Steps for Ordering TPOXX for Michigan Health Care Providers

1. Review CDC Guidance for Tecovirimat Use Under Expanded Access Investigational New Drug Protocol during 2022 U.S. Mpox Cases to determine if the patient meets treatment eligibility criteria.
    a. TPOXX treatment may be initiated for patients with laboratory confirmed non-variola orthopoxvirus infection or suspected infection based on known exposure(s) and/or clinical manifestations of disease (EA-IND 116,039 Tecovirimat, Version 6.1, Section 2.1.1 – Primary or Early Empiric Treatment, page four).
    b. Patients should be informed about the clinical trial for tecovirimat (STOMP clinical trial) and encouraged to consider enrollment. While many patients may not reside near one of the participating study sites, remote enrollment is now available across the U.S. (Call 1-855-876-9997) for additional information.
2. Refer to guidance regarding treatment with TPOXX in special populations, if relevant:
    a. For people with HIV, review Clinical Considerations for Treatment and Prophylaxis of Mpox Infection in People Who are Immunocompromised.
    b. For people who are pregnant or breastfeeding, review CDC Clinical Considerations for Mpox in People Who are Pregnant or Breastfeeding.
    c. For treatment of children and adolescents, review CDC Clinical Considerations for Mpox in Children and Adolescents.
3. If patient has a clear indication for treatment, and they are not eligible or interested in participating in the STOMP clinical trial, health care provider should review CDC Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Mpox, including all required documentation:
    1. CDC Expanded Access IND Protocol. (Updated October 24, 2022.)
    2. Informed Consent Form. The patient or patient guardian signature may be written or electronic and may be emailed back to the health care provider. Alternative Short Form Consent and Written Summary may be used instead. (Provide copy to patient and retain a copy as part of patient record, **do not send to CDC.**)
    3. Submit FDA Form 1572 via Tecovirimat (TPOXX) IND Registry within seven calendar days of treatment initiation.
    4. Submit Patient Intake Form via Tecovirimat (TPOXX) IND Registry within seven calendar days of treatment initiation.
    5. Medwatch Serious Adverse Events Form. (Submit to FDA within 72 hours of awareness or sooner.)
    6. **Optional** forms for submission of lesion images or other clinical data available at Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Mpox.
    7. Form completion and submission of required Tecovirimat IND forms is exclusively through the CDC's Tecovirimat (TPOXX) IND Registry. Upon registration, the registry will provide tokenized links to required TPOXX IND forms (Patient Intake and Clinical Outcome Form) to providers' email addresses.
4. **CDC Clinical Consults**: If patient does not have a clear indication for treatment with TPOXX but the health care provider still feels that the patient would benefit from treatment, the health care provider may seek a clinical consult from the CDC Mpox Clinical Team. Clinical consults are also available for concerns about patient management, particularly if a patient has an atypical or severe presentation.
    a. If a consult is needed urgently, call the CDC Emergency Operations Center at 770-488-7100 and ask for a clinical consultation with a member of the Mpox Clinical Team, and specify if their consult is regarding whether treatment is indicated for their patient or if they have questions regarding clinical management.
5. **Ordering TPOXX**:
    a. Health care providers should first contact their local health department (LHD) to see if TPOXX has been prepositioned and is available to be dispensed upon request. When product is available, requester and the LHD will arrange delivery of product locally.
    b. When product is not available through local jurisdiction, the provider should then complete the MDHHS Request Link to request needed doses and provide required deidentified patient and provider information.