

DEPARTMENT OF  
**HEALTH AND HUMAN SERVICES**

Promoting and protecting health, well-being, self-sufficiency, and safety of all in Marin County.

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## **PUBLIC HEALTH ADVISORY**

### **Monkeypox Virus Activity in Marin County | Increasing Access to Treatment**

Marin County Public Health (MCPH) is responding to a global outbreak of monkeypox in non-endemic countries, including the United States. This Advisory provides guidance for healthcare providers to obtain and use Tecovirimat (TPOXX) for the treatment of monkeypox.

#### **Background**

On July 21, 2022, Centers for Disease Control and Prevention Institutional Review Board issued a [non-research expanded access Investigational New Drug \(EA-IND\) protocol](#) to increase access to TPOXX for treatment of monkeypox.

Since then, the increasing use of TPOXX among eligible patients across the Bay Area suggests that treatment is generally well tolerated and can bring significant relief to patients with painful monkeypox lesions.

Marin County Public Health encourages health care providers to obtain and use TPOXX for the treatment of monkeypox when clinically indicated and with [informed consent](#).

#### **TPOXX (Tecovirimat) for Treatment of Monkeypox**

Marin healthcare providers should be alert for patients who have a rash [consistent with monkeypox](#), regardless of gender or sexual orientation. The [Jynneos Monkeypox Vaccine](#) is not a treatment for patients with monkeypox infections.

[Tecovirimat](#) may be considered for treatment in the following persons infected with Monkeypox virus (see [Treatment Algorithm](#) below):

- Patients with severe disease
- Patients at high risk of severe disease (i.e., immunocompromising conditions)
- Pediatric populations
- Pregnant or breastfeeding women
- Patients with history or presence of active exfoliative skin conditions (e.g., eczema, severe acne)
- Patients with one or more complication (e.g., secondary bacterial skin infection)
- Patients with mucosal lesions (incl. genital, perianal, mouth)

While there is no treatment approved specifically for monkeypox infections, antivirals developed for use in patients with smallpox seem to be beneficial against

monkeypox. [TPOXX](#) inhibits the orthopoxvirus VP37 envelope wrapping protein. Efficacy may be reduced in immunocompromised patients.

*Dosing and Administration:* Pediatric and Adult Patients weighing 40 kg or more (Oral Dosing): 600 mg of TPOXX every 12 hours for 14 days [Capsules 200 mg]

*Adverse Reactions:* The most common adverse reactions are headache, nausea, abdominal pain, and vomiting.

### **Actions Requested of Providers and Facilities**

1. Review the [TPOXX Provider Packet](#) and determine readiness to obtain and use TPOXX for the treatment of active monkeypox.
2. If you plan to obtain and use TPOXX, follow instructions in the Provider Packet including completing [FDA Form 1572](#) to become an Investigator under the CDC Expanded Access to Investigational Drugs for Treatment Use
3. Contact Marin County' Medical Health Operational Area Coordinator (MHOAC) by email [MHOAC@marincounty.org](mailto:MHOAC@marincounty.org) to order TPOXX.
4. Evaluate symptomatic persons. Consider monkeypox as a possible diagnosis in persons with a rash consistent with monkeypox, especially in men who have sex with men (MSM) with multiple partners.
5. Review clinical considerations ([links below](#)) for preventing, diagnosing, and managing monkeypox in people with HIV, children, adolescents, and people who are pregnant or breastfeeding.
6. Report suspect monkeypox cases to Marin County Public Health during business hours (Monday thru Friday). Call (415) 473-4163 or email [marinCD@marincounty.org](mailto:marinCD@marincounty.org).
7. Obtain [informed consent](#) and provide TPOXX to patients who would benefit from [non-research expanded access Investigational New Drug \(EA-IND\) protocol](#) for primary or early empiric treatment of monkeypox.
8. Providers may contact the Health Officer on call to review cases [in need of urgent treatment](#) after hours at (415) 499-7237.

### **Additional Resources**

- [Clinical Considerations for Monkeypox in People Who are Pregnant or Breastfeeding | Monkeypox | Poxvirus | CDC](#)
- [Clinical Considerations for Monkeypox in Children and Adolescents | Monkeypox | Poxvirus | CDC](#)
- [Clinical Considerations for Treatment and Prophylaxis of Monkeypox virus Infection in People with HIV | Monkeypox | Poxvirus | CDC](#)

**Marin County Provider Packet**  
Tecovirimat (TPOXX)

**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.

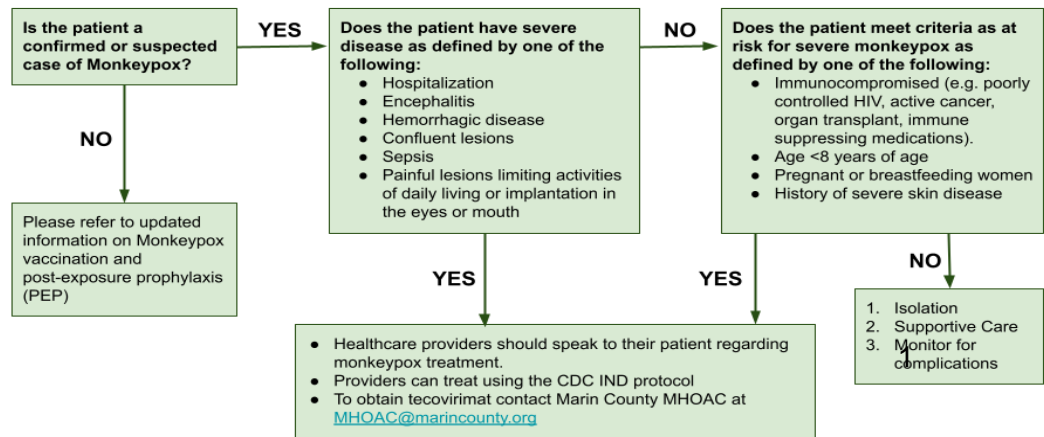
1. Review the following documents:
  - [Tecovirimat-IND-Protocol-CDC-IRB July 20 2022](#)
  - [Tecovirimat IND Form FDA 1572](#)
  - List of CDC minimum requirements regarding tecovirimat treatment under the IND protocol (see [Appendix A](#), below)
2. Clinical facility and/health care provider decide 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](mailto: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](mailto:regaffairs@cdc.com)
  - Fax: 404-902-5921
4. Contact MHOAC to initiate the request process for Tecovirimat at [MHOAC@marincounty.org](mailto: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 (Monday thru Friday), call (415) 473-4163 or [marinCD@marincounty.org](mailto:marinCD@marincounty.org).
- 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](mailto:poxvirus@cdc.com)).
- Pediatric patients may be treated under CDC-sponsored tecovirimat EA-IND protocol.

### Tecovirimat Treatment Algorithm



**Appendix A: Minimal Required Information for the Use of TPOXX**

1. [Informed Consent Form](#) [5 pages]: Obtain prior to treatment. Notify CDC via email ([regaffairs@cdc.gov](mailto: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](mailto: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](mailto: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: If any life-threatening or serious adverse events associated with TPOXX occur, complete a [PDF MedWatch Form \[3 pages\]](#) and returning it to CDC via email ([regaffairs@cdc.gov](mailto: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](#).

**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, please contact the Health Officer at 415-473-4163 or MHOAC at 415-473-3100 during business hours. After hours, please call 415-479-2311.