

Checklist for Providers to Initiate Treatment with Tecovirimat

The STOMP trial for TPOXX treatment is now recruiting patients with moderate and even mild disease in Los Angeles. The trial is also able to provide financial support and transportation for participants. Additional information can be found at www.stomptpoxx.org. For referral, please contact the trial coordinator Maricela Gonzalez at 310-557-3759 or [email](mailto:maricela.gonzalez@uclahealth.org) and they will return your message within one business day. (uclahealth.org/news/STOMP2022)

Clinicians, care facilities, and hospitals providing tecovirimat (TPOXX) can immediately transition to the CDC [revised protocol and forms \(version 6.1 dated August 10, 2022\) \[495 KB, 22 pages\]](#). All visits can be done through telemedicine and institutions should follow their internal protocols for obtaining consent. Los Angeles County healthcare providers with a suspected or diagnosed monkeypox patient now can immediately treat and prescribe TPOXX by:

- Dispensing from onsite pre-positioned TPOXX stock OR
- Prescribing directly to a community pharmacy which carries tecovirimat (TPOXX) and sending the required forms OR
- Referring the patient to an urgent care which stocks TPOXX OR
- Calling the DPH healthcare provider line (213) 240-7941 or email TPOXX@ph.lacounty.gov to request assistance

Required steps to prescribe TPOXX:

1. Obtain informed consent prior to treatment.

Informed Consent Form [English \[268 KB, 6 pages\]](#) | [Spanish \[335 KB, 6 pages\]](#):

- a. Alternative [Short Form Consent \[134 KB, 3 pages\]](#) and [Written Summary \[230 KB, 5 pages\]](#) can also be used.
 - b. Clinicians should explain that tecovirimat is an investigational new drug (IND) and is not approved yet for treatment of monkeypox.
 - c. The patient signs and completes the consent form.
 - d. Clinician to fax/email consent form to the community pharmacy with other required documents if dispensing via that mechanism.
 - e. Store in patient records (no need to submit to CDC or DPH).
2. Conduct baseline assessment and complete the [Patient Intake Form \(Form A\) \[PDF Attached\]](#):
 - a. For each patient, the clinician completes the patient intake form
 - b. Clinician sends one copy to:
 - i. DPH at TPOXX@ph.lacounty.gov.
 - ii. CDC via the regaffairs@CDC.gov or upload via the Sharepoint site.
 - iii. Community pharmacy if dispensing through them



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3. Complete FDA Form 1572 (once per facility).
 - a. [FDA Form 1572 \[PDF Attached\]](#):
 - i. Facility completes and signs the form; one signer must be a physician.
 - ii. One 1572 form per facility suffices for all TPOXX treatments dispensed or prescribed at the same facility regardless of the prescriber.
 - iii. All other clinic providers (optional) can be added under section 6 (sub-investigators) but facility providers do not need to be listed in order to prescribe.
 - iv. For clinics: IRB section can be left blank since CDC IRB has approved.
 - v. For institutional: request exemption/determine whether your IRB will defer to CDC IRB
 - vi. Send form to CDC via the regaffairs@CDC.gov or upload via the Sharepoint site.
 - vii. Send one completed form to any community pharmacy with TPOXX prescription and then store the 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) dosing:
 - i. Patients who weigh less than 265 lbs (120 kg):
 1. Oral tecovirimat 600mg every 12 hours for 14 days with a full glass of water, 30 minutes after eating a full meal of moderate or high fat.
 - ii. Patients who weigh over 265 lbs (≥ 120 kg):
 1. Oral tecovirimat 600mg every 8 hours for 14 days with a full glass of water, 30 minutes after eating a full meal of moderate or high fat.
 - b. Fax or e-mail three required documents:
 - i. Informed consent
 - ii. Form 1572 (only needs to be sent once)
 - iii. Completed patient intake form A (must list weight, medication list and allergies)
 - iv. Patient face sheet with their contact information including address.



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5. Providers with on-site TPOXX stock can dispense directly from their stock
 - a. Email completed patient intake form (can be one email) to:
 - TPOXX@ph.lacounty.gov
 - CDC@regaffairs.gov

6. Reporting 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.)

Requesting a pre-positioned stock of TPOXX:

For clinics or health systems that have a pharmacist and want to have a stock of tecovirimat on hand for additional patients please email tpoxx@ph.lacounty.gov to request.

