



## Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox

CDC, in partnership with FDA, has made it easier for healthcare providers to provide tecovirimat (TPOXX) treatment to patients with monkeypox under Expanded Access-Investigative New Drug (EA-IND).

### TPOXX should be considered for use in people who have:

- Severe disease — meaning that someone has a condition such as hemorrhagic disease, confluent lesions (individual sores have joined into one larger sore), sepsis, encephalitis, eye infections, or other infections that require hospitalization
- Involvement of anatomic areas which might result in serious disease including scarring

### TPOXX should also be considered for use in people who are at high risk for severe disease, including:

- People with immunocompromising conditions
- Children, particularly patients younger than 8 years of age
- People who are pregnant or breastfeeding
- People with certain skin infections



TPOXX is available as oral capsules. Each capsule contains 200 mg of tecovirimat active ingredient and comes in bottles containing 42 capsules each. TPOXX for injection is available in a single-dose vial containing 200 mg of tecovirimat in 20 ml. Oral dosing for adults, children, and adolescents is found in Table 1

**Table 1. Recommended Oral Dosage Instructions for 14 Days**

Weight (kg)	Weight (lbs)	Recommended Dose
< 6	< 13	50 mg (¼ capsule) every 12 hours
6 to < 13	13 to < 28	100 mg (½ capsule) every 12 hours
13 to < 25	28 to < 55	200 mg (1 capsule) every 12 hours
25 to < 40	55 to < 88	400 mg (2 capsules) every 12 hours
40 to < 120	88 to < 264	600 mg (3 capsules) every 12 hours
120 and above	≥ 264	600 mg (3 capsules) every 8 hours

\* Tecovirimat capsules should be taken within 30 minutes after a full meal containing moderate or high fat. Treatment duration is 14 days but may be longer (not to exceed 90 days) or shorter depending on the progression of the disease and clinical condition of the patient. Data on duration other than 14 days are limited.

[Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Monkeypox Outbreak | Monkeypox | Poxvirus | CDC](#)





## How to obtain TPOXX

- TPOXX is available through the Strategic National Stockpile, and
  - Houston Health Department has pre-positioned supplies of TPOXX. Clinicians and care facility pharmacists requesting TPOXX should contact the health department at 832-393-4220. Pre-positioned supply may be the fastest route to obtain TPOXX.
- Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent.
- 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](mailto: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.

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**For urgent clinical situations after hours, providers may contact the CDC Emergency Operations Center (770-488-7100) for clinical consultation on patient cases.**



## Protocol

- Because TPOXX is FDA-approved only for treatment of smallpox, CDC holds a protocol (version 6.1 dated August 10, 2022) to allow access to and use of TPOXX for treatment of non-variola orthopoxvirus infections, including monkeypox, in adults and children.
- The TPOXX EA-IND protocol is intended to be used in concert with CDC's guidance for treatment.
  - The protocol includes instructions for mixing TPOXX capsules with food: This patient instruction sheet explains how to open TPOXX capsules and mix with breastmilk, infant formula, milk or food for infants and children who cannot swallow pills.
- The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs.
- The EA-IND also provides liability coverage under the PREP Act for compensation to patients if seriously injured via the Countermeasures Injury Compensation Program (CICP).
- On August 13, 2022, CDC IRB approved a protocol amendment; continuation was approved on July 20.
- Clinicians, care facilities, and hospitals providing TPOXX can immediately transition to the revised protocol and forms (version 6.1 dated August 10, 2022). Healthcare providers should complete the following forms:

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## Follow these steps to prescribe tecovirimat for eligible patients:

### Required Forms (1-4)

1. Have the patient complete an [Informed Consent Form: English](#)  
Obtain prior to treatment.
  - a. Other languages are available on CDC website:
    - Arabic • Korean • Russian • Simplified Chinese • Spanish • Tagalog • Vietnamese
  - Alternative Consent Forms that can be used to obtain informed consent:
    - English • Arabic • Korean • Simplified Chinese • Russian • Spanish • Tagalog • Vietnamese
2. Complete [Patient Intake Form](#): Baseline assessment.
3. Complete [FDA Form 1572](#): One signed 1572 and treating clinician's CV per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
  - a. The form, once submitted, will cover all prescriptions for that provider and all listed providers within a facility.
  - b. Facilities and providers can enroll at any time and submit this form in advance of prescribing tecovirimat to patients.
  - c. If submitting for the first time to prescribe tecovirimat for a patient, it should be submitted within seven days of starting treatment for the patient.
4. Complete (if applicable) [Serious Adverse Events Form](#): Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form 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. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)



## Optional

- **Patient diary:** 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.
- **Clinical Outcome Form:** Progress and outcome information post treatment.
- **Photos of lesions:** If feasible, take lesion photos at baseline prior to TPOXX treatment, and post-treatment to follow lesion progression and healing during treatment.
- **Lesions samples for resistance testing:** Ideally, a sample from at least 1 lesion prior to TPOXX treatment but only if baseline diagnostic testing wasn't performed, as well as samples from any new lesions that develop during and after TPOXX treatment to assess for development of antiviral resistance mutations. Optional Lesion Samples for Resistance Testing has instructions on collection, storage, and submission of samples.
- **Pharmacokinetic samples for testing:** During TPOXX treatment, plasma samples may be collected to monitor TPOXX levels for adequate drug exposure in patients. Optional Pharmacokinetic Samples for Testing has instructions on collection, storage, and submission of samples.

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## Institutional Review Board (IRB) Approval

- CDC IRB serves as the central IRB for review and approval. Facilities may elect to rely on the CDC IRB for centralized review and approval by submitting a request to the CDC's Human Research Protection Office within 7 calendar days of tecovirimat treatment at your facility. CDC will promptly document an agreement in writing using the CDC IRB Authorization Agreement (Sample Template) which must be signed by both parties.
- Facilities that elect to obtain their own IRB review must ensure compliance with applicable FDA regulations related to the TPOXX EA-IND protocol. Note that the posted TPOXX EA-IND protocol and the attachments must be used without any changes being made by the IRB.
- Since this TPOXX EA-IND protocol is solely for treatment use, CDC determined that its use does not constitute research involving human subjects as defined by 45 CFR 46.102, therefore, the federal-wide assurance requirements do not apply.