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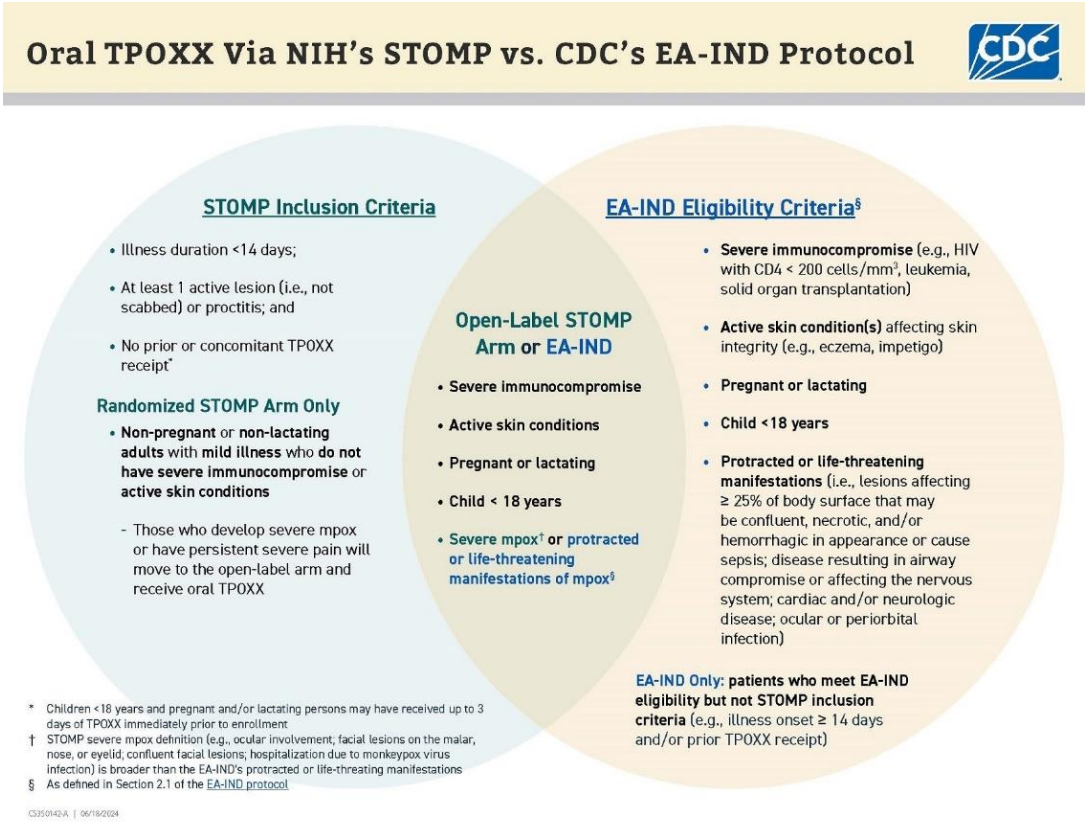
Tecovirimat (TPOXX) is an antiviral drug FDA-approved for the treatment of smallpox disease. The use of TPOXX for treatment of mpox is investigational. The efficacy of TPOXX has not been established in human mpox. Therefore, oral TPOXX (package insert) is available through:

1. The Study of Tecovirimat for Human Mpox Virus (STOMP), a clinical trial sponsored by NIH to evaluate efficacy of TPOXX in treating human mpox, or
2. A CDC-held Expanded Access Investigational New Drug (EA-IND) protocol for compassionate use.



1. Accessing Tecovirimat via STOMP Trial

The **Study of Tecovirimat for Human Mpox Virus (STOMP),** sponsored by the National Institute of Allergy and Infectious Disease, is designed to assess whether TPOXX is safe and effective for the treatment of mpox. **Providers are encouraged to inform patients with mpox about STOMP.**

- **STOMP is open to people with mild-to-moderate disease who are not eligible for treatment with TPOXX under the EA-IND.**
- Eligible participants with mild-to-moderate disease will be randomized 2:1 to receive either TPOXX or placebo. At any time during the study, if those enrolled in the randomized arm develop severe disease or persistent pain, they are switched to the open-label arm.
- Individuals with severe disease, significant active skin conditions, severe immunocompromise, or who are pregnant or lactating, or under 18 years of age will receive open-label TPOXX through the STOMP trial if they choose to participate.
- Participants in both the randomized and open-label arms of STOMP will be followed for at least 57 days and asked to fill out a symptom diary, do daily skin checks at home, and attend clinic appointments (in-person or telehealth).
- Regardless of disease severity, individuals must have mpox illness for less than 14 days prior to study entry to be eligible to participate in STOMP.
- People who have had prior treatment with TPOXX or need intravenous (IV) TPOXX are not eligible.

