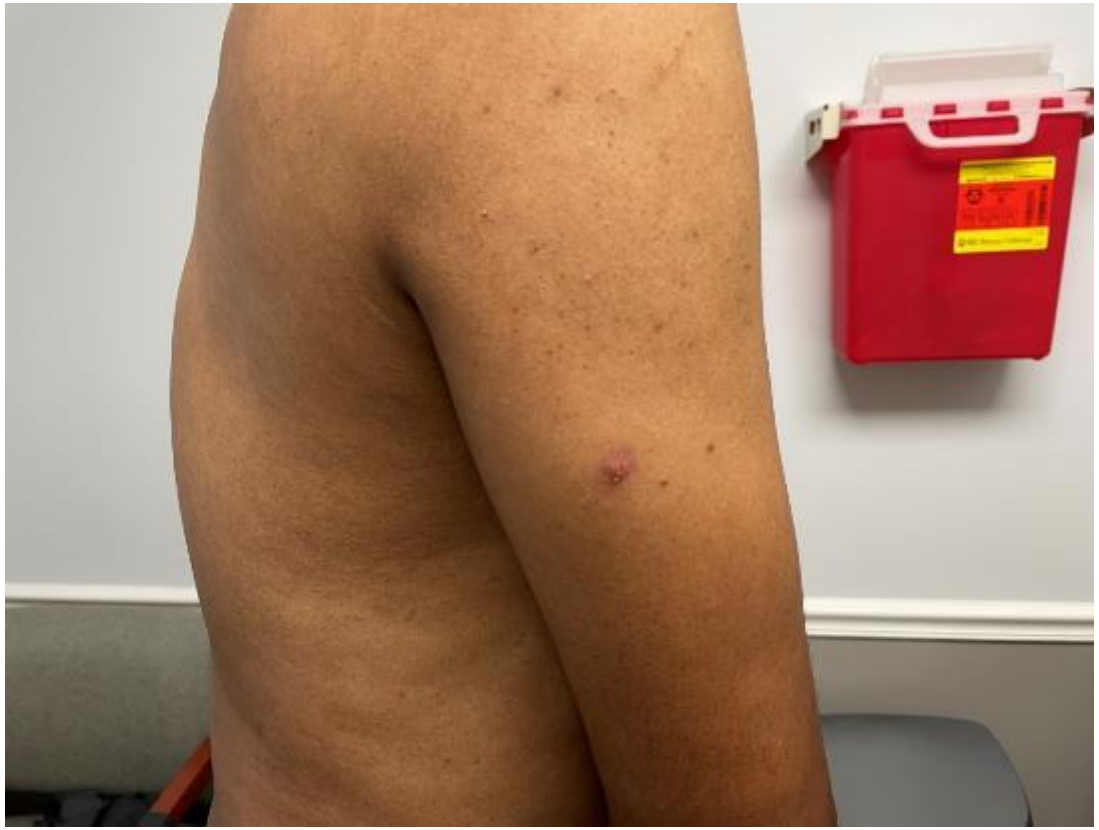
- Alternate therapeutics have more concerning safety profiles than TPOXX

