

HEALTH ALERT

August 30, 2022

Updated August 18, 2022, CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with Monkeypox (**MPX**) under Expanded Access Investigational New Drug (**EA-IND**) protocol. Tecovirimat efficacy for treatment of MPX disease in humans is unknown and undergoing evaluation. The streamlined process reduces the number of required forms and gives patients the option to see their doctor virtually.

How to obtain Tecovirimat (TPOXX) from Humboldt County Public Health Department

- Clinicians and care facility pharmacists requesting TPOXX should contact Humboldt County Public Health at (707)268-2108 to access pre-positioned TPOXX stock.
- Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent.

Healthcare providers should complete the following required forms:

1. **Informed Consent Form** [English \[261 KB, 5 pages\]](#) | [Spanish \[335 KB, 6 pages\]](#): Obtain prior to treatment. Notify CDC within 3 working days of tecovirimat initiation when the treatment determination was made based on the above-mentioned certification by the treating physician and an independent physician.
2. **Patient Intake Form [321 KB, 3 pages]**: Baseline assessment. Treating physician or designee should complete this form **prior** to tecovirimat initiation. Return to CDC within **7 calendar days** of initiation of therapy.
3. **FDA Form 1572 [1 MB, 2 pages]**: One signed 1572 per prescribing facility suffices for all TPOXX treatments administered under the EA-IND at the same facility. Return to CDC within **7 calendar days** of initiation of therapy.

Forms requested under the (EA-IND) can be returned to CDC **after** treatment begins. Please return completed forms to CDC via encrypted email (regaffairs@cdc.gov) or uploading to secure [ShareFile](#) (please zip multiple files and use filenames with patient initials, patient age, hospital/facility name, state, tecovirimat start date, and file contents [e.g., 1572, CV, Patient Intake Form]). Personally identifiable information should not be emailed without encryption.

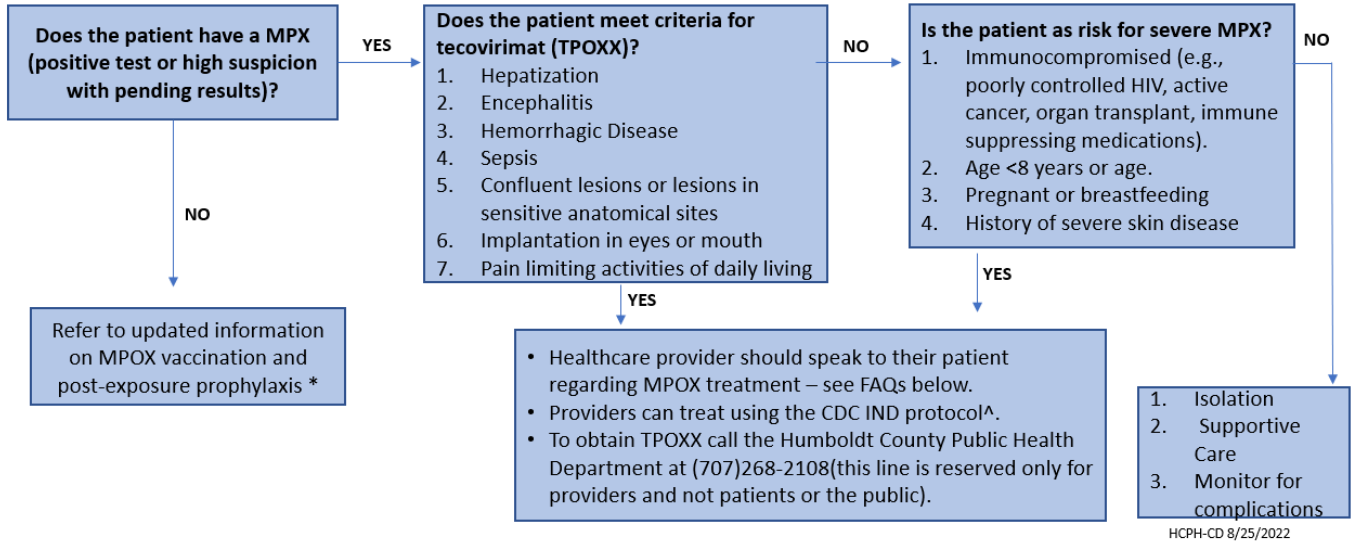
Immediate need – Patient with urgent tecovirimat need

If a provider has a 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. Forms requested under the EA-IND can be returned to CDC after treatment begins.*



Protocol

- Tecovirimat TPOXX is FDA-approved only for treatment of smallpox, CDC holds the protocol that allows access to and use of TPOXX for treatment of non-variola Orthopoxvirus infections, including monkeypox, in adults and children of all ages during an outbreak. TPOXX is available for use in Humboldt County for patients who meet the [CDC clinical criteria](#). (See Algorithm below).



