Process to Provide Tecovirimat (TPOXX) for Treatment of Monkeypox

(Updated as of 9/7/2022)

Tecovirimat (TPOXX) is an antiviral medication that is approved by the United States Food and Drug Administration (FDA) [PDF – 24 pages for the treatment of smallpox in adults and children. It is the first-line medication to treat monkeypox in adults and children weighing 13kg or more.

Clinical trials in people showed the drug was safe and had only minor side effects. Based on limited available data, it is felt that tecovirimat may shorten the duration of patients' illness and viral shedding.

CDC holds an expanded access protocol (sometimes called "compassionate use") that allows for the use of stockpiled tecovirimat to treat monkeypox during an outbreak.

If a provider has a patient in urgent need of treatment, the provider may proceed with TPOXX treatment once informed consent has been obtained. Required CDC IND protocol forms may be submitted to CDC after the patient has initiated treatment. In these situations, pre-positioned TPOXX can be obtained from OCHCA pre-positioned cache and can be picked up from OCHCA Public Health Services during normal business hours. Healthcare providers with immediate (urgent) need, can submit a request by email to IAP@ochca.com. For after office hours, please call 714-834-8180 and ask for the on-call public health nurse.

Required Documentation for Tecovirimat (TPOXX) – New Potential Treatment Provider

- You must obtain informed consent prior to treatment.
  - Retain in patient medical record. It does not need to be submitted to CDC.
- Complete the Patient Intake Form.
  - Must be submitted to CDC per instructions on the form. Retain a copy in patient medical record.
- Your organization must completed and sign the FDA Form 1572. One signed 1572 form per facility suffices for all (including future) TPOXX treatments administered under the EA-IND at the same facility. Send completed 1572 form to regaffairs@cdc.gov or by fax 404-902-5921.
- Required safety reporting by clinicians and healthcare facilities will focus on serious adverse events only and should be reported by filling out a PDF MedWatch Form [226KB, 3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible.
  - Safety reporting is only required if a serious adverse event should occur.
  - Instructions on how to complete MedWatch form here.

Oral Tecovirimat (TPOXX) Treatment

One bottle comes with 42 200mg oral capsules.

- Pediatric and Adult Patients weighing 40 kg or more (Oral Dosing):
  - For children who weigh less than 28.6 pounds (<13 kg), the capsule can be opened, and medicine mixed with semi-solid food.

- >40 kg to less than <120 kg
  - 600 mg (3 caps) of TPOXX every 12 hours w/meal for 14 days (2 bottles)
- 120 kg or more: 600 mg of TPOXX every 8 hours for 14 days
  - 600mg (3 caps TID x 14 days w/meal (3 bottles)

- Provider should order a 3 week supply based on estimated patient volume
  - Typical orders are 5-20 oral treatment courses (treatment course is defined as 2 bottles or 84 pills)

IV Tecovirimat

The preferred formulation for treatment MPX is the oral formulation. The IV formulation is available for patients unable to tolerate the oral formulation or disease severity/co-morbidities or absorption issues that warrant use. Patient should be switched to the oral formulation as soon as clinically able.

IV tecovirimat is pre-positioned in limited quantities with facilities throughout the state and county. If a patient needs IV treatment, the MHOAC should be contacted to identify product in the County or Region.

IV TPOXX requests should include a brief clinical description of the patient in need of IV treatment (e.g., MPX case with pharyngitis, unable to take oral medications.) Federal supply of IV tecovirimat is now based on individual patient need. CDPH will use the clinical description to meet immediate needs using the small state cache of IV tecovirimat and to request a re-supply from CDC/SNS.

Reimbursement

Organizations are prohibited from selling or seeking reimbursement for TPOXX (tecovirimat) and must provide TPOXX (tecovirimat) regardless of the recipient's ability to pay administration fees. Organization may seek appropriate reimbursement from a program or plan that covers any TPOXX (tecovirimat) administration fees for the recipient.

Tracking Inventory

Providers and their facility are expected to track number of new patient starts and inventory of tecovirimat. These data will be collected at the time of tecovirimat requests or monthly if no request has been received.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH

ORAL TECOVIRIMAT (TPOXX) REQUEST& DATA COLLECTION FORM

Purpose

The purpose of this form is to i.) standardize oral tecovirimat resource requests, and, ii.) to facilitate monthly data collection. The data requested will be used to meet ASPR reporting requirements for inventory, administration and submission of required regulatory forms.

For the latest information for TPOXX providers, see: Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC

Instructions

(Form Must Be Typed. Handwritten forms will not be accepted. A survey link may be provided in the future.)

- Complete all sections of the form when placing orders.
- Providers are encouraged to estimate and order a three-week supply. For orders greater than 20 treatment courses, please indicate brief justification in the Notes section below (e.g., the number of new patient starts per week for the last 3 weeks.) Requests will be reviewed and quantity adjustments may be made by CDPH upon receipt of the request.
- Form submission:
  - Email the completed request form to IAP@ochca.com

TPOXX Receiving Facility Information

Date Submitted		❒ New Site ❒ FDA Form 1572 submitted to CDC on_____(date)		❒ Current Site	
Site Name:					
Street Address:		City:		Zip Code:	
Delivery location (e.g. inpatient pharmacy)					
Site Contact Name #1:		Title:			
Phone Number:		Email Address:			
Site Contact Name #2:		Title:			
Phone Number:		Email Address:			

Days and Times Receiving Facility Address is/is not Available for Delivery: _____

Desired delivery date/time:_____

TPOXX Data and Resource Request

	TPOXX Data				Resource Request
PRODUCT	# Total Patients started to-date	# Total Form A submitted to CDC	Current Inventory (# Bottles)	Total received to date (# Bottles)	Request* (# Bottles)
Tecovirimat® (TPOXX-Oral) Courses = 2 Bottles					
	#Total Patients started to-date	# Total Form A submitted to CDC	Current Inventory (# doses)	Total received to date (# doses)	Request* (# Doses)
Tecovirimat (IV) 200mg/20mL (increments of 7 doses, maximum order 7 doses)					

☐ Resource request is for LHJ/Public Health Pre-positioning for urgent needs
☐ Please include 1 Credo Cube SKU # CR16A41696 AND 1 Data Logger SKU # LTTRED3016R for IV TPOXX

Requester Notes:

* If requesting more than 20 oral treatment courses, include a brief justification in the Requester Notes section, e.g., the number of patients treated per week for the last 3 weeks or other justification and/or if requesting IV TPOXX, please provide justification in the Requestor Notes section above:

Multicounty TecovirimatProviders

Are you requesting tecovirimat as a multicounty provider? If yes, please list the locations where tecovirimat treatment is being provided in the chart below.

Clinic Name	Address