Seen next page for a list of LA County community pharmacies that stock TPOXX



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List of Los Angeles County community pharmacies which stock TPOXX

To prescribe please send the:

- 1) Prescription
- 2) Patient intake
- 3) Patient consent
- 4) Form 1572

TPOXX DISPENSING PHARMACIES – as of 9/26/22

All offer shipping

Site	Address	Hours	Courses	Delivery/Shipping Fees
986/Cosmed Pharmacy James Chang james.chang@986pharmacy.com	6521 Van Nuys Blvd Van Nuys, CA 91401 (818) 933-2010	M-F: 9-6 Sat: 9-4 Closed Su	6	
Elements Pharmacy Sherri Cherman sherri@elementspharmacyrx.com	12602 Ventura Blvd Studio City, CA 91604 (818) 762-2055	M-F: 9-6 Sat: 9-4 Closed Su	6	
LA Compounding Pharmacy Mousa Mirakhor masterscompounding@gmail.com	8600 W 3rd St #1 Los Angeles, CA 90048 (310) 362-4122	M-F: 9-6 Closed Sa & Su	12	
Medex Pharmacy Monte Keshishian monte@medexpharmacies.com	8441 Foothill Blvd Los Angeles, CA 91040 (818) 925-1321	M-F: 9-7 Sat: 9-2 Closed Su	6	<ul style="list-style-type: none"> - Next day w/in 10-mile radius: free - Same day w/in 10-mi radius: \$15.00 - Same day w/in a 20-mile radius: \$25.00 - Patients must call for beyond 20 miles



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Mercy (Carson) Pharmacy Jean Ly jean.ly@mercy-pharmacy.com	21720 S Vermont Ave Suite 101 Torrance, CA 90502 (310) 328-0982	M-F: 9:30-6:30 Saturday: 9:30-4 Closed Su	6	
Mickey Finne Pharmacy Jeff Gross jeff@mickeyfine.com	433 N Roxbury Dr, Beverly Hills, CA 90210 (310) 271-6123	M-Th: 8:30-6:30 F: 8:30-6 Sat & Sun: 9-2	6	
Price Care Pharmacy Parth Parikh pilocarerx@gmail.com	10837 Downey Ave, Downey, CA 90241 (562) 825-5923	M-F: 10-5 Closed Sa & Su	6	\$10-15 shipping costs
986 Pharmacy Temple City Minh Chau – Pharmacy Manager Minh.chau@986pharmacy.com	9612 Las Tunas Dr. Temple City, CA 91780 626-780-4849	M-F: 9-6 Sat: 9-4 Closed Su	6	
White Memorial Medical Plaza Pharmacy Dr. Patel Pareshkumar Wmmp.pharmacy@gmail.com	1701 E Cesar E Chavez Ave, Suite 109, Los Angeles, CA 90033 (323) 221-6000	M-F: 8-7 Sat: 9-2 Closed Sa	6	
Olympia Plaza Pharmacy Dr. Joshua Thorburn Email: joshuathorburn@hotmail.com Website: www.OlympiaPlazaRx.com	5901 W. Olympic Blvd. Suite 103 Los Angeles, Ca 90036 Phone: 323-937-2590 Fax: 323-937-0259	M-F: 8:30 am – 6 pm Sat & Sun: Closed	12	<ul style="list-style-type: none"> • In-store pick-up by friend or family representative, or curbside pick-up • Same day or next day delivery: \$10, must receive by 10a
HealthRx Pharmacy Pharmacist: Mai Thai Email: mai@healthrxpharmacy.com	1844 E. RTE 66 Glendora, Ca 91740 Phone #: 626-335-4777	M-F: 10am – 7pm Sat: 10am – 3pm Sun:	6	



FORM A: Required Patient Intake Form (v6.2 October 24, 2022)

This Patient Intake form must be completed for each patient treated with tecovirimat. Completed Patient Intake form must be submitted to CDC **within 7 calendar days** of prescribing or initiating therapy. ***Denotes required fields. This fillable PDF version is for LA County Department of Public Health Use ONLY.**

