Tecovirimat (TPOXX) Treatment Referral Form
Meritus Medical Center

Unmet Medical Need and Rationale for Use of Tecovirimat under Expanded Access IND

Currently, there is no treatment approved by the Food and Drug Administration (FDA) for non-variola orthopoxvirus, including Monkey Pox (MPX). Although tecovirimat is FDA-approved for treatment of smallpox in adults and children, the approved indication is limited to smallpox. Therefore, this intermediate-size EA-IND 116,039 Tecovirimat (CDC IRB #6402) Page 2 Version 6.1 August 10, 2022 patient population expanded access Investigational New Drug (IND), sponsored by the Centers for Disease Control and Prevention (CDC) and authorized by FDA, is to allow access to and use of stockpiled tecovirimat for treatment of non-variola orthopoxvirus (NV-OPXV) infection in adults and children.

Oral Tecovirimat Eligibility Criteria:

All patient populations, who meet eligibility criteria, can receive tecovirimat treatment under this IND program (e.g., children and all adults including pregnant and nursing individuals, and prisoners). Clinical considerations of tecovirimat therapy during an outbreak may evolve depending on the duration and nature of the outbreak and event-based information that may become available during the outbreak. For up-to-date interim clinical guidance for treatment of monkeypox during the current 2022 monkeypox outbreak, please refer to CDC website at: https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor_1655488137245

Primary or early empiric treatment

Tecovirimat 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. Patients with an initial negative OPXV test, but for whom both epidemiologic and clinical evidence suggests OPXV disease (particularly if clinical progression is worsening), should be re-tested but be treated with tecovirimat while results are pending. If results from re-testing confirm orthopoxvirus, patients should continue tecovirimat treatment. If results from re-testing are in agreement with the initial negative orthopoxvirus results, tecovirimat should be suspended in those patients.

Post-exposure prophylaxis (PEP)

Tecovirimat may be considered for post-exposure prophylaxis on an individual case-by-case basis in consultation with CDC (Emergency Operations Center [EOC] (770) 488-7100) depending on the known high-risk exposure to a confirmed or probable case of NV-OPXV infection (as defined on https://www.cdc.gov/poxvirus) and clinical conditions that necessitate an alternative or complementary option to PEP vaccination based on clinical judgment (e.g., severe allergic reaction to vaccine or vaccine components, immunocompromising conditions).

Meritus Medical Center, currently, **DOES NOT administer IV tecovirimat**. Considerations for IV tecovirimat

Adults and children who are unable to take oral therapy or for whom there is a concern that oral drug absorption may be altered should be considered for treatment with IV tecovirimat. These include critically ill patients hospitalized and unable to feed sufficiently by mouth, as oral tecovirimat absorption is expected to be lower in these patients since bioavailability of oral tecovirimat is dependent on adequate intake of a full, fatty meal. Patients with gastric bypass or evidence of gastrointestinal disfunction that may negatively impact drug absorption may also be considered for treatment with IV tecovirimat. In the absence of an oral tecovirimat suspension formulation, IV tecovirimat may be considered for children weighing less than 13 kg based on clinical assessment of risk/benefit and if determined appropriate by the treating clinician. Opening the capsule and mixing the tecovirimat powder with food to give a fraction of a capsule content (1/4 or 1/2 of a capsule) is an alternative option for younger children weighing less than 13 kg (See Table 4.1) and allowed under the IND. However, oral doses less than a full capsule content (200 mg) require careful preparation by a caregiver and has the inherent potential for inaccurate dosing

Oral Tecovirimat Ineligibility

- Patient or legally authorized representative unwilling to sign an informed consent and refuse tecovirimat treatment
- Known allergy to tecovirimat and/or inactive ingredients in tecovirimat

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Please complete the information in this form to its <u>entirety</u>, all information is <u>required</u>.
<u>Please fax</u> the completed form to the Meritus Retail Pharmacy at 301-790-9282.

- Patient Name (First and Last):
- DOB:
- Gender (circle one): Male Female Other/Unknown
- Patient preferred contact number:
- Patient Address:
- Patient preferred language (circle one): English Spanish Other: _____
- Date of laboratory confirmed non-variola orthopoxvirus infection: _____
- Patients with an initial negative OPXV test, but for whom both epidemiologic and clinical evidence suggests OPXV disease (particularly if clinical progression is worsening), should be re-tested but be treated with tecovirimat while results are pending. Date of re-test: _____

Meritus Medical Center may have further criteria for use depending on scarcity of medication supply or capacity for medication administration/dispensation.

Please notify the patient to expect a call from Meritus Retail Pharmacy within 24-48 hours for outcome of referral and next steps.

****☐ Order (check box to confirm ordering): Dispense Tpoxx (tecovirimat), Take 600 mg by mouth every 12 hours for 14 days**

I, the referring provider, am the patient's PCP or other continuity provider, have read and understand the FDA indications and/or the EUA information for the mentioned therapies above.
**** ☐ Indicates Provider Agreement (must check box)**

I, the referring provider, am the patient's PCP or other continuity provider, have advised the patient on the benefits and possible adverse reactions (stated in the prescribing information or EUA) on the mentioned therapies.
**** ☐ Indicates Provider Agreement (must check box)**

Provider name (print): _____ Date: _____

Provider signature: _____ Contact number: _____