CDC Guidance for Tecovirimat Use

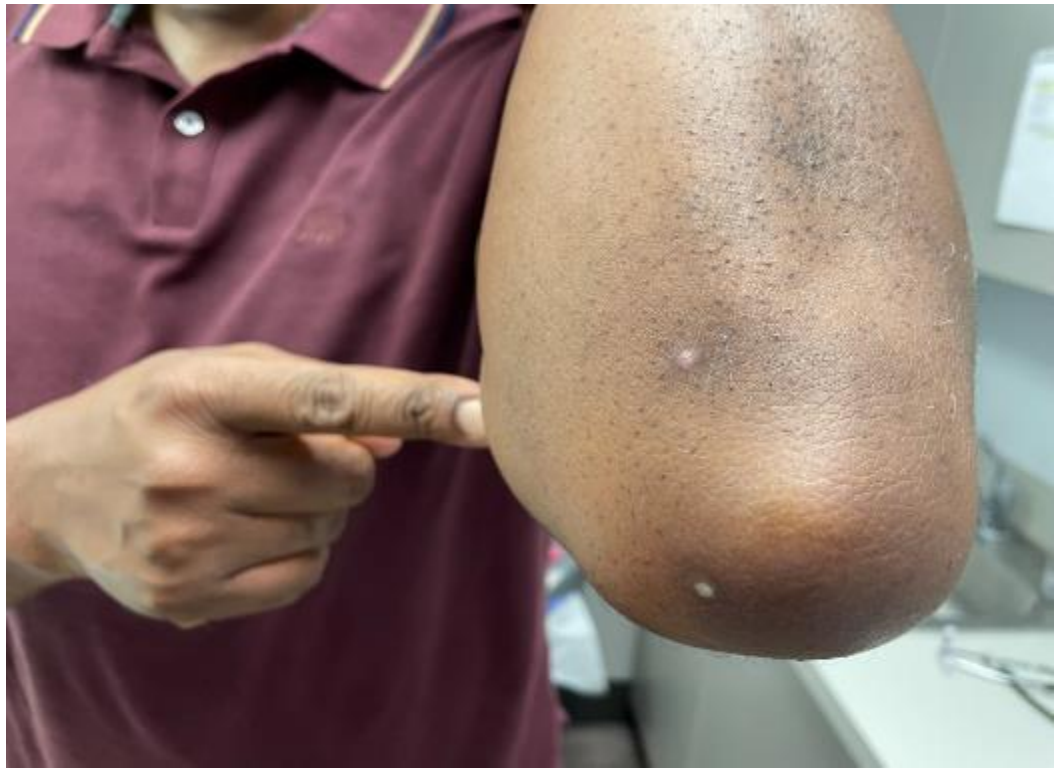
ANECDOTALLY, TECOVIRIMAT WORKS (DAY 1)



DAY 4 ON TREATMENT



DAY 11 OF TREATMENT



DAY 11

TREATMENT OPTIONS: TPOXX

- **CDC offers clinical consultation service (email eocevent482@cdc.gov) or call CDC Emergency Operations Center at 770-488-7100**
- Tecovirimat may be considered for people
  - With **severe disease** (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, ocular or periorbital infection, or other conditions requiring hospitalization)
  - With involvement of **anatomic areas** that might result in serious sequelae that include scarring or strictures
  - Who are at **high risk of severe disease**:
    - People with severe immunocompromise
    - Pediatric patients, particularly those younger than 1 year of age
    - Pregnant or breastfeeding women
    - People with a condition affecting skin integrity

CDC Treatment Information for Healthcare Professionals

STUDY OF TECOVIRIMAT ON HUMAN MPOX VIRUS (STOMP) CLINICAL TRIAL

- Preferred mechanism for TPOXX access is through STOMP Trial
- Funded by NIAID (National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health)
- Clinical trial to evaluate the effectiveness of TPOXX
- Research site at Virginia Commonwealth University (VCU)
- Adults and children with mpox eligible to enroll, do not have to have severe mpox or be at increased risk of severe mpox
  - Aim to enroll > 500 people from up to 80 U.S. clinical research sites
- Open-label arm: those with or at risk of severe disease receive TPOXX
- Second arm: 530 adults randomly assigned in a 2:1 ratio to receive TPOXX or placebo pills for 14 days
- Patients not eligible or willing to enroll in STOMP can still get TPOXX via EA-IND (expanded access investigation new drug) protocol

Study of Tecovirimat for Human Monkeypox Virus

VIRGINIA DEPARTMENT OF HEALTH (VDH)

