

Process for obtaining tecovirimat (TPOXX)

Tecovirimat is an antiviral that has been approved in Europe, not approved in US. It is thought to prevent formation of secondary viral envelope needed to produce extracellular virus. Animal studies demonstrate decrease mortality with orthopoxviruses, studies on humans have demonstrated safety but not efficacy. Case series may suggest shorter duration, but there are no randomized control trials to date. In the United States it is only available as an expanded access investigational drug (EA-IND) and should be considered purely investigational. Side effects include headache, nausea, abdominal pain, vomiting and it can cause hypoglycemia with repaglinide.

The following is the internal process for UCLA Health to obtain tecovirimat (TPOXX). Please note that UCLA will be a site for trials to assess the efficacy in the future, but this process is solely for the purpose of using tecovirimat through the expanded access investigational drug pathway (EA-IND).

Patients should have had a PCR sent by the time a referral for treatment is placed. Referral is REF 1204, Referral for Monkeypox Outpatient Treatment.

1. If PCR is positive, OR if patient is high suspicion for monkeypox, patient is advised that tecovirimat 600mg po q12 (q8 if ≥ 120 kg) x 14 days can be considered **as an investigational drug (with no known efficacy)** if they have the following conditions:
 - a. Patients with severe disease, defined by evidence of sepsis or other clinical evidence of viremia, and lesion location or type
 - i. Lesion location or type: Confluent lesions, lesions in anatomical areas at special risk of scarring or stricture, such as those near or directly involving the eye, mouth, rectum, or urethra.
 - b. Patients with evidence of illness complications or patient hospitalization
 - i. Complications: Severe or difficult to control secondary bacterial infection (including sepsis), proctitis (particularly with tenesmus, challenges in pain control, or rectal bleeding), bronchopneumonia, and encephalitis
 - c. Patients at high risk for severe disease:
 - i. patients less than 8 years of age
 - ii. patients who are pregnant or breastfeeding
 - iii. patients with diseases that could increase risk of stricture or fistula such as inflammatory bowel disease
 - iv. Severe immunocompromising conditions:

People living with HIV who are not virally suppressed or have active opportunistic infection; hematologic malignancy; history of solid organ transplantation; hematopoietic stem cell transplant <24 months post-transplant or ≥ 24 months but with graft-versus-host disease or malignant disease relapse; any condition actively requiring chemotherapy, radiation, or continuous or high-dose systemic corticosteroids; and autoimmune disease requiring immunosuppression or with immunodeficiency as a clinical component.

- v. Significant dermatologic conditions include presence of atopic dermatitis or other active exfoliative skin conditions or infections (e.g., psoriasis, Darier disease [keratosis follicularis], eczema, impetigo, primary varicella, zoster, or herpes).
2. Notify Monkeypox Care Coordination team (REF 1204) (aka MAB team) if you desire treatment for your patient. They will help schedule patient for consent and intake.
 - a. MAB admin team contacts patient and provides: Informed Consent (via DocuSign soon), CTRC Nutrition Handout, NYDOH Supportive Care Handout.
 - b. MAB admin calls patient, gives patient information about NIH/DAID study and informs them that if they meet certain criteria they will be guaranteed treatment.
 - i. If patient wants to pursue study, Mab team gives patient contact information (study coordinators Maricela Gonzalez at 310 557 3759 or email to mmgonzalez@mednet.ucla.edu). MAB team also will let study coordinators know.
 - ii. If patient does not want to pursue study schedules ID evaluation via video visit into open slots within 24-48 hours of referral. (If referral occurs on a Friday night or over the weekend, then schedule NO LATER than Tuesday).
 - c. MAB admin to schedule patients at CARE or SM ID (TPOXX slots have been blocked on schedules).
 - d. Clinician sees patient and submits order via eRX (choose eRx with IRB number 22-5008), notifies MABTeam@mednet.ucla.edu and PharmacyIDS@mednet.ucla.edu that patient will be signing consent and order is in. Clinician includes patient MRN in email. Clinician also fills smartphrase .monkeypoxpatientintake in Care Connect note. Clinician counsels patient to take oral capsule with a full glass of water after eating food twice a day (three times a day if weight is ≥ 120 kg)
 - e. MAB admin team follows up with patient to obtain signed consent and sends signed consent for clinician to sign. Clinician emails back consent to MABTeam@mednet.ucla.edu and PharmacyIDS@mednet.ucla.edu.
 - f. MAB Team responds to email with patient name, MRN, address and phone number.
 - g. IDS coordinates delivery of medication, responds to MAB admin email. MAB admin to assist with delivery coordination if necessary and communicates with patient with courier and tracking information.
 - h. CTRC RN/MAB RN to place Form A in box folder. MAB Team to place informed consent in box folder. MAB Team sends informed consent and Form A to regaffairs@cdc.gov and Form A alone to TPOXX@ph.lacounty.gov
 - i. MAB Admin enter patient information in log in secure Box folder
 - j. CTRC/MAB RN to contact patient for check in 3-5 days after patient starts treatment, cc's clinician in telephone encounter. If patient desires follow up with clinician, RN notifies clinician to coordinate.
 - k. All adverse events must be reported by ordering clinician

