UCLA Health
Tecovirimat Process, 8/23/22

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. 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 ≥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 Monkeypox Care Coordination team (REF 1204) if you desire treatment for your patient. They will help schedule patient for consent and intake. The following is the process for individuals on the IRB.
    a. One 1572 needed per institution, already submitted. Bruin IRB: IRB-22-5008.
    b. Patient must sign informed consent, upload into Care Connect and send to PharmacyIDS@mednet.ucla.edu. Please try to include name, MRN, address and phone number in email if possible
    c. Order eRX, email PharmacyIDS@mednet.ucla.edu with phone number and address and cc admin (WW: Susana, Naomi, SM: Monica, Care: Mike). Patient is to take oral capsule with a full glass of water after eating food twice a day (three times a day if weight is ≥120kg)
    d. IDS coordinates delivery of medication, responds to your email
    e. Complete patient intake form (Form A) and send to CDC. Form A is now available as a smartphrase .monkeypoxintakeform Return completed consent and intake form +/- photographs to CDC within 7 days of starting tecovirimat by email: regaffairs@cdc.gov
    f. Enter patient information in log in secure Box folder
    g. Patient handouts include NYDOH and CTRC nutrition handouts
    h. Patient can be scheduled for telehealth within 3-14 days after treatment completion with one of the clinicians on the IRB and clinical outcomes forms are sent to regaffairs@cdc.gov. Send forms within 7 days of patient follow-up. Photos and labs are optional
    i. All adverse events must be reported

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

Workflow below.

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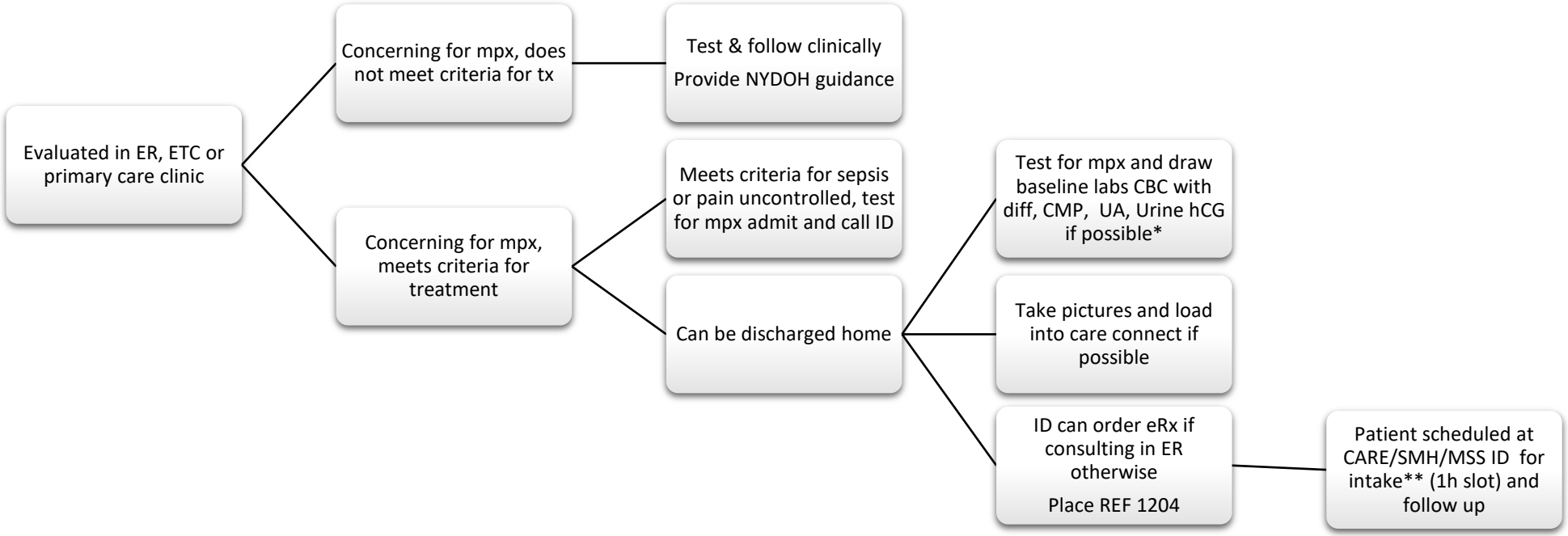
If patient is seen in clinic, ETC, ER:



*recommended if has hx of liver or kidney disease or immunocompromised or ≥65. If otherwise healthy, can forgo as long as patient has CBC

** 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.

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Workflow if patient is in CARE/MSS /SMH ID clinic: