Yukon-Kuskokwim HEALTH CORPORATION

Clinical Guideline

Monkeypox: Emergency Use of Tecovirimat

Tecovirimat (also called TPOXX)

- Tecovirimat is a is an inhibitor of the orthopoxvirus VP37 envelope wrapping protein, which prevents the formation of egress-competent enveloped virions necessary for cell-to-cell and long-range dissemination of virus.
- Tecovirimat is approved by the FDA to treat smallpox under the **Animal Rule Regulations**. It has not been studied in humans, as smallpox has been eradicated globally, and exposing people to smallpox virus for the purpose of a clinical trial is not ethical.
- Tecovirimat has also not been studied in the treatment of monkeypox. However, the FDA and CDC have an expanded access Investigational New Drug (IND) protocol (also known as "compassionate use") that allows tecovirimat to be used to treat monkeypox under strict requirements. The drug is only available from the Strategic National Stockpile.
- YKHC's Institutional Review Board has approved the use of tecovirimat as long as the **CDC/FDA protocols** are followed.

CDC Expanded Access IND Protocol

Patient with lesions suspicious for monkeypox with an indication to consider tecovirimat (see box).

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Swab lesions and send for **testing**.
Note: decision to treat is clinical, as results take a long time to return.

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Counsel patient/family on tecovirimat, including experimental nature and possible risks.
May use this **informed consent** form to guide counselling.

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If patient/family agrees to tecovirimat, contact COVID-19 Response Team by Tiger Connect.
Note: only providers on the IND registry may prescribe tecovirimat; thus, the COVID team has agreed to manage this drug.

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- COVID team will discuss further with patient, prescribe drug, complete all required IND forms, complete consent form, and document in RAVEN.
- Standard course of therapy is 14 days. See **protocol** for dosing and mixing instructions.
- COVID team will do periodic telehealth visits with patient to monitor progress and document in RAVEN.

Please see **these resources** for pain management and other supportive measures.

Indications to Consider Tecovirimat

- Severe disease: hemorrhagic disease; large number of confluent lesions; sepsis; encephalitis; ocular or periorbital infections; or other conditions requiring hospitalization.
- Involvement of anatomic areas which might result in scarring or strictures: lesions directly involving the pharynx causing dysphagia, inability to control secretions, or need for parenteral feeding; 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); and severe infections (including secondary bacterial skin infections), especially those that require surgical intervention such as debridement.
- Severe immunocompromise: advanced or poorly controlled human immunodeficiency virus (HIV), leukemia, lymphoma, generalized malignancy, solid organ transplantation, therapy with alkylating agents, antimetabolites, radiation, tumor necrosis factor inhibitors, or high-dose corticosteroids, being a recipient of a 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 8 years of age.
- Pregnant or breastfeeding people
- Concurrent conditions affecting skin integrity: 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).

Contraindications & Risks

- 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
- For IV tecovirimat only: patients with severe renal impairment (CrCl <30 mL/min)*. Oral tecovirimat is an option for patients with severe renal impairment.
- Co-administration with repaglinide may cause hypoglycemia. Monitor blood glucose and monitor for hypoglycemic symptoms during co-administration.

Adverse Reactions

In a Phase 3 clinical trial, the most common reported events were headache; nausea: vomiting; abdominal pain; and infusion site pain, swelling, erythema, and extravasation. Other events were reported in <2% of patients.

Reporting of Adverse Events

The prescribing health care provider is responsible for mandatory reporting of all medication errors and adverse events potentially related to tecovirimat. Reports must be made within seven days of the event.
Serious adverse events include: death; life-threatening adverse event; inpatient hospitalization or prolongation of existing hospitalization; persistent or significant incapacity or substantial disruption of the ability to conduct normal life function; congenital anomaly/birth defect; or medical or surgical intervention to prevent death, a life-threatening event, hospitalization, disability, or congenital anomaly.

Submit report to FDA MedWatch by completing the online form **here**.
The report should include "use of tecovirimat under Emergency Use Authorization (EUA)" in the "Describe Event" section.

See the **FDA MedWatch program** for more information.

This guideline is designed for the general use of most patients but may need to be adapted to meet the special needs of a specific patient as determined by the medical practitioner.
Approved by Clinical Guideline Committee 3/13/23.
If comments about this guideline, please contact Leslie_Herrmann@ykhc.org.