Erie County Department of Health
Public Health
Prevent. Promote. Protect.
606 W. Second St.,
Erie, PA 16507
Phone: 814-451-6700
Toll free: 1-800-352-0026
eriecountypa.gov/health

TPOXX Expanded Access Investigational New Drug (EA-IND) Protocol

As of Sept. 2, 2022

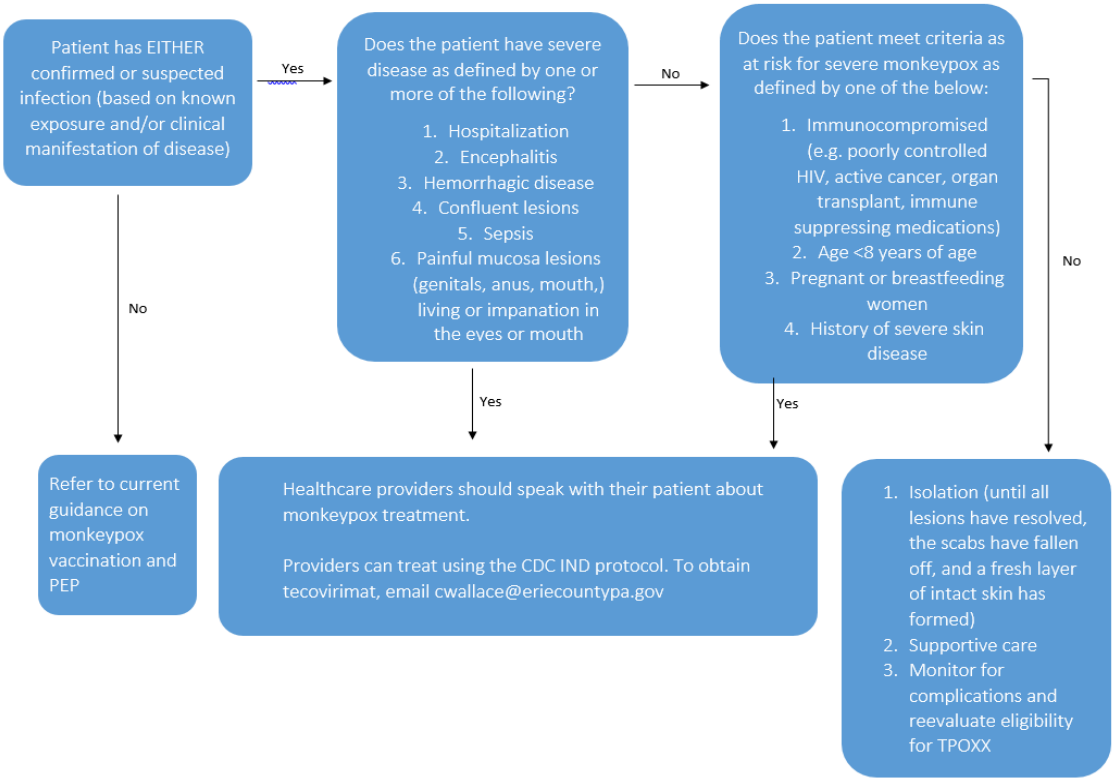
Treatment for monkeypox

Tecovirimat (TPOXX) is a Food and Drug Administration (FDA)-approved antiviral medication for the treatment of smallpox. The Centers for Disease Control and Prevention (CDC) holds an expanded access Investigational New Drug (EA-IND) protocol that allows for the use of stockpiled TPOXX to treat monkeypox. TPOXX is available for use in patients who meet the CDC's clinical criteria (see algorithm below). Informed consent is required for all patients treated with TPOXX.

While the effectiveness of TPOXX in treating monkeypox has not been evaluated, it is reasonable to anticipate potential treatment benefits based on animal efficacy data that supported FDA-approval for smallpox treatment and limited clinical uses of tecovirimat in the treatment of non-variola orthopoxvirus infected individuals.

The risk of TPOXX in people with monkeypox is not known. In the limited data available, it has only caused minor side effects. Safety and side effects have not been studied in immunocompromised individuals, pregnancy, breastfeeding, and pediatrics.

If the patient is not a candidate for pharmacological treatment of monkeypox, supportive and symptomatic care such as fluids, antipyretics and pain control is recommended. If the patient's monkeypox disease worsens, they should be re-assessed for TPOXX therapy.



Obtaining Tecovirimat (TPOXX)

Erie County Department of Health (ECDH) has a supply of oral TPOXX for transfer to area providers. If IV therapy is required, the ECDH can assist in facilitating transfer of the medication from the Pennsylvania Department of Health.

