TPOXX – tecovirimat (capsules and injection)

EA – IND (Expanded Access- Investigational New Drug

➔ **Treating physician or designee should complete these forms to provide patient's baseline condition prior to tecovirimat initiation.**

➔ Return to CDC within **7 working days** of initiation of therapy by email (regaffairs@cdc.gov) or upload to secure ShareFile at https://centersfordiseasecontrol.sharefile.com/r-r3941801ebcbd4002b4dfe98e314ec697.

➔ **Protocol:** https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Protocol-CDC-IRB.pdf

REQUIRED ITEMS:

☐ 1. **Obtain prior to treatment:** Informed Consent Form, *5 pages* | (Spanish version, *6 pages*)
- Alternative: Short Form Consent, *3 pages* and Written Summary, *5 pages* that can be used to obtain informed consent.

☐ 2. **Baseline assessment:** Patient Intake Form, *2 pages*

☐ 3. **Signed** FDA Form 1572, *2 pages. One signed 1572 per facility suffices for all TPOXX Treatments administered under the EA-IND at the same facility.*

☐ 4. **Serious Adverse Events Reporting:** Report life-threatening or serious adverse events associated with TPOXX by completing: PDF MedWatch Form, *5 pages* and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible.

OPTIONAL ITEMS:

- Patient diary**,** *2 pages:* Ideally, give the diary to the patients during baseline assessment. Patient can use this form to record how they feel and any side effects to TPOXX.
- Clinical Outcome Form, *2 pages.* Progress information during and post treatment.
- **Photos of lesions**: If feasible, take lesion photos at baseline prior to TPOXX treatment, and post-treatment to follow lesion progression and healing during treatment.
- **Lesions samples for resistance testing:** Ideally, a sample from at least 1 lesion prior to TPOXX treatment but only if baseline diagnostic testing wasn't performed, as well as samples from any new lesions that develop during and after TPOXX treatment to assess for development of antiviral resistance mutations. Optional Lesion Samples for Resistance Testing, *1 page* has instructions on collection, storage, and submission of samples.
- **Pharmacokinetic samples for testing:** During TPOXX treatment, plasma samples may be collected to monitor TPOXX levels for adequate drug exposure in patients. Optional Pharmacokinetic Samples for Testing, *4 pages* has instructions on collection, storage, and submission of samples.
- Instructions for mixing TPOXX capsules with food, *2 pages*: This patient instruction sheet explains how to open TPOXX capsules and mix with breastmilk, infant formula, milk or food for infants and children.

RESOURCE WEBSITES:

- https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html
- https://www.cdc.gov/poxvirus/monkeypox/clinicians/treatment.html#anchor_1655488284069
- https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/214518s000lbl.pdf