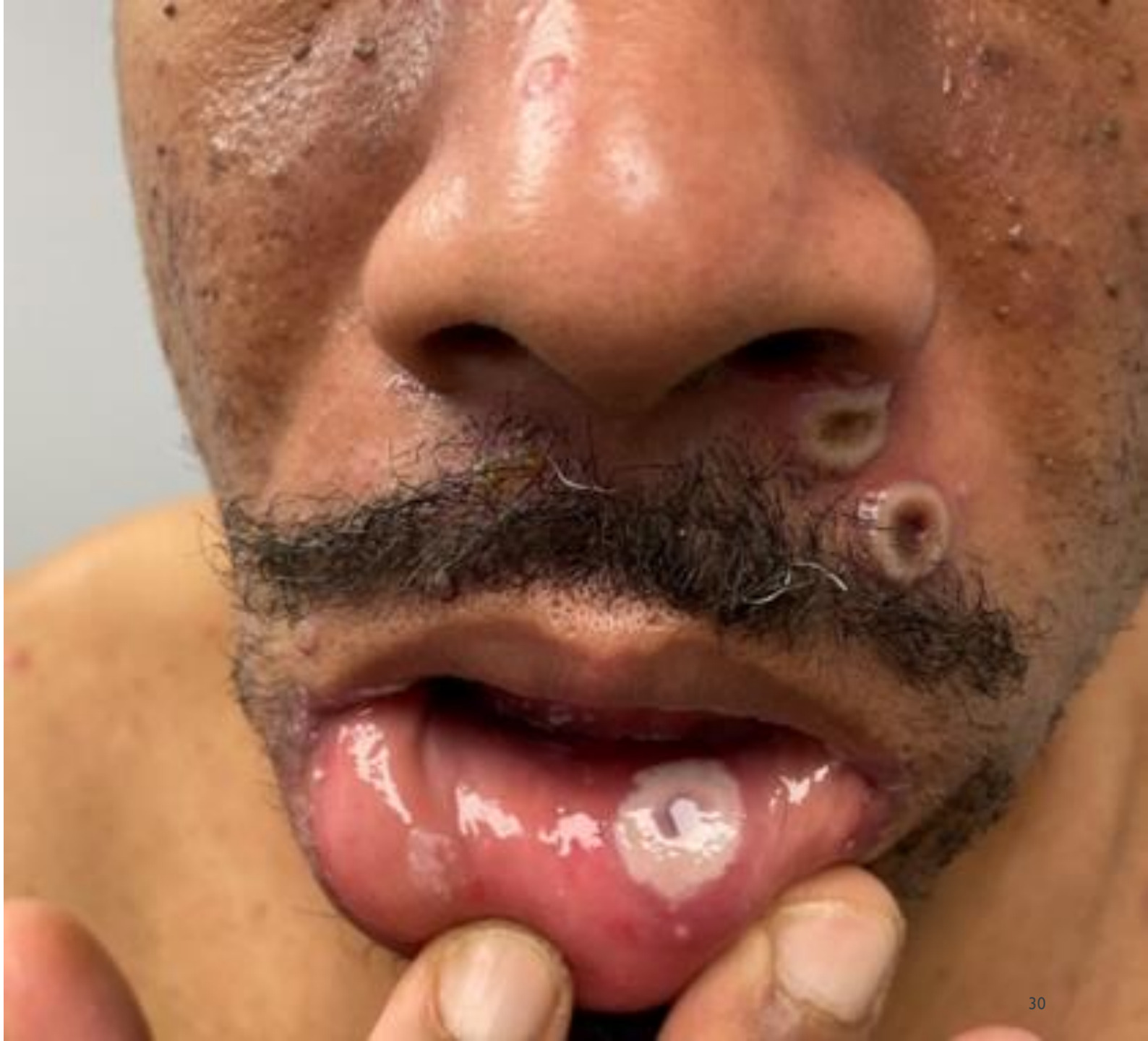
- Website: search "Mpox, VDH"
  - Scroll down to "For health providers, treatment guidance"

- Guidance for obtaining Tpoxx
  - First priority is to enroll on the clinical trial "STOMP"
  - Trial sites: VCU, Duke, Hopkins
    - Some availability for virtual visits