HCPH-CD 8/25/2022

Algorithm footnotes

Adapted from [CDC Interim clinical guidance](#).

*See [Provider Communication from HCPH dated August 12, 2022](#)

[^][CDC IND protocol information](#)

Optional:

- [Clinical Outcome Form - Optional \[279 KB, 4 pages\]](#): Progress information during and post treatment.
- [Patient Diary \[296 KB, 2 pages\]](#): Ideally, give the diary to the patients during baseline assessment. Patient can use this form to record how they feel and any side effects to TPOXX.

Serious Adverse Events - REQUIRED REPORTING

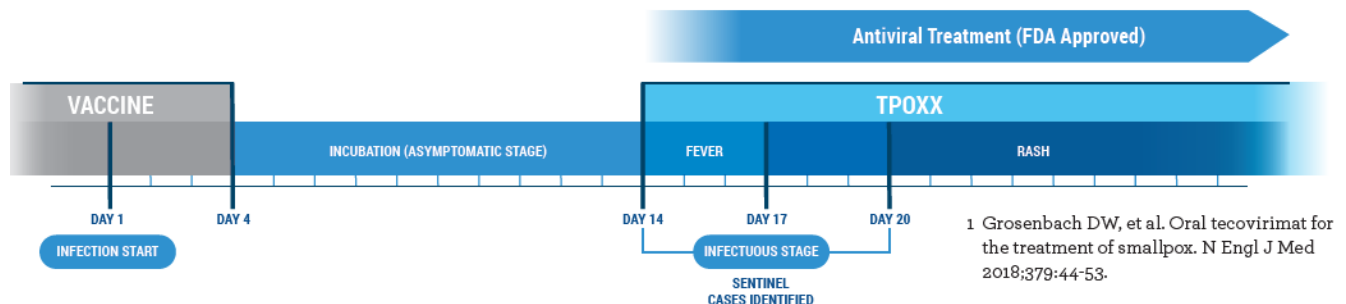
Report life-threatening or serious adverse events associated with TPOXX by completing a [PDF MedWatch Form \[956 KB, 5 pages\]](#) and returning it to CDC via email (regaffairs@cdc.gov) or uploading to [ShareFile](#) within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from [the FDA website](#).



Frequently Asked Questions about MPX Treatment with Tecovirimat

What drugs are available in Humboldt County Public Health for the treatment of MPX? Tecovirimat (TPOXX) is an investigational new drug available for the treatment of MPX and is available in Humboldt County Public Health for patients with severe MPX disease, including those with lesions or pain that interferes with the activities of daily living, and patients at high risk for severe disease. TPOXX is an antiviral medication available through an expanded access Investigational New Drug (EA-IND) protocol for the treatment of MPX infection. Informed consent is required for all patients treated with tecovirimat. Tecovirimat is available in oral and intravenous formulations. While data is not available on the effectiveness of tecovirimat in treating MPX infections in people, animal studies have shown it is well tolerated and effective in treating disease, improving resolution time of illness and reducing the risk of complications from Orthopoxviruses. Clinical trials in people have shown the drug is safe with few drug interactions and minor side effects, most commonly headache and nausea. One case report describes a shortened duration of illness and viral shedding in a patient who received tecovirimat (Adler, 2022).

[TPOXX FACT SHEET - SIGA Technologies](#)



Dosage and Administration of Tecovirimat (TPOXX)

Dose adjustment for patients <80kg, but not for hepatic or renal disease.

- [Expanded Access IND Protocol: Use of Tecovirimat \(TPOXX®\) for Treatment of Human Section 4.0 Dosage and Administration of TPOXX - Expanded access IND protocol for tecovirimat is held by the CDC](#)
- [Highlights of Prescribing Information TPOXX - SIGA Technologies](#)
- [TPOXX FACT SHEET - SIGA Technologies](#)
- [Instructions for Opening and Mixing Tecovirimat Capsules with Food](#)

Resources

- [CDC: Expanded Access IND Protocol: Use of Tecovirimat \(TPOXX®\) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children protocol \(version 6.1 dated August 10, 2022\) \[495 KB, 22 pages\]](#)
- [CDC: Instructions for Opening and Mixing Tecovirimat Capsules with Food \[287 KB, 1 page\]](#)
- [Information for Healthcare Providers on Obtaining and Using TPOXX \(Tecovirimat\) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC](#)
- [CDC: Institutional Review Board \(IRB\) Approval of Amendment #6 of the Expanded Access Investigational New Drug \(IND\) protocol "Use of Tecovirimat \(TPOXX®\) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children", Version 6.1 \(IND 116039/CDC #6402\) CDC IRB approved \[134 KB, 1 page\]](#)

