Process for obtaining tecovirimat (TPOXX) for the treatment of MPox

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 is a site for treatment trial to assess the efficacy of tecovirimat. **All patients should be referred to the STOMP trial team (PI Landovitz) first. You may contact Dr. Landovitz directly or if a referral is placed, the Mpox team (part of the Covid Outpatient Treatment Team) will also reach out to the study coordinators (as noted below).** The process below 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 Mpox (formerly known as Monkeypox) Outpatient Treatment.

1. If PCR is positive, OR if patient is high suspicion for mpox, patient is advised that tecovirimat 600mg po q12 (q8 if ≥120kg) 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:

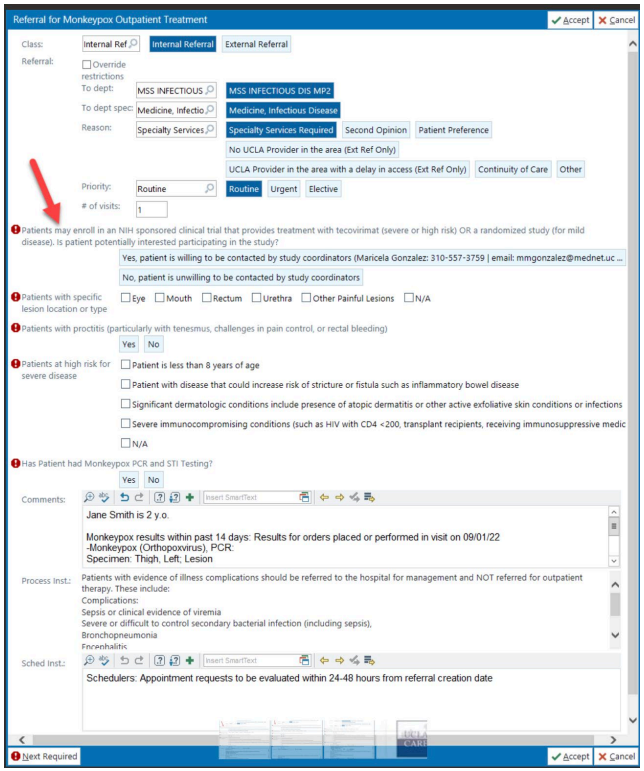
            People living with HIV who are not virally suppressed or have active opportunistic infection; hematologic malignancy; history of solid organ transplantation; hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or malignant disease relapse; any 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).

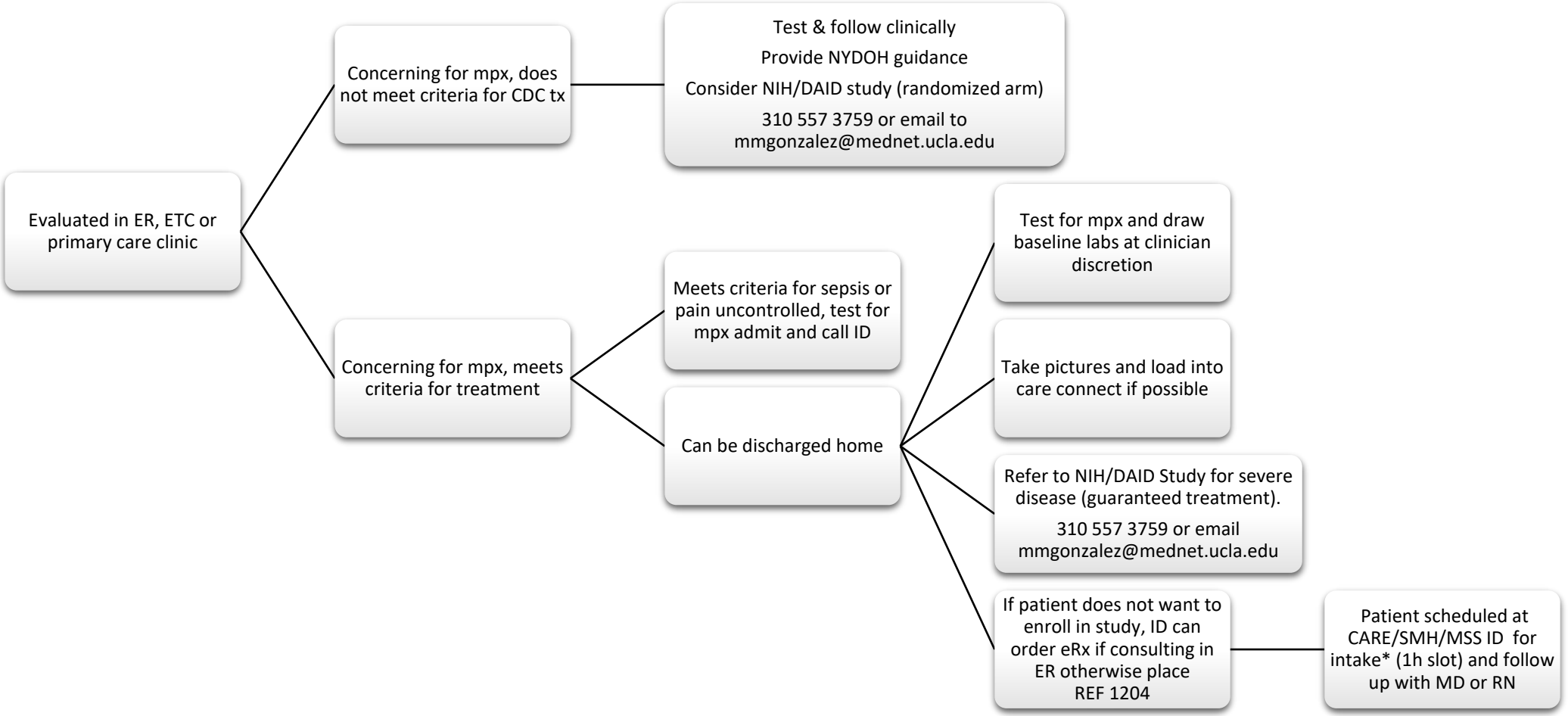
2. Notify Mpox Care Coordination team (REF 1204) (aka MAB team) if you desire treatment for your patient. They will help schedule patient for consent and intake.
    a. MAB admin team contacts patient and provides: Informed Consent, CTRC Nutrition Handout, NYDOH Supportive Care Handout.
    b. MAB admin 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. (There are currently no slots blocked for this due to low volume.)
        - **CARE Clinic (DEP: 70077)**
        - **SM ID (DEP: 70096)**
    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. Please manually fill out the new Form A. 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 ≥120kg)
    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. MAB team to place Form A in box folder. MAB Team to place informed consent in box folder. MAB Team sends Form A and consent to TPOXX@ph.lacounty.gov
    i. MAB Admin enter patient information in log in secure Box folder
    j. MD can contact patient for check in 3-5 days after patient starts treatment.
    k. All adverse events must be reported by ordering clinician

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



UCLA Health, Monkeypox Treatment Team Workflow, 06_09_23

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.

MAB Admin patient script:

As discussed with your physician, you may be eligible for TPOXX (tecovirimat), an investigational drug offered by the CDC. If you are interested in receiving this medication, I will send you a consent form with drug information, a nutrition handout and the recommendations for self-care and schedule you to see one of our Infectious Disease physicians via video who will discuss your condition and decide with you if this investigational medication is appropriate for you. If you decide to pursue the treatment, you will sign the consent and return to me. The medication will be ordered and sent directly to your home. It is an oral medication you take for 14 days. While a follow up visit is optional, we recommend touching base with either our nurses or our MDs at least once 3-7 days after completion of your treatment.