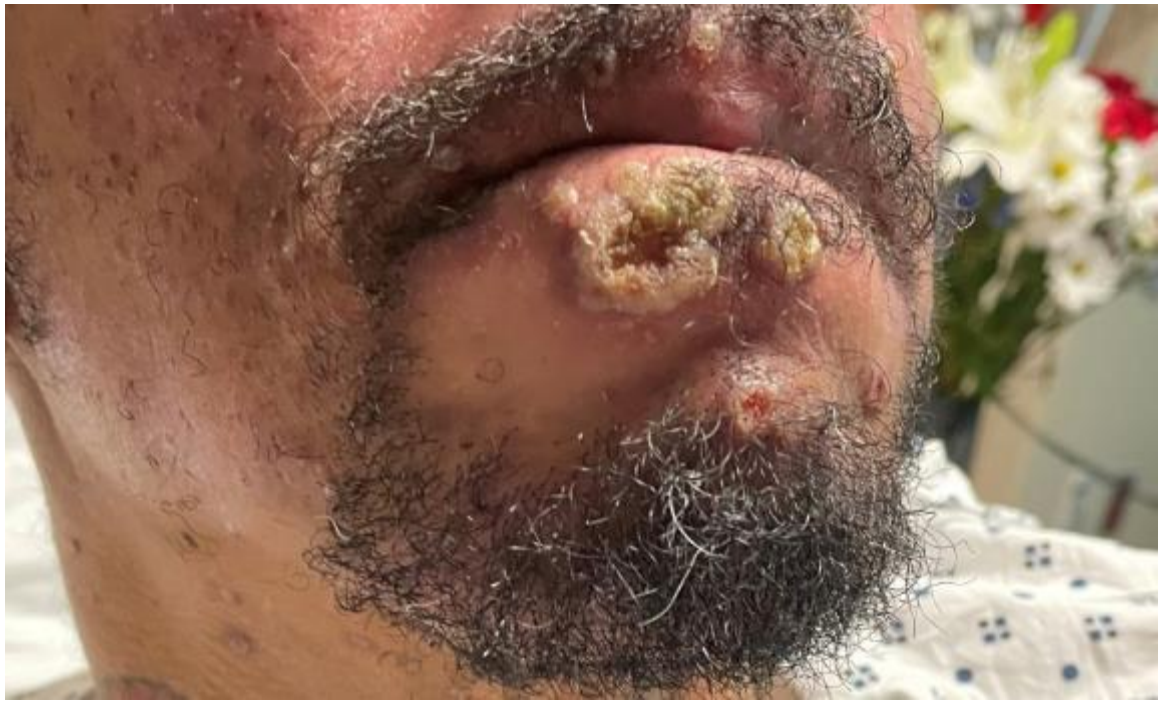
  - Availability of the drug through expanded access
    - Steps for registering as an investigator

