Marin County Provider Packet

Tecovirimat (TPOXX)

August 2, 2022

Steps to Becoming a Tecovirimat (TPOXX) Provider

The use of tecovirimat (TPOXX) for monkeypox is under the Expanded Access—Investigational New Drug Application (EA-IND), which has been Centers for Disease Control and Prevention (CDC) Institutional Review Board (IRB)-approved and authorized by the Food and Drug Administration (FDA) to proceed.

Marin County health care providers and clinical facilities should determine readiness to obtain and use TPOXX for the treatment of active monkeypox.

1. Review the following documents:

    - Tecovirimat-IND-Protocol-CDC-IRB_July_20_2022
    - Tecovirimat IND_Form FDA 1572
    - List of CDC minimum requirements regarding tecovirimat treatment under the IND protocol (see Appendix A, below)

2. Clinical facility and/health care provider decide to become a tecovirimat provider.

    - Providers can either rely on the CDC IRB (recommended by CDC) or can submit the protocol to their local IRB for review. This decision is at the discretion of the provider and their clinical institution.
        - For facilities requiring a reliance agreement, CDC IRB will provide a pre-signed reliance agreement for facilities to sign documenting reliance on CDC IRB (huma@cdc.gov)

3. Submit required forms (see Appendix A, below) using one of the following methods:

    - Secure Share File for large file sizes (please zip multiple files and use filenames with patient identifier, hospital name, and date)
    - Email: regaffairs@cdc.com
    - Fax: 404-902-5921

4. Contact MHOAC to initiate the request process for Tecovirimat at MHOAC@marincounty.org or 415-473-3100.

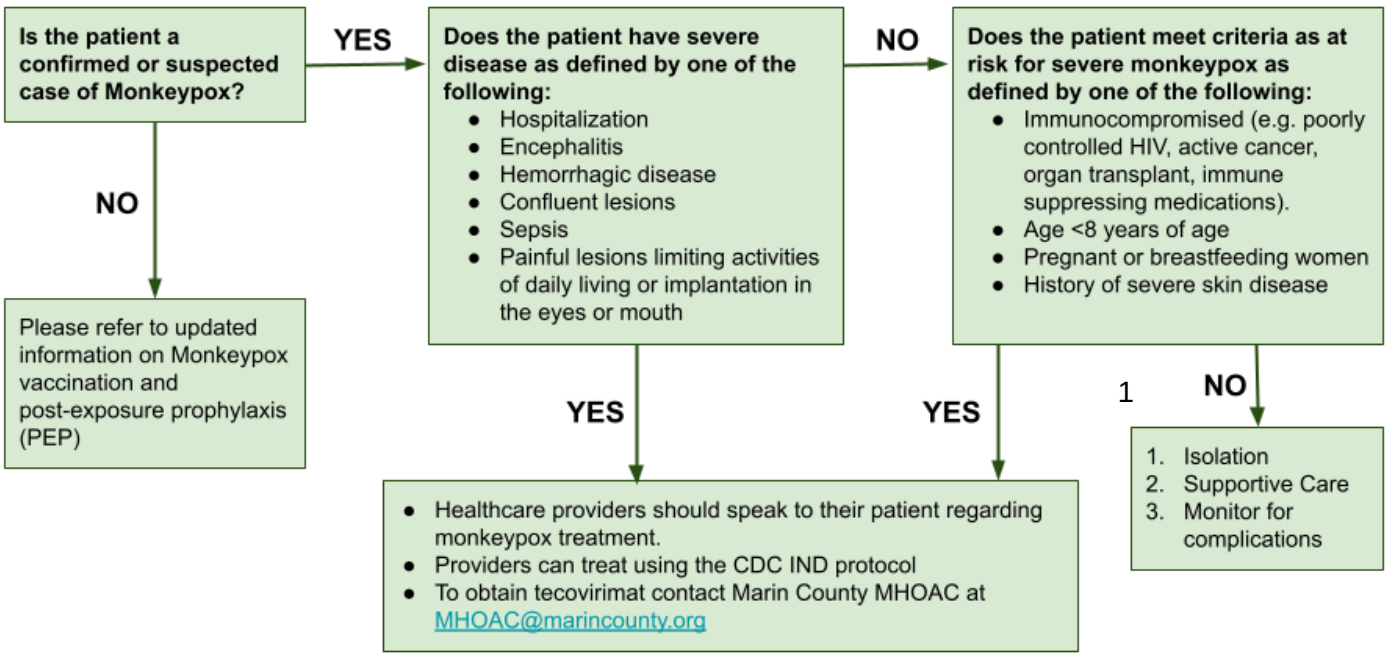
    - Providers will receive instructions on how to initiate a request through Salesforce.
    - Providers and their facility are expected to track their inventory of tecovirimat including number of treatments started and amount of medication supply still available.

Clinical Indications for Treatment

Eligibility is at the discretion of the provider.

- Please refer to Tecovirimat Treatment Algorithm below.
- A positive lab result is not necessary to initiate treatment. Tecovirimat treatment may be initiated for patients with laboratory confirmed non-variola orthopoxvirus infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease.
- Providers should notify Marin County Public Health when they initiate treatment. During business hours, call (415) 473-4163. After hours, call the Health Officer On Duty at (415) 499-7237.
- Tecovirimat may also be considered for post-exposure prophylaxis on an individual case by-case basis as reviewed in the protocol and in consultation with CDC (Emergency Operations Center [EOC] 770-488-7100; poxvirus@cdc.com).
- Pediatric patients may be treated under CDC-sponsored tecovirimat EA-IND protocol.

Tecovirimat Treatment Algorithm



Appendix A: Minimal Required Information

1. Informed Consent Form [5 pages]: Obtain prior to treatment. Notify CDC via email (regaffairs@cdc.gov) within 3 working days of tecovirimat initiation.
2. Patient Intake Form [3 pages]: Complete this form to provide patient's baseline condition prior to tecovirimat initiation. Return to CDC within 3 working days of initiation of therapy by email (regaffairs@cdc.gov) or upload to secure ShareFile.
3. FDA Form 1572 [2 pages]: Only one provider per clinical facility should submit this form. If it is an urgent situation, see Immediate Need process, below. Return to CDC within 3 working days of initiation of therapy by email (regaffairs@cdc.gov) or upload to secure ShareFile along with a CV of the point-of-contact physician.
4. Clinical Outcome Form [4 pages]: Progress information during and post treatment.
5. Serious Adverse Events: Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Immediate Need

If a provider has a non-pediatric patient in urgent need of treatment, the provider may proceed with tecovirimat treatment once informed consent has been obtained. Paperwork does not need to be completed to initiate treatment. If a pediatric patient requires treatment at this time, CDC requires use of a single-patient IND, which would require patient-level FDA authorization prior to administration.

- Indications for urgent treatment:
    - Hospitalization
        - Encephalitis
        - Sepsis
        - Hemorrhagic disease
    - Confluent lesions
    - Painful lesions limiting activities of daily living or implantation in the eyes or mouth
- If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment once informed consent has been obtained. The tecovirimat EA-IND protocol for monkeypox treatment has been reviewed and approved by the CDC IRB and no further patient-level approval is required from FDA in order to initiate treatment. Other steps listed above can be completed after the patient has initiated treatment.
- To obtain tecovirimat for an immediate need, call (415) 473-4163 during business hours (Mon - Fri, 9 am - 5 pm). After hours, call the On Call Health Officer (415) 499-7237.