Checklist for providers to initiate treatment with tecovirimat (TPOXX)

Clinicians, care facilities, and hospitals are able to access TPOXX through <u>CDC'S Expanded</u> Access Investigational New Drug (EA-IND) only:

- 1. Updated eligibility protocol (Version 6.4 dated June 5, 2024)
 - a. Eligibility criteria are outlined in Section 2.0 of the protocol
- 2. All providers and facilities need to register with the <u>TPOXX IND Online Registry</u> as participating providers and facilities to utilize the CDC EA-IND TPOXX protocol to provide TPOXX and submit forms.

All CDC EA-IND needed forms and information available on the <u>CDC Tecovirimat (TPOXX)</u> for Treatment of Mpox Website

Once CDC EA-IND forms are completed, Los Angeles County healthcare providers can prescribe TPOXX by utilizing one of the following routes:

- Dispensing from onsite TPOXX stock
- Prescribing directly to a community pharmacy which carries tecovirimat (TPOXX) and sending the required forms
- Calling the DPH healthcare provider line at <u>213-368-7441 (Weekdays 8:00am-4:30pm)</u> or <u>213-974-1234 (Weekends and Holidays: 8:00am-5:00pm, or evenings (urgent situations)</u> or emailing <u>TPOXX@ph.lacounty.gov</u> to request assistance



Required steps to prescribe TPOXX via CDC EA-IND route:

1. Obtain informed consent prior to treatment (one per patient)

- a. Informed Consent Form English | Spanish
- b. Alternative Short Form Consent and Written Summary can also be used.
- c. Clinicians should explain that tecovirimat is an investigational new drug (IND) and is not approved yet for treatment of mpox.
- d. If utilizing a community pharmacy for dispensing TPOXX, send a copy to the pharmacy for their records as required
- e. Store in patient records (no need to submit to CDC or DPH).

2. Complete Patient Intake Form (one per patient)

- a. Conduct baseline assessment
- b. For each patient, the clinician completes the patient intake form
 - i. Ensure weight, medication list and allergies are included
- c. Clinician fills and submits patient intake form online via TPOXX IND Online Registry within 3-7 calendar days of patient completing TPOXX treatment
- d. If utilizing a community pharmacy for dispensing TPOXX, send a copy to the pharmacy for their records as required

3. Complete FDA Form 1572 (once per facility).

- a. Facility completes and signs the form *one time only* online via <u>TPOXX IND</u> <u>Online Registry</u>; one signer must be a physician.
- b. Only one 1572 form is required per facility for all TPOXX treatments dispensed or prescribed regardless of the prescriber.
 - i. All clinic providers can be added under section 6 (sub-investigators) but this is optional and not needed in order to prescribe.
 - ii. For clinics: IRB section can be left blank since CDC IRB has approved.
 - iii. For research institutions: request exemption/determine whether your IRB will defer to CDC IRB
- c. If utilizing a community pharmacy for dispensing TPOXX, send a copy to the pharmacy for their records as required
- d. Store form on file to be used for all patients/treatments/external partners moving forward.

4. Prescribe directly to a community pharmacy which carries tecovirimat

a. Prescribe directly to pharmacy (e-prescribe or written)



- i. Example: Oral tecovirimat 600mg twice daily for 14 days if patient weights < 120 kg or three times per day if patient weighs ≥ 120 kg with a full glass of water 30 minutes after eating a full meal of moderate or high fat
- b. Fax or e-mail the below required documents:
 - i. Patient Informed consent
 - ii. Form 1572 (once)
 - iii. Completed patient intake form (must list weight, medication list and allergies)
 - iv. Patient facesheet (contact, address)
- 5. Providers with onsite TPOXX stock can dispense directly from their stock
 - a. Please make sure that all EA-IND forms are completed and submitted via the TPOXX IND Online Registry.
- 6. Complete the Clinical Outcome Form (optional, one per patient)
 - a. This form focuses on the progress and outcome information post treatment
 - b. Access to the form is via the <u>TPOXX IND Online Registry</u> and must be completed within 7 days of the last patient follow up visit

7. Reporting Serious Adverse Events:

- a. Per FDA requirement, report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form
- b. Once completed, then send to CDC via email (regaffairs@cdc.gov) within 72 hours of awareness or sooner, if possible
 - i. 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.)



List of Los Angeles County community pharmacies that carry TPOXX

Participating pharmacy locations

986 PHARMACY TEMPLE CITY

9612 Las Tunas Dr. Temple City, CA 91780 (626) 309-5052

CARSON PHARMACY

21720 S Vermont Ave Ste 101 M-F: 9:30am - 6:30pm Torrance, CA 90502 (310) 328-0982

COSMED PHARMACY

6521 Van Nuys Blvd Van Nuys, CA 91401 (818) 933-2010

EDDIE'S PHARMACY

8408 Beverly Blvd Los Angeles, CA 90048 (310) 358-2400

ELEMENTS PHARMACY

12602 Ventura Blvd Studio City, CA 91604 (818) 762-2055

M-F: 9am - 6pm Sat: 9am - 4pm Sun: Closed

Hours:

Sat: 9:30am - 4pm Sun: Closed

Hours:

M-F: 9am - 7pm Sat: 9am - 4pm Sun: Closed

Hours:

M-F: 9am - 6pm Sat: 9am - 1pm Sun: Closed

Hours:

M-F: 9am - 6pm Sat: 9am - 4pm Sun: Closed

WHITE MEMORIAL MEDICAL PLAZA PHARMACY

1701 E Cesar E Chavez Ave Suite 109 Los Angeles, CA 90033 (323) 221-6000

HEALTHRX PHARMACY

1844 E. RTE 66 Glendora, Ca 91740 (626) 335-4777

Hours:

Hours:

Hours:

M-F: 9am - 7pm Sat: 10am - 3pm Sun: Closed

M-F: 9am - 5pm

Sat-Sun: Closed

M-F: 9am - 7pm

Sat: 9am - 2pm

M-Th: 8:30am - 6:30pm

Fri: 8:30am - 6pm

Sat-Sun: 9am - 2pm

M-F: 10am - 5:30pm

Sat-Sun: Closed

Sun: Closed

LA COMPOUNDING PHARMACY

8600 W 3rd St #1 Los Angeles, CA 90048 (310) 362-4122

MEDEX PHARMACY

8441 Foothill Blvd Los Angeles, CA 91040 (818) 925-1321

MICKEY FINE PHARMACY

433 N Roxbury Dr Beverly Hills, CA 90210 (310) 271-6123

PRICE CARE PHARMACY

10837 Downey Ave Downey, CA 90241 (562) 825-5923

Hours:

M-F: 8:30am - 6:30pm Sat: 9am - 1:30pm Sun: Closed



Requesting a pre-positioned stock of oral TPOXX stock for your facility

For clinics or health systems that have a pharmacist and want to obtain a supply through DPH, please email tpoxx@ph.lacounty.gov for assistance.

Oral TPOXX Required Reporting

The US Department of Health and Human Services (US HHS) requires all partner providers to report their stock inventory, usage, and disposal of all oral TPOXX on the enhanced Health Partner Order Portal (HPOP). This replaces any previous reporting and tracking processes.

- TPOXX stock (inventory, usage, and disposal) needs to reported on (HPOP) on a
 weekly basis by Tuesday, 2:00 PM.
- If you received and currently have any pre-positioned stock of oral TPOXX from LACDPH, then this needs to be reported on HPOP
- For questions about HPOP reporting, email TPOXX@ph.lacounthy.gov