UCLA Health, Monkeypox Treatment Team Workflow, 09_13_22

Please note that if the patient is a Kaiser patient, there is an available resource for them at Kaiser. Would email Dr. Hema Buddha (Hema.V.Buddha@kp.org) and the Expanded Access Program at RE-ExpandedAccessProgram@kp.org

Referral for Monkeypox Outpatient Treatment [Accept] [Cancel]

Class: Internal Referral | Internal Referral | External Referral

Referral: Override restrictions

To dept: MSS INFECTIONIOUS | MSS INFECTIONIOUS DIS MP2

To dept spec: Medicine, Infectio | Medicine, Infectious Disease

Reason: Specialty Services | Specialty Services Required | Second Opinion | Patient Preference

Priority: Routine | Routine | Urgent | Elective

of visits: 1

1 Patients may enroll in an NIH-sponsored clinical trial that provides treatment with tecovirimat (severe or high risk) OR a randomized study (for mild disease). Is patient potentially interested participating in the study?
Yes, patient is willing to be contacted by study coordinators (Maricela Gonzalez: 310-557-3759 | email mmgonzalez@mednet.ucla.edu)
No, patient is unwilling to be contacted by study coordinators

1 Patients with specific lesion location or type
 Eye Mouth Rectum Urethra Other Painful Lesions N/A

1 Patients with proctitis (particularly with tenesmus, challenges in pain control, or rectal bleeding)
Yes No

1 Patients at high risk for severe disease
 Patient is less than 8 years of age
 Patient with disease that could increase risk of stricture or fistula such as inflammatory bowel disease
 Significant dermatologic conditions include presence of atopic dermatitis or other active exfoliative skin conditions or infections
 Severe immunocompromising conditions (such as HIV with CD4 <200, transplant recipients, receiving immunosuppressive medication)
 N/A