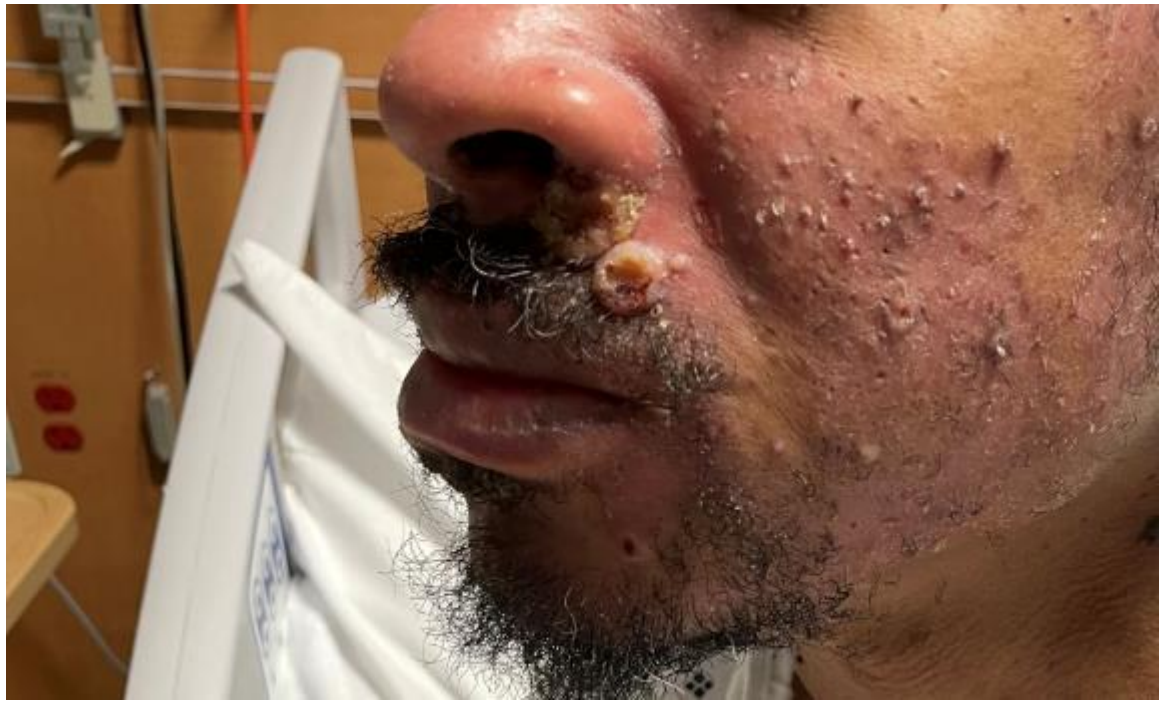
PATIENT WITH ADVANCED HIV AND MPOX

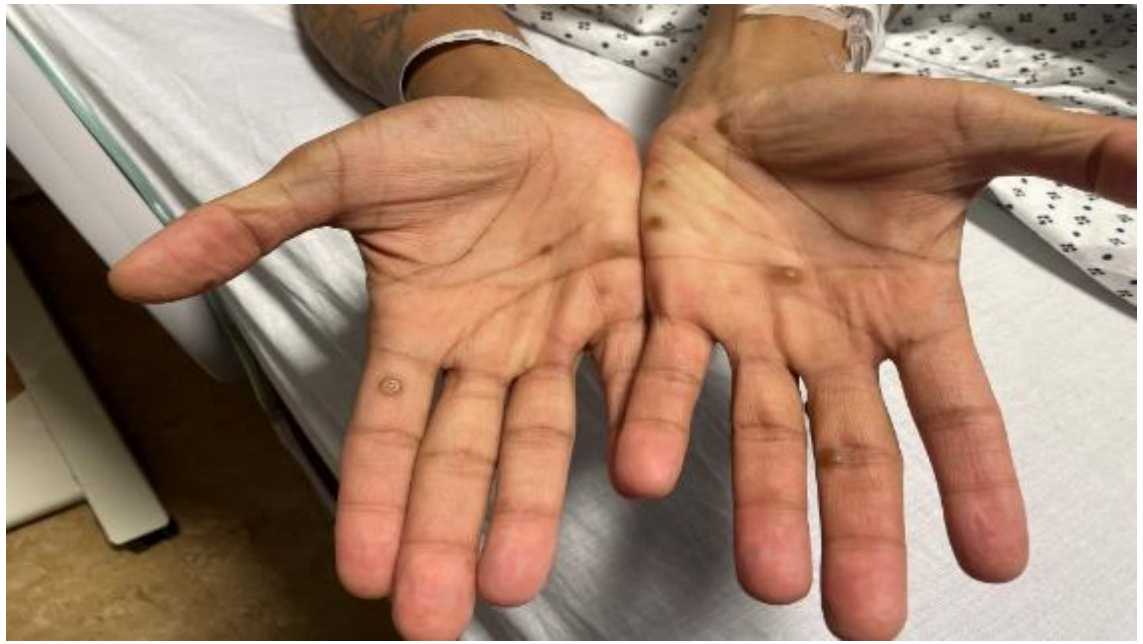
- Started on Tpoxx
- HIV testing: + CD4-17
  - Thrush
  - + RPR
- Developed dyspnea at day 10
  - Admitted to Fairfax
  - + PCP (treated with Bactrim)
    - Shortened course of steroids

