



Tecovirimat (TPOXX) Ordering and Dispensing Process

Tecovirimat, also known as TPOXX, is an antiviral drug that is FDA approved for the treatment of smallpox. TPOXX is available for the treatment of monkeypox under a CDC non-research Expanded Access Investigational New Drug (EA-IND) protocol.

Because TPOXX is an investigational drug, patients must meet criteria (specified in this link: [MonkeyPox Provider Form](#)) and have a medical provider, who obtains consent, completes CDC required forms, and monitors the patient throughout treatment and evaluates potential patient reported adverse reactions. Pima County Health Department (PCHD) will process your TPOXX order once the following information has been received: completed and signed PCHD electronic ordering form, signed CDC consent form, valid prescription, and patient medication reconciliation form (if available).

Ordering and Dispensing Process:

- Complete this electronic PCHD TPOXX Ordering Form: [MonkeyPox Provider Form](#)
- Please contact the PCHD EPI Team at 520-724-7797 or epi@pima.gov if you have questions or are having difficulty completing the form.
- Once EPI Team receives your completed electronic TPOXX Ordering Form, they will reach out to you with questions. If there are no questions, than PCHD EPI Team member will provide the documentation to a dispensing pharmacy and that pharmacy will dispense to your patient.

CDC requires the treating physician to complete the following CDC Forms:

- **Informed Consent**—must be obtained prior to treatment.
 - Physician must maintain in the patient's medical record and provide a copy to the patient
 - [INFORMED CONSENT/ PARENTAL PERMISSION FORM FOR TECOVIRIMAT TREATMENT UNDER AN EXPANDED ACCESS INVESTIGATIONAL NEW DRUG \(IND\) PROGRAM \(cdc.gov\)](#)
 - [CONSENTIMIENTO INFORMADO/FORMULARIO DE PERMISO PARENTAL PARA EL TRATAMIENTO CON TECOVIRIMAT \(cdc.gov\)](#)
- **Patient Intake Form: Baseline Assessment.**
 - Physician must return to CDC within 7 calendar days of initiation of therapy by email or uploaded to the CDC secure portal:
 - Email: regaffairs@cdc.gov
 - CDC secure portal: [Centers for Disease Control \(sharefile.com\)](https://sharefile.com)



- **FDA Form 1572**—One signed 1572 form per facility allows for all TPOXX treatments administered under the EA-IND at the same facility
 - [FORM FDA 1572 \(cdc.gov\)](#)
 - Physician to submit within 7 days of treating first patient.
- **Serious Adverse Events**—must be completed for life threatening or serious adverse events associated with TPOXX
 - [FORM FDA 3500 \(cdc.gov\)](#)
 - Physician must submit within 72 hours of awareness or sooner, if possible
 - Email: regaffairs@cdc.gov
 - CDC secure portal: [Centers for Disease Control \(sharefile.com\)](#)

CDC Physician Optional Forms and Testing:

- Patient diary: provided to the patients during baseline assessment so that patients can record how they feel and any side effects to TPOXX.
 - [FORM C: Patient Diary - Tecovirimat Capsules \(cdc.gov\)](#)
- Clinical Outcome Form: Provides progress information during and post treatment.
 - [Optional Clinical Outcome Form \(cdc.gov\)](#)
 - Physician has option to conduct patient follow-up within 3-14 calendar days after completion
 - Physician returns within 7 calendar days of last patient follow-up.
 - Email: regaffairs@cdc.gov
 - CDC secure portal: [Centers for Disease Control \(sharefile.com\)](#)
- Lesion samples for resistance testing
 - Only, if baseline diagnostic testing wasn't performed prior to TPOXX treatment
 - Samples from any new lesions that develop during and after TPOXX treatment can be submitted to assess for development of antiviral resistance mutations.
 - [Attachment 4: Optional Lesion Samples to CDC for Resistance Testing](#)
 - If requested, EPI to coordinate through ADHS EPI.
- Pharmacokinetic samples for testing:
 - During treatment, plasma samples may be collected to monitor TPOXX levels for adequate drug exposures in patients.
 - [Attachment 5: Optional Pharmacokinetic Samples for Testing at Alturas Analytics \(cdc.gov\)](#)
 - If requested, EPI to coordinate through ADHS EPI.



For Reference – CDC TPOXX Protocol

- CDC Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat):
 - <https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html>
 - updated on August 18, 2022

- CDC Expanded Access IND (EA-IND) Treatment for adults and children:
 - [Tecovirimat-IND-Protocol-CDC-IRB.pdf](#)
 - Version 6.1, dated August 10, 2022, 22 pages
- 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)
 - <https://www.phe.gov/Preparedness/legal/prepact/Pages/prepqa.aspx>
 - [Countermeasures Injury Compensation Program \(CICP\) | HRSA](#)
- CDC IRB amendment approved a protocol amendment:
 - [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 \(IND 116039/CDC #6402\)](#)