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. Monkeypox 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 Emperic Treatment, page two).
2. Refer to guidance regarding treatment with TPOXX in special populations, if relevant:
    a. For people with HIV, review CDC Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV.
    b. For people who are pregnant or breastfeeding, review CDC Clinical Considerations for Monkeypox in People Who are Pregnant or Breastfeeding.
    c. For treatment of children and adolescents, review CDC Clinical Considerations for Monkeypox in Children and Adolescents.
3. If patient has a clear indication for treatment, health care providers should review CDC Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox, including all required documentation:
    1) CDC Expanded Access IND Protocol. (Updated August 10, 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) FDA Form 1572. (Submit to CDC within seven calendar days of treatment initiation.)
    4) Patient Intake Form. (Submit to CDC within seven calendar days of treatment initiation.)
    5) Medwatch Serious Adverse Events Form. (Submit to CDC 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 Monkeypox.
    7) Methods for submitting required forms to CDC.
    Forms requested under the EA-IND can be returned to CDC **after** treatment begins. Please return completed forms to CDC via one of the following encrypted methods:
        a. Uploading to secure ShareFile (please zip multiple files and use filenames with patient initials, patient age, hospital/facility name, state, tecovirimat start date, and file contents [e.g., 1572, CV, Patient Intake Form]).
        b. Encrypted email: regaffairs@cdc.gov.
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 Monkeypox 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 Monkeypox 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.