Please be reminded to inform patients about the Study of Tecovirimat for Human Monkeypox Virus (STOMP) for their voluntary participation.			
Please indicate why the patient is receiving TPOXX under this expanded access IND rather than choosing to enroll in STOMP* (Select all that apply)			
<input type="checkbox"/> STOMP not available at this healthcare facility <input type="checkbox"/> Patient declined to participate in STOMP after being informed and offered to consent in for participation <input type="checkbox"/> Provider felt that STOMP was not appropriate for the patient <input type="checkbox"/> Provider did not offer the patient enrollment in STOMP <input type="checkbox"/> Other, specify _____			
Date of assessment* _____		Treating Physician Full Name* _____	
PATIENT INFORMATION			
Patient Name (first and last name)* _____		Hospital/Medical Facility-assigned Patient ID* _____	Date of Birth* _____
Weight* (kg) _____	Sex assigned at birth* <input type="checkbox"/> M <input type="checkbox"/> F	Gender patient identifies as* <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Transgender male <input type="checkbox"/> Transgender female <input type="checkbox"/> Other <input type="checkbox"/> Unknown	Is the patient pregnant?* <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, weeks of gestation _____ <input type="checkbox"/> Unknown
Ethnicity* <input type="checkbox"/> Hispanic or Latino <input type="checkbox"/> Not Hispanic or Latino <input type="checkbox"/> Unknown		Race* (select all that apply) <input type="checkbox"/> African American/Black <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Asian <input type="checkbox"/> Native Hawaiian or Other Pacific Islander <input type="checkbox"/> White <input type="checkbox"/> Other <input type="checkbox"/> Unknown	
Is patient willing to be contacted for potential follow-up surveys? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown If yes, Patient Cell Phone _____ Patient Email Address _____			
TECOVIRIMAT TREATMENT			
<input type="checkbox"/> Date prescribed* _____	Administration route* check all that apply		Dosage* _____
<input type="checkbox"/> Date first dose administered _____	<input type="checkbox"/> Oral <input type="checkbox"/> NG Tube <input type="checkbox"/> IV <input type="checkbox"/> Other, specify _____		Frequency* _____
Is this the patient's first time being treated with tecovirimat?*	Yes No <input type="checkbox"/> Unknown If no, date of last tecovirimat treatment course _____ Duration (days) _____		
REASON FOR TECOVIRIMAT TREATMENT			
What is the indication for tecovirimat treatment?			
1. Primary Treatment for Orthopoxvirus Infections <input type="checkbox"/> Yes <input type="checkbox"/> No			
<ul style="list-style-type: none"> • Is the patient laboratory-confirmed orthopoxvirus positive? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Results pending <input type="checkbox"/> Unknown • Reason(s) for tecovirimat treatment* (check all that apply): <ul style="list-style-type: none"> <input type="checkbox"/> Lesions in anatomic areas which might result in serious sequelae (e.g. lesions involving pharynx, genitals, urethra, rectum, anus) <input type="checkbox"/> Risk of severe outcome due to uncontrolled HIV or other conditions, pregnancy, pediatric patient, or condition affecting skin integrity <input type="checkbox"/> Severe infections (e.g., hemorrhagic disease; large number of lesions such that they are confluent; sepsis; encephalitis; ocular or periorbital infections; or other conditions requiring hospitalization) <input type="checkbox"/> Pain <input type="checkbox"/> If Other selected, please specify _____ 			
OR			
2. Post-exposure prophylaxis for high-risk contact of a confirmed or probable orthopoxvirus positive case			

Yes No ** Note: PEP use is determined on an **individual basis** in consultation with CDC.**

OR

3. Secondary Treatment for Complications Resulting from ACAM2000 Vaccination Yes No

Patient developed vaccine-related complications from being?