Health care providers who determine that their patients require TPOXX treatment will do the following

1. Obtain **Informed Consent** prior to treatment – **this must be completed before TPOXX can be transferred.**

2. Complete the **Patient Intake Form.**

3. Determine a designee to accept/receive the medication, this designee will be required to sign a form confirming the transfer of TPOXX.

4. Call the ECDH at 814-636-7351 or 814-451-6700 option 2.
   Outside normal business hours call 814-451-6700; please notify the answering service that you are a provider that needs to speak with the nurse on call.

5. Provide the following information to ECDH staff:
   - Patient's Name
   - Patient's DOB
   - Number of bottles of TPOXX needed (determined by patients weight)
   - Patients weight
   - Confirmation the **Informed Consent** (will also be sent to CDC with other required forms) has been signed
   - Confirmation the **Patient Intake Form** (will also be sent to CDC with other required forms) is completed
   - Ordering providers contact information and credentials (MD, DO, CRNP)
   - Name of designee accepting the medication on behalf of the provider

6. After coordinating with ECDH staff, arrange pick-up at
   Erie County Department of Health
   606 W Second St., Erie
   PA 16507
   There may be times the staff at ECDH can deliver to your facility.

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
  - 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.
- **When forms are sent to the CDC, copy ECDH cwallace@eriecountypa.gov and jdiprinzio@eriecountypa.gov.**

Required

1. **Informed Consent Form** Obtain prior to treatment.
   English [238 KB, 6 pages] | Spanish [263 KB, 7 pages]
   Arabic [308 KB, 6 pages] | Korean [431 KB, 7 pages] | Russian [245 KB, 7 pages]
   Simplified Chinese [316 KB, 6 pages] | Tagalog [243 KB, 7 pages] | Vietnamese [338 KB, 7 pages]

   Alternative Consent Forms that can be used to obtain informed consent:

   Short Form
   Short Form (English) [155 KB, 3 pages] | Spanish [140 KB, 4 pages]
   Arabic [188 KB, 3 pages] | Korean [304 KB, 3 pages] | Russian [173 KB, 4 pages]
   Simplified Chinese [211 KB, 3 pages] | Tagalog [121 KB, 4 pages] | Vietnamese [225 KB, 4 pages]

   Written Summary
   Written Summary (English) [229 KB, 5 pages] | Spanish [284 KB, 6 pages]
   Arabic [290 KB, 5 pages] | Korean [462 KB, 6 pages] | Russian [364 KB, 6 pages]
   Simplified Chinese [347 KB, 5 pages] | Tagalog [249 KB, 6 pages] | Vietnamese [466 KB, 6 pages]

2. **Patient Intake Form [385 KB, 2 pages]:** Baseline assessment.

3. **FDA Form 1572 [1 MB, 2 pages]:** One signed 1572 and treating clinician's CV per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.

4. **Serious Adverse Events:** Per FDA requirement, 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. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

Optional

- **Patient diary [180 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.

- **Clinical Outcome Form [383 KB, 2 pages]:** 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 [106 KB, 1 page] 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 [375 KB, 4 pages] has instructions on collection, storage, and submission of samples.

https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Protocol-CDC-IRB.pdf

Summary of Clinical Assessment and Monitoring Parameters

Parameters \ Days	Pre-Tecovirimat Treatment [a]	Post Completion of Tecovirimat Treatment [a]
	Patient Intake Form (Attachment 2 -A)	**Optional Clinical Outcome Form (Attachment 2 -B)**
	Prior to first dose of Tecovirimat (≤ 24 hours)	**Outpatients: 3-14 Days after treatment completion**
Sign Informed Consent	x	N/A
Inclusion/Exclusion Criteria	x	N/A
Baseline clinical assessment Give patient the Diary form[c]	x	N/A
Clinical progress	N/A	x
Serious Adverse Events[d]	N/A	Report if SAEs occur
Lesion Photos[b]	Optional	Optional
Hematology, chemistry, urinalysis	Optional	Optional
Lesion samples	Optional	Optional (for any new lesions post-treatment)
PK samples	Optional	

a For outpatients, assessment may be conducted via telemedicine.
b Optional digital photos of lesions at baseline and during therapy, if feasible.
c Give Patient Diary form to the patient for completing and returning directly to CDC by the patient.
d SAEs must be reported by emailing a completed fillable PDF MedWatch Form to CDC (***regaffairs@cdc.gov***) within 72 hours of awareness or sooner if possible.