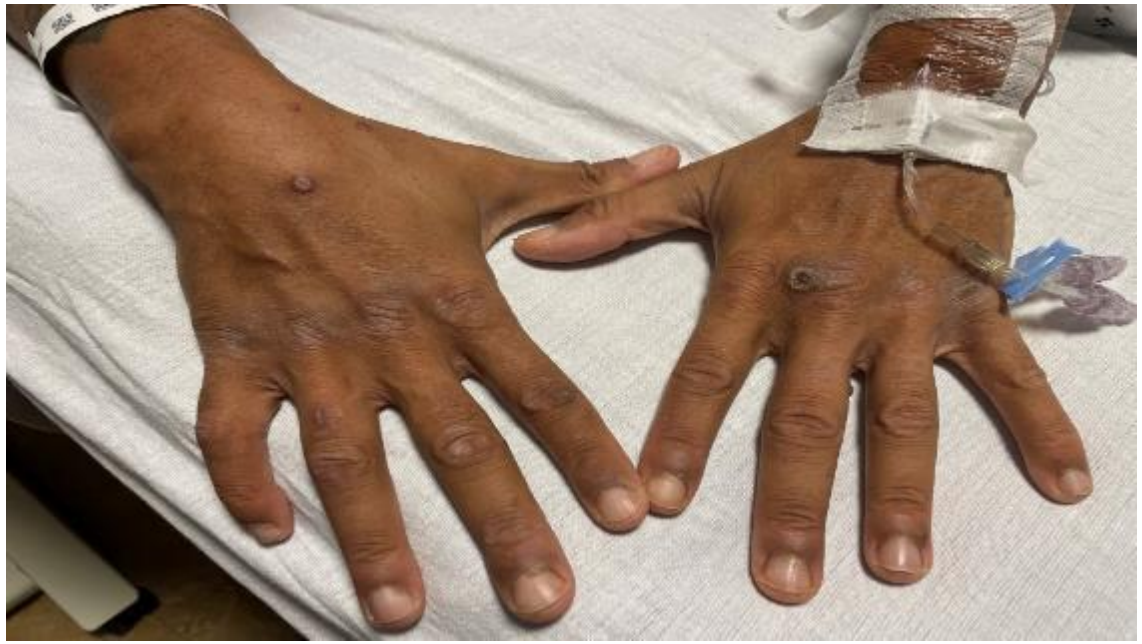


DAY 16





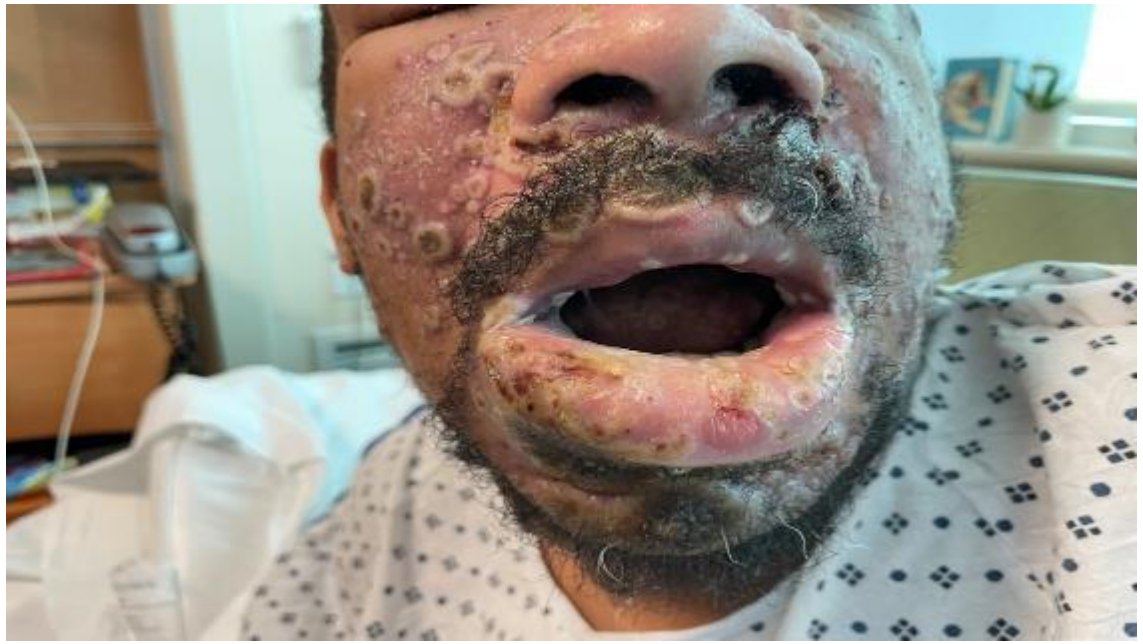


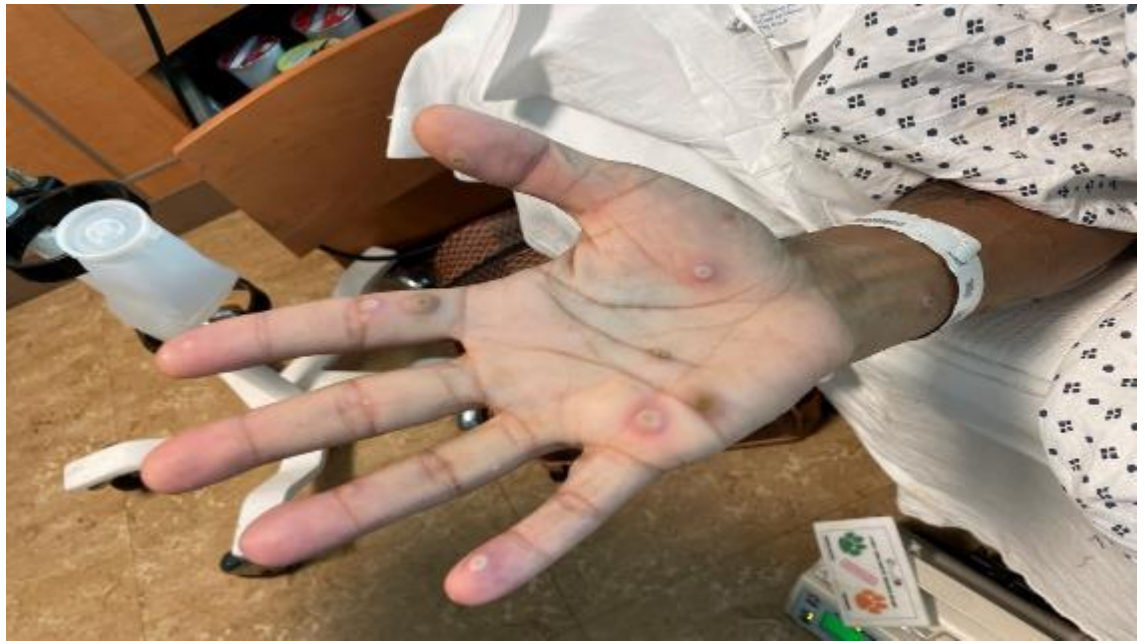


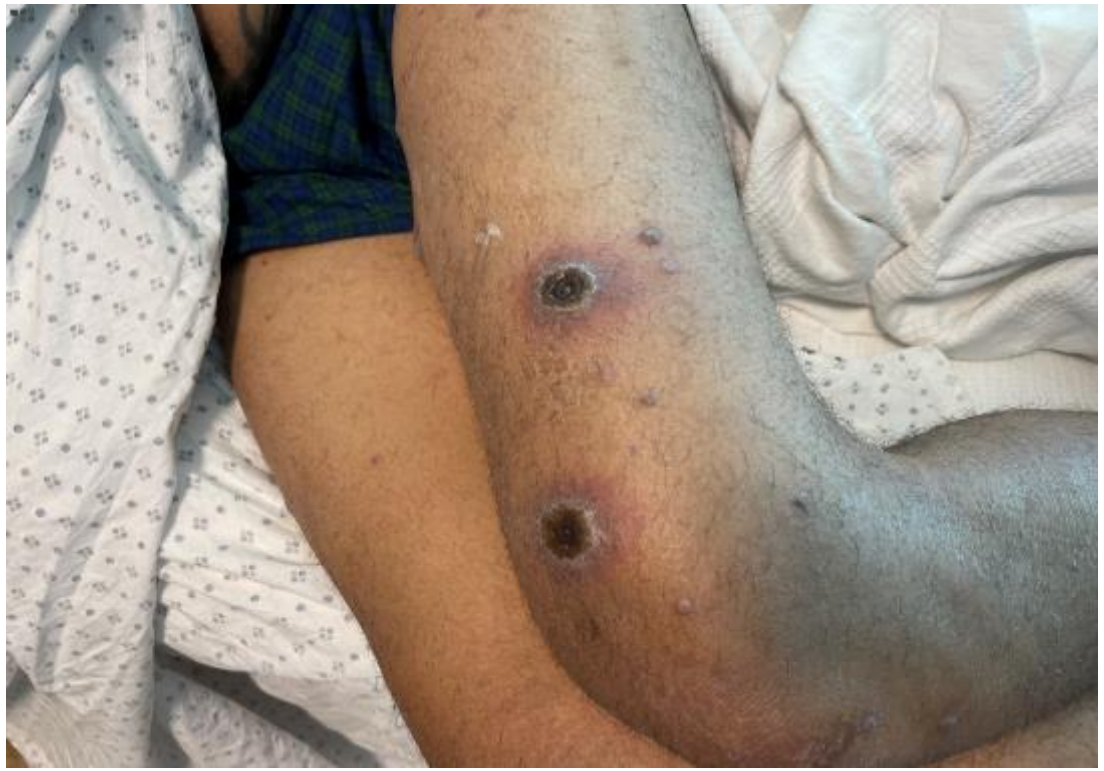
PROGRESSION OF DISEASE

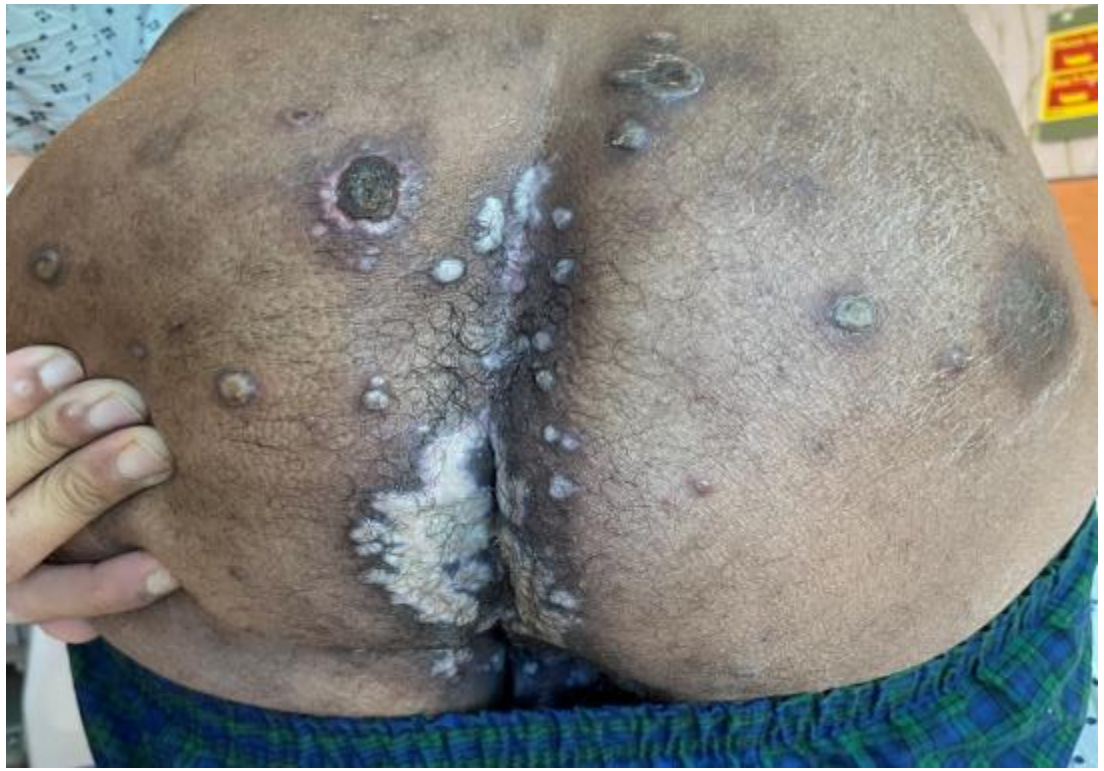
- Initiated IV tecovirimat
  - Urgent delivery from VDH
- Started HIV treatment
- Completed treatment for PCP
- Began evolving new lesions
  - Swelling of mouth, oral lesions
  - Explosion of facial lesions
  - Confluence of peri-anal ulcers

DAY 30 ON TREATMENT









CRITICAL ILLNESS

- Conference calls with CDC experts
- Typical clinical course among small number of individuals with advanced HIV
- Given vaccinia immune globulin
- Broad antibacterial therapy
- Continued IV Tpoxx
- Initially maintained good renal and respiratory function
- Developed organ failure, ICU transfer
- Died

MPOX AND HIV

- People with HIV-associated immunosuppression or who are not virologically suppressed can be at increased risk of severe mpox disease
- Vaccination with JYNNEOS is considered safe for people with HIV
- Antivirals for mpox have few interactions with antiretroviral therapy (ART)
- TPOXX should be considered in people with HIV, particularly if immunosuppressed
- Addition of other therapeutics (cidofovir, brincidofovir, VIGIV) may be considered for those not improving or progressing

Clinical Considerations for Treatment and Prophylaxis of Mpox Infection in People Who are Immunocompromised

MPOX AND HIV

- For people with HIV diagnosed coincident with mpox or who are not taking ART, CDC recommends starting ART as soon as possible, and in consultation with an expert in HIV medicine if needed

- STI screening for sexually active persons evaluated for mpox, treat if test positive

- Virologic and Immunologic Characteristics of Severe Mpox in People with Advanced HIV (VIRISMAP) Study to determine why some patients have severe mpox and understand pathogenesis

Clinical Considerations for Treatment and Prophylaxis of Mpox Infection in People Who are Immunocompromised

THANK YOU!