Information below is from the CDC website:

[Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox | Monkeypox | Poxvirus | CDC]

https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html

There is also CDC Clinical Guidance found on the following page:

https://www.cdc.gov/poxvirus/monkeypox/clinicians/Tecovirimat.html#

**How to obtain TPOXX**

- TPOXX is available through the Strategic National Stockpile. To request TPOXX, clinicians and care facility pharmacists can contact their state/territorial health department
- Prior to making a request, please review the Patient Intake Form to confirm that your patient likely meets criteria for receipt of therapy. You should then review and complete the Informed Consent Form with the patient to ensure they agree to proceed before making the treatment request.
- Once these are complete, please contact your regional Public Health Department for initial coordination and to facilitate case review (contact: https://dhhs.ne.gov/CHPM%20Maps/LHD-EPISurvelliance.pdf). Your regional Public Health Department will be in touch with Nebraska DHHS leadership to verify case appropriateness and arrange necessary logistical details for receipt of product. You will need to have determined the dose, interval, and duration of the TPOXX regimen that is most appropriate for the patient in order to communicate how much TPOXX you are requesting (details within Protocol 6402).
- Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities.
- All other forms, aside from the informed consent, requested under the EA-IND can be returned to CDC **after** treatment begins.

**Protocol**

- CDC holds an intermediate-size patient population EA-IND(IND 116,039/Protocol 6402) to allow access to and use of TPOXX for treatment of orthopoxvirus infections, including monkeypox. The EA-IND provides an umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. The EA-IND also provides liability coverage under the PREP Act for compensation to patients if injured via the Countermeasure Injury Compensation Program (CICP).

- On July 21, 2022, CDC IRB approved an amendment [123KB, 1 page] and continuation [105KB, 1 page] of Protocol 6402 [430KB, 21 pages]. Clinicians, care facilities, hospitals providing TPOXX can immediately transition to the revised protocol and forms.
- CDC IRB serves as the central IRB for review and approval of the TPOXX EA-IND protocol and determined that its use does not constitute research involving human subjects as defined by 45 CFR 46.102. Since this EA-IND protocol for TPOXX is solely for treatment use and not considered human subjects research, federal-wide assurance requirements do not apply.
- For facilities requiring a reliance agreement, CDC IRB will provide a pre-signed reliance agreement for facilities to sign documenting reliance on CDC IRB (huma@cdc.gov).
- Healthcare providers should complete the following forms:

**Required**

1. Informed Consent Form English [261 KB, 5 pages] | Spanish [335 KB, 6 pages]: Obtain prior to treatment.

   Per communication with CDC Regulatory Affairs, Patty Yu – "Informed consent may be obtained via telemed process — for documentation of consent, the patient may electronically sign the consent form or can print the signature page, sign, and take a photo or scan the signature page and send to their providers.

1. Patient Intake Form [321KB, 3 pages]: Baseline assessment.
2. FDA Form 1572 [1MB, 2 pages]: One signed 1572 per facility suffices for all TPOXX treatments administered under the EA-IND at the same facility.
3. Clinical Outcome Form [279KB, 4 pages]: Progress information during and post treatment.
4. Serious Adverse Events : Report life-threatening or serious adverse events associated with TPOXX by completing a PDF MedWatch Form [226KB, 3 pages] and returning it to CDC via email (regaffairs@cdc.gov) or uploading to ShareFile within 72 hours of awareness or sooner, if possible. The PDF MedWatch Form can also be downloaded from the FDA website. (Note: The MedWatch Form can only be viewed on the Adobe desktop app. Please save or download the form for viewing.)

**Optional Photos and Samples – Note: there is no funding available to pay for sample collection or shipping**

- **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. See Optional Lesion Samples for Resistance Testing [117KB, 1 page] for 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. See Optional Pharmacokinetic Samples for Testing [253KB, 5 pages] for instructions on collection, storage, and submission of samples.

**Optional Patient Diary and Instructions –Note: these are not yet available in any other language.**

- Patient diary [226 KB, 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.
- Instructions for mixing TPOXX capsules with food [261KB, 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.