STOMP Enrollment:

- STOMP allows in-person or remote enrollment. To enroll in STOMP or for questions about this study, call the STOMP Call Center at **(855) 876-9997** Monday through Friday 9 AM–10 PM, Saturday 9 AM–4 PM, and Sunday 1–6 PM. STOMP encourages using the call center rather than directly contacting study sites to be directed to the site that can help quickest.
- Yale School of Medicine CRS is the STOMP site in Connecticut. The Yale study team can be reached at (**203) 907-6044** Monday through Friday 9 AM–3 PM to arrange for phone intake and an in-person visit. Voicemail messages left after hours will be returned the next business day.
- Participants enrolled remotely at study sites outside of Connecticut receive study medication via courier and attend study visits via telehealth.

2. Accessing Tecovirimat under CDC EA-IND

Patients who meet treatment eligibility criteria below AND decline or are ineligible for STOMP can access TPOXX under CDC's non-research EA-IND protocol. Oral and IV formulations are available. The protocol and required documents are at **Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Mpox.**

EA-IND Treatment Eligibility Criteria

Use of TPOXX under the EA-IND protocol is for patients with laboratory-confirmed or suspected mpox who meet the following criteria (see Section 2.0 of the protocol):

- **Patients with severely immunocompromised conditions**, including:
  - HIV with CD4 < 200 cells/mm^3
  - Leukemia or lymphoma
  - Generalized malignancy
  - Solid organ transplantation
  - Therapy with any of the following within 180 days prior to mpox onset: alkylating agents, antimetabolites, radiation therapy, tumor necrosis factor inhibitors
  - Taking high-dose corticosteroids within 90 days prior to mpox onset
  - Receipt of hematopoietic stem cell transplant <24 months post-transplant or ≥24 months post-transplant but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component
  - Other comparable severe immunocompromise

- **Patients in the following categories**:
  - Active skin conditions that place them at higher risk for disseminated infection (atopic dermatitis, active exfoliative skin conditions, such as eczema, burns, impetigo, active varicella zoster virus infection, psoriasis, or Darier disease)
  - Pregnant or lactating patients, regardless of illness severity or underlying comorbidities at presentation
  - Children (< 18 years) regardless of illness severity or underlying comorbidities at presentation
- **Patients with protracted or life-threatening manifestations of mpox at presentation**, as defined by:
  - Lesions affecting 25% or more of body surface that may be confluent, necrotic, and/or hemorrhagic or cause sepsis
  - Disease resulting in airway compromise or affecting the nervous system
  - Cardiac (e.g., myocarditis) and/or neurologic disease (e.g., encephalitis)
  - Ocular or periorbital infection, regardless of the time since infection onset

EA-IND Required Documents:

For oral or IV TPOXX administered under the EA-IND, the following documentation MUST be submitted to CDC via the Tecovirimat IND Online Registry. Required documents may be sent after treatment has been initiated**.**

1. **Informed consent form** (consent must be obtained prior to treatment initiation)
2. **FDA Form 1572** (submit only once per institution, please include all prescribing physicians)
3. **Patient intake form**
4. **Clinical outcome form**
5. **Serious adverse event form** (Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form and returning it to CDC via email regaffairs@cdc.gov within 72 hours. Send a copy to DPH at DPH.mpox@ct.gov. DPH personnel may contact the provider for further information if required).

Obtaining TPOXX Under EA-IND:

Oral TPOXX:

A limited quantity of oral TPOXX is available at the University of Connecticut Health Pharmacy Services, Inc. (UHPSI) for **patients eligible for treatment under the CDC EA-IND**. Prescriptions may be sent Monday–Friday, 8 AM–4:30 PM. Once processed, TPOXX will be delivered from UHPSI on the next business day to the recipient (whether medical provider or directly to the patient).

Please use one of the following options to prescribe TPOXX for an outpatient:

1. Send UHPSI an e-prescription requesting the medication. In the "notes", please specify the delivery address.
2. Fax a prescription to (860) 679-0303, and please include the delivery address.
3. Call in the prescription to UCHC pharmacy at (860) 679-4036 or (833) 777-4276.

Intravenous (IV) TPOXX:

Certain healthcare systems have prepositioned IV TPOXX at their own health system pharmacy for inpatient use by their providers for patients eligible for treatment under the CDC EA-IND. Please check with your health system pharmacy first. If IV TPOXX is not available through your health system, please contact UHPSI during regular business hours (Monday–Friday, 8 AM – 4:30 PM) at (860) 679-4036 or (833) 777-4276, or John Dempsey Hospital Pharmacy after hours or on weekends at (860) 679-7627.

For Oral or IV TPOXX accessed under EA-IND: please remember to submit all required documentation via the Tecovirimat IND Online Registry.