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STATE OF CONNECTICUT
DEPARTMENT OF PUBLIC HEALTH

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Document Summary:

1. **Accessing Tecovirimat (TPOXX) via STOMP Trial**
2. **Accessing TPOXX under CDC EA-IND**
    a. **Treatment eligibility**
3. **REQUIRED documents for prescribing TPOXX must be submitted to CDC via the Tecovirimat IND Online Registry**
    a. **Informed consent**
    b. **FDA Form 1572**
    c. **Patient intake form**
    d. **Clinical outcome form**
4. **Information for reporting adverse effects**

Accessing Tecovirimat via STOMP Trial

Oral tecovirimat (package insert) for treatment of mpox is available through the Study of Tecovirimat for Human Mpox Virus (STOMP), which is designed to assess whether tecovirimat is safe and effective for the treatment of mpox. **Providers are encouraged to inform patients with mpox about STOMP and to recommend that they consider enrollment.**

- **STOMP is open to people with less severe disease who might not be otherwise eligible for treatment with TPOXX under the EA-IND.**
- The trial includes a placebo-controlled, randomized arm and an open-label option for patients with severe disease, who have severe immunodeficiency, are pregnant or breastfeeding, are under 18 years of age, or are taking medications that could affect tecovirimat levels.
- Although there are no trial sites in Connecticut, remote enrollment is available. Remotely enrolled participants receive study medication via courier and attend study visits via telehealth.
- People who have had prior treatment with tecovirimat or need intravenous tecovirimat are not eligible.

For more information, the STOMP call center can be reached at (855) 876-9997 from 9 a.m. to 10 p.m. Monday through Friday, on Saturday from 9 a.m. to 4 p.m., and on Sunday from 1-6 p.m.

Accessing Tecovirimat under CDC EA-IND

Access to tecovirimat is also available under CDC's non-research expanded access Investigational New Drug (EA-IND) protocol for patients with mpox who decline or are ineligible for STOMP and meet EA-IND treatment eligibility (e.g., have severe disease or involvement of anatomic areas that might result in serious sequelae, are at risk for severe disease). The EA-IND provides umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. Oral and intravenous (IV) formulations are available. **The protocol and required document submission for tecovirimat use under the EA-IND can be found at Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Mpox. To prescribe tecovirimat, a clinical suspicion of mpox plus a confirmatory or pending viral test is required**.

Keeping Connecticut Healthy
DPH
Connecticut Department of Public Health

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Hartford, Connecticut 06134-0308
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EA-IND Treatment Eligibility (consistent with CDC's Guidance for Tecovirimat Use):

- Severe disease, such as hemorrhagic disease, large number of lesions such that they are confluent, sepsis, encephalitis, ocular or periorbital infections, or other conditions requiring hospitalization
- Involvement of anatomic areas which might result in serious sequelae that include scarring or strictures:
  - Lesions involving the pharynx causing dysphagia, inability to control secretions, or need for parenteral feeding
  - Lesions affecting the penile foreskin, vulva, vagina, urethra, or rectum with the potential for causing strictures or requiring catheterization
  - Anal lesions interfering with bowel movements (for example, severe pain)
  - Severe infections (including secondary bacterial skin infections), especially for those requiring surgical intervention such as debridement
- High risk of progression to severe disease:
  - People experiencing severe immunocompromise (e.g., advanced or poorly controlled HIV/AIDS, leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, high-dose corticosteroids, being a recipient with hematopoietic stem cell transplant <24 months post-transplant or ≥24 months but with graft-versus-host disease or disease relapse, or having autoimmune disease with immunodeficiency as a clinical component)
  - Pediatric populations, particularly patients younger than 1 year of age
  - Pregnant or breastfeeding people
  - People with a condition affecting skin integrity — conditions such as atopic dermatitis, eczema, burns, impetigo, varicella zoster virus infection, herpes simplex virus infection, severe acne, severe diaper dermatitis with extensive areas of denuded skin, psoriasis, or Darier disease (keratosis follicularis)

Required Documents:

For outpatient and inpatient prescriptions, the following required documentation must be submitted to CDC via the Tecovirimat IND Online Registry. Required documents may be sent after treatment has been initiated**.**

1. Please ensure **informed consent** is obtained prior to treatment initiation
2. Please submit an **FDA Form 1572** (submit only once per institution, please include all prescribing physicians)
3. **Patient intake form**
4. **Clinical outcome form**

Outpatient Prescriptions:

Certain healthcare systems have prepositioned oral tecovirimat at their own health system pharmacy for outpatient use by their providers. Please check availability with your health system pharmacy first. If unavailable, oral tecovirimat is available at the University of Connecticut Health Pharmacy Services, Inc. (UHPSI) for providers to prescribe to outpatients. Prescriptions may be sent M-F, 8 AM-4:30 PM. Once processed, tecovirimat 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 tecovirimat 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.

Inpatient Prescriptions:

Certain healthcare systems have prepositioned oral and IV tecovirimat at their own health system pharmacy for inpatient use by their providers. If tecovirimat is not available through your health system please contact UHPSI during regular business hours (M-F 8 AM to 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.

Patient Monitoring and Follow-up:

In the event of a serious adverse effect, complete a MedWatch Form (MedWatch Form PDF) as directed by the CDC and send a copy to DPH at DPH.mpox@ct.gov. DPH personnel may contact the provider for further information if required.