Vaccinated with ACAM2000 or Contact with an ACAM2000 recipient

▪ If Yes, date of vaccination or exposure _____ Unknown

▪ What is the complication? (check one below)

- Severe generalized vaccinia (GV)
- Eczema vaccinatum
- Progressive vaccinia (vaccinia necrosum)
- Serious inadvertent inoculation

Date of illness onset	Date of exposure
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Signs/symptoms at illness onset (Select all that apply)

Rash Lymphadenopathy Fever Proctitis Abscess Cellulitis Dysuria

Shortness of breath Headache Malaise Other, specify _____

MEDICAL HISTORY

Patient treatment started as inpatient or outpatient?*

Outpatient Inpatient, date of admission _____

If inpatient, admitted to ICU? Yes, date _____ No Unknown

Does patient have history of prior smallpox/monkeypox vaccination?* Yes No Unknown

- If yes, indicate the vaccine(s) received: ACAM2000 Jynneos Other, specify _____
- Unknown vaccine product, but patient self-reports prior smallpox/monkeypox vaccination
- If vaccinated with ACAM2000, was there a documented vaccine “take”?*
- Yes No If yes, date of take _____ Unknown
- Date of vaccination _____ Unknown

Prior Medical History* (select all that apply)

Prior monkeypox illness*

Yes No Unknown

If yes, date of prior illness _____

Indicate all treatment(s) the patient received for prior monkeypox illness

	Date(s) given	Administration Route	Dosage	Frequency	Duration (days)
<input type="checkbox"/> Oral tecovirimat capsules					
<input type="checkbox"/> IV tecovirimat					
<input type="checkbox"/> Cidofovir					
<input type="checkbox"/> Vaccinia immune globulin intravenous (VIGIV)					
<input type="checkbox"/> Trifluridine eye drops					
<input type="checkbox"/> Other treatment type, specify _____					
<input type="checkbox"/> None					
<input type="checkbox"/> Unknown					

HIV/AIDS

CD4 count _____ Viral load _____

Is patient on ART? Yes No Unknown

If yes, specify _____

Atopic dermatitis or eczema active historical

If yes, please describe _____

Other skin disease, specify _____ active historical

Congenital/acquired immune defect

Autoimmune/connective tissue disorder

Bone marrow/organ transplant

Leukemia

Lymphoma

Other cancer, specify _____

History of psychiatric condition (e.g., depression)

If yes, is patient on medication? Yes No Unknown

If yes, specify _____

Other pre-existing condition(s), specify _____

Other infection(s), specify _____

SIGNS/SYMPTOMS AT PRESENTATION FOR TPOXX THERAPY

Number of lesions?*	Size of maximal lesion (mm)	Percent of body affected by lesions (%)
<input type="checkbox"/> 0 lesions <input type="checkbox"/> 1–10 lesions		
<input type="checkbox"/> 11 – 50 lesions		
<input type="checkbox"/> 51 – 100 lesions		
<input type="checkbox"/> > 100 lesions		
Approximate # of lesions _____		

DISTRIBUTION OF LESIONS

Indicate the location of the patient’s lesions?* (select all that apply)

Skin Anogenital Ocular Oral mucosa Other, specify _____

Clinical Narrative (*describe presenting illness, signs/symptoms, lesions*)

OTHER TREATMENTS FOR CURRENT ILLNESS

Indicate other adjunct or concurrent treatment(s) specific for orthopoxvirus/monkeypox virus infection given

Date initiated Administration Route Dosage Number of Doses Duration (days)

<input type="checkbox"/> Cidofovir					
<input type="checkbox"/> Brincidofovir					
<input type="checkbox"/> Vaccinia immune globulin intravenous (VIGIV)					
<input type="checkbox"/> Trifluridine eye drops					
<input type="checkbox"/> Other treatment type, specify _____					

HOSPITAL/MEDICAL FACILITY

Hospital/Medical Facility Name*	City*	State or Territory*	Zip code*

Indicate if facility is a federal entity

- No Bureau of Prisons
 Indian Health Service Health Resources & Services Administration
 Department of State Veterans Health Administration
 Other, specify _____

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

STATEMENT OF INVESTIGATOR
(TITLE 21, CODE OF FEDERAL REGULATIONS (CFR) PART 312)
(See instructions on reverse side.)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2022
See OMB Statement on Reverse.

NOTE: No investigator may participate in an investigation until he/she provides the sponsor with a completed, signed Statement of Investigator, Form FDA 1572 (21 CFR 312.53(c)).