1 Has Patient had Monkeypox PCR and STI Testing?
Yes No

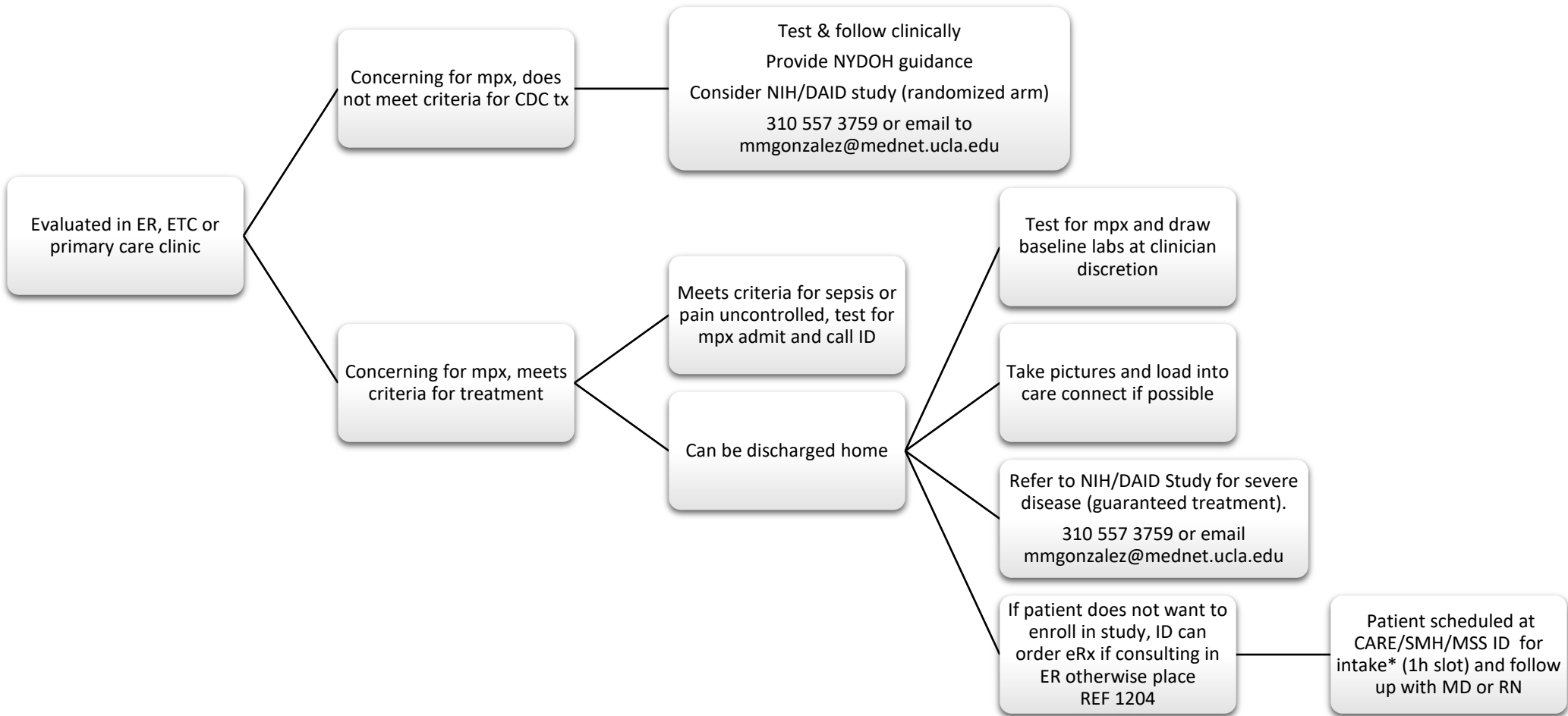
Comments: Jane Smith is 2 y.o.
Monkeypox results within past 14 days: Results for orders placed or performed in visit on 09/01/22
Monkeypox (Orthopoxvirus), PCR
Specimen: Thigh, Left; Lesion

Process Inst: Patients with evidence of illness complications should be referred to the hospital for management and NOT referred for outpatient therapy. These include:
Complications:
Sepsis or clinical evidence of viremia
Severe or difficult to control secondary bacterial infection (including sepsis),
Bronchopneumonia
Pneumothorax

Sched Inst: Schedulers: Appointment requests to be evaluated within 24-48 hours from referral creation date

[Next Required] [Accept] [Cancel]

If patient is seen in clinic, ETC, ER:



* intake and follow ups can be done via telehealth. If patient needs to be seen in person, clinic will be notified, and patients will be triaged accordingly to the appropriate clinic. Labs can be done in ID clinic if needed.