



TECOVIRIMAT (TPOXX) PROCUREMENT PROCESS

General guidance from CDC:

Refer to <https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html> for up-to-date information.

Important notes:

- a. Treatment with TPOXX (tecovirimat) can begin upon receipt of the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities.
- b. Forms requested under the EA-IND can all be returned to CDC after treatment begins.
- c. Laboratory confirmation of infection is not required to request drug if patient meets CDC case definition for suspected case. [CDC Case Definition](#)
- d. Patients where treatment should be considered (per CDC guidance, please see CDC website for most up-to-date information ([CDC Treatment Guidance](#)))
 - i. *With severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalitis, myocarditis, severe lymphadenopathy that can be necrotizing or obstructing, involvement involving multiple organ systems, or other conditions requiring hospitalization)*
 - ii. *Who are at high risk of severe disease:*
 1. *People with immunocompromising conditions (e.g., HIV/AIDS (poorly controlled), 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)*
 2. *Pediatric populations, particularly patients younger than 1 year of age*
 3. *Pregnant or breastfeeding women*
 4. *People with a history or presence of atopic dermatitis, people with other active exfoliative skin conditions (e.g., 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])*
 5. *People with one or more complication (e.g., secondary bacterial skin infection; gastroenteritis with severe nausea/vomiting, diarrhea, or dehydration; bronchopneumonia; concurrent disease or other comorbidities)*
 - iii. *With aberrant infections involving accidental implantation in eyes, mouth, or other anatomic areas where MPOX virus infection might constitute a special hazard (e.g., the genitals or anus)*

Process (only available M-F during normal business hours. If outside of these hours and urgent inpatient treatment needed, please contact ID on call):

1. Patient provides verbal consent for personal data, including date of diagnosis and patient medical history to CDC (please document in notes)
2. **Inpatient:** Consult Infectious Diseases for all adult or pediatric patients hospitalized with suspected or confirmed MPOX. If ID decides treatment is warranted, they will follow Steps 4-9.
3. **Outpatient:** Non-ID providers initiating **outpatient Tecovirimat treatment for a suspected MPOX case** (orthopox testing in process; diagnosis not confirmed) should contact ID to discuss case and confirm patient meets treatment eligibility criteria. Contacting ID is not required for outpatients with confirmed MPOX infection. In all cases in which treatment is warranted, the non-ID provider should follow Steps 4-9 to procure drug.
 - a. Adult Outpatients: Place an E-consult, or for more time-sensitive questions, page adult ID physician on triple team 8AM-5PM M-F (see ID on-call schedule). For urgent questions after-hours or on weekends, contact ID emergency pager: #39716
 - b. Pediatric Outpatients: Place an E-consult, or for more time-sensitive questions, page the Pediatric ID physician on M-Line/Outpatient call 8AM-5PM M-F (see pediatric ID on-call schedule). For urgent questions after-hours or on weekends, contact the Pediatric ID Consult Pager: #6008

4. Send an email to UM-Expanded-Access-Request@med.umich.edu with the patient name and MRN and indicate that you are initiating this workflow.
 - a. Subject Line – **Last Name, First Name (MRN) – TPOXX Request**
 - b. Include pertinent information in body of email, including brief case history, patient location (inpatient vs outpatient; if outpatient, whether the patient would prefer to pick up the drug at a U of Michigan location or it be shipped to their house), whether health department has been contacted, and any other case-specific information that may be relevant
 - c. Attach patient intake form which can be accessed at <https://www.dropbox.com/s/nflzb6pg8a9mtgv/Attachment-2-Form-A-Patient-Intake-Form.pdf?dl=0>
5. If outside business hours (M-F, 0700-1700), notify Research Pharmacy On-Call Pharmacist (pager 2944).
6. Physician or designee, including APPs, must obtain informed consent. CDC Informed Consent Form ([English](#)) and ([Spanish](#))
 - a. This should be scanned in to MiChart as a “research consent” once signed.
7. Patient may be treated once consent has been signed. Research Pharmacy (pager 2944, if not already engaged via email or phone) facilitates placing the order and delivery of the medication.
 - a. Paper order form: [Tecovirimat Paper Order Form \(outpatient only\)](#)
8. Confirm with Expanded Access group once treatment has begun
 - a. If the patient has had a serious adverse event that is related to this treatment, or the patient has died, Expanded Access group must be informed.
 - b. Report life-threatening or serious adverse events associated with TPOXX by completing 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

Antimicrobial Subcommittee Approval: N/A	Originated: 08/2022
P&T Approval: N/A	Last Revised: 11/2022
Revision History: 9/6: Updated patient education hyperlink and provider follow-up instructions 11/28: Updated nomenclature	

The recommendations in this guide are meant to serve as treatment guidelines for use at Michigan Medicine facilities. If you are an individual experiencing a medical emergency, call 911 immediately. These guidelines should not replace a provider’s professional medical advice based on clinical judgment, or be used in lieu of an Infectious Diseases consultation when necessary. As a result of ongoing research, practice guidelines may from time to time change. The authors of these guidelines have made all attempts to ensure the accuracy based on current information, however, due to ongoing research, users of these guidelines are strongly encouraged to confirm the information contained within them through an independent source.

If obtained from a source other than med.umich.edu/asp, please visit the webpage for the most up-to-date document.