1. NAME AND ADDRESS OF INVESTIGATOR

Name of Clinical Investigator

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

2. EDUCATION, TRAINING, AND EXPERIENCE THAT QUALIFY THE INVESTIGATOR AS AN EXPERT IN THE CLINICAL INVESTIGATION OF THE DRUG FOR THE USE UNDER INVESTIGATION. ONE OF THE FOLLOWING IS PROVIDED (*Select one of the following.*)

Curriculum Vitae

Other Statement of Qualifications

3. NAME AND ADDRESS OF ANY MEDICAL SCHOOL, HOSPITAL, OR OTHER RESEARCH FACILITY WHERE THE CLINICAL INVESTIGATION(S) WILL BE CONDUCTED

**CONTINUATION PAGE
for Item 3**

Name of Medical School, Hospital, or Other Research Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

4. NAME AND ADDRESS OF ANY CLINICAL LABORATORY FACILITIES TO BE USED IN THE STUDY

**CONTINUATION PAGE
for Item 4**

Name of Clinical Laboratory Facility

Address 1

Address 2

City

State/Province/Region

Country

ZIP or Postal Code

5. NAME AND ADDRESS OF THE INSTITUTIONAL REVIEW BOARD (IRB) THAT IS RESPONSIBLE FOR REVIEW AND APPROVAL OF THE STUDY(IES)

**CONTINUATION PAGE
for Item 5**

Name of IRB

Human Research Protection Office, Centers for Disease Control and Prevention

Address 1

1600 Clifton Rd.

Address 2

MS D-73

City

Atlanta

State/Province/Region

GA

Country

United States

ZIP or Postal Code

30329

6. NAMES OF SUBINVESTIGATORS (*If not applicable, enter "None"*)

CONTINUATION PAGE – for Item 6

7. NAME AND CODE NUMBER, IF ANY, OF THE PROTOCOL(S) IN THE IND FOR THE STUDY(IES) TO BE CONDUCTED BY THE INVESTIGATOR

Expanded Access IND Protocol: Use of Tecovirimat (TPOXX) for Treatment of Human Orthopoxvirus Infections (CDC IND 116039, CDC IRB Protocol #6402)

8. PROVIDE THE FOLLOWING CLINICAL PROTOCOL INFORMATION. (Select **one** of the following.)

- For Phase 1 investigations, a general outline of the planned investigation including the estimated duration of the study and the maximum number of subjects that will be involved.
- For Phase 2 or 3 investigations, an outline of the study protocol including an approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; the clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be conducted; the estimated duration of the study; and copies or a description of case report forms to be used.

9. COMMITMENTS

I agree to conduct the study(ies) in accordance with the relevant, current protocol(s) and will only make changes in a protocol after notifying the sponsor, except when necessary to protect the safety, rights, or welfare of subjects.

I agree to personally conduct or supervise the described investigation(s).

I agree to inform any patients, or any persons used as controls, that the drugs are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and institutional review board (IRB) review and approval in 21 CFR Part 56 are met.

I agree to report to the sponsor adverse experiences that occur in the course of the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the drug.

I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study(ies) are informed about their obligations in meeting the above commitments.

I agree to maintain adequate and accurate records in accordance with 21 CFR 312.62 and to make those records available for inspection in accordance with 21 CFR 312.68.

I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. Additionally, I will not make any changes in the research without IRB approval, except where necessary to eliminate apparent immediate hazards to human subjects.

I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

**INSTRUCTIONS FOR COMPLETING FORM FDA 1572
STATEMENT OF INVESTIGATOR**

1. Complete all sections. Provide a separate page if additional space is needed.
2. Provide curriculum vitae or other statement of qualifications as described in Section 2.
3. Provide protocol outline as described in Section 8.
4. Sign and date below.
5. FORWARD THE COMPLETED FORM AND OTHER DOCUMENTS BEING PROVIDED TO THE SPONSOR. The sponsor will incorporate this information along with other technical data into an Investigational New Drug Application (IND). INVESTIGATORS SHOULD NOT SEND THIS FORM DIRECTLY TO THE FOOD AND DRUG ADMINISTRATION.

10. DATE (mm/dd/yyyy)

11. SIGNATURE OF INVESTIGATOR

Sign

(WARNING: A willfully false statement is a criminal offense. U.S.C. Title 18, Sec. 1001.)

The information below applies only to requirements of the Paperwork Reduction Act of 1995.

The burden time for this collection of information is estimated to average 100 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden to the address to the right:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

**DO NOT SEND YOUR COMPLETED FORM
TO THIS PRA STAFF EMAIL ADDRESS.**