



August 31, 2022

## TPOXX Reporting Changes for Monkeypox Countermeasures

### Update on TPOXX Expanded Access Investigational New Drug (EA-IND) Protocol Reporting

On Thursday, August 25, 2022, the Indian Health Service (IHS) Chief Medical Officer Dr. Loretta Christensen, MD, distributed an email updating the agency's monkeypox activities and directed individual sites who treat patients under the simplified Expanded Access Investigational New Drug ([EA-IND](#)) Protocol for tecovirimat (TPOXX) to also report a copy of those forms to the IHS National Pharmacy and Therapeutics Committee (NPTC). The NPTC will utilize Smartsheet software, a FEDRAMP-approved and HIPAA compliant program, to collect copies of TPOXX documents. Please submit copies via the [NPTC Smartsheet TPOXX Collection Form](#).

### [Tecovirimat \(TPOXX\)](#): Recent Changes to the EA-IND Protocol

On August 18, 2022, the U.S. Centers for Disease Control and Prevention (CDC) posted a revised TPOXX [EA-IND Protocol](#). The EA-IND Protocol was amended to shorten the Patient Intake Form with required vs. optional data fields delineated, make the Clinical Outcome Form optional for one time follow-up within 3-14 days after treatment completion, eliminate during treatment follow-up, extend the time for returning the requested forms (e.g. within 7 calendar days of treatment initiation), add drug interactions information on tecovirimat and certain antiretroviral drugs, further clarify IV tecovirimat infusion via syringe pumps (avoid use of pre-filled IV bags and glass IV bottles), update opening the capsule and mixing with food instructions (replaced water with liquids), and include an alternative option for obtaining informed consent (short form with a written summary). Informed consent must still be obtained **prior** to the initiation of TPOXX treatment.

As a reminder, TPOXX is not FDA-approved for monkeypox but is available under the EA-IND protocol for treatment of people infected with monkeypox, particularly those with severe disease, or at risk for severe disease such as immunocompromised, and pediatric cases. A list of considerations can be found under [Interim Clinical Guidance](#) for the Treatment of Monkeypox. The CDC holds the EA-IND protocol to allow access to and use of TPOXX for treatment of monkeypox. The EA-IND provides umbrella regulatory coverage to clinicians, so facilities do not need to request and obtain their own INDs. The EA-IND also provides liability coverage under the PREP Act only when appropriate documentation is filed for each patient receiving treatment, and the drug is administered in accordance with the EA-IND.

Appropriate monitoring of patient safety and clinical outcomes for anyone receiving TPOXX is required. When treating a patient with TPOXX, healthcare providers should complete the following forms, as indicated below:

#### **Required:**

1. [Informed Consent Form](#): Obtain prior to treatment.
  - Alternative [Short Form Consent](#) and [Written Summary](#) that can be used to obtain informed consent.
2. [Patient Intake Form \(Form A\)](#): Submitted within 7 days of starting treatment. Baseline assessment.
3. [FDA Form 1572](#): One form per facility for all TPOXX treatments administered at the same facility, submitted within 7 days of starting treatment.
4. ***\*Updated: Submit copies of TPOXX documents via IHS [NPTC Smartsheet TPOXX Collection Form](#)***
5. [Serious Adverse Events](#): Report life-threatening or serious adverse events associated with TPOXX by completing a [PDF MedWatch Form](#) and returning it to CDC within 72 hours of awareness or sooner, if possible.

***\*\*Federal, Tribal, and Urban programs: When using the online voluntary Reporting Form or the FDA 3500 form, it is essential that the words "IHS" appear on the form, ideally in the address of the "Reporter" section.***

#### **References:**

1. Centers for Disease Control and Prevention. [Information for Healthcare Providers on Obtaining and Using TPOXX \(Tecovirimat\) for Treatment of Monkeypox](#). Updated August 18, 2022.