

Procedures for Obtaining TPOXX (Antiviral - PO and IV) and Jynneos Vaccine for Monkeypox (MPX)

ALABAMA
PUBLIC
HEALTH

TPOXX and Jynneos can be received from the Strategic National Stockpile (SNS) through the Alabama Department of Public Health.

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

- A. FDA Form 1572 needs to be signed by a Principal Investigator (MD) and include a CV. All other providers (including mid-levels) at the same facility who may treat MPX should be listed under secondary investigators. Send the signed FDA Form 1572 with one single CV to CDC (regaffairs@cdc.gov). Send a copy of the FDA Form 1572 to ADPH (Burnestine.taylor@adph.state.al.us). Keep a copy in your files. Should you add additional secondary investigators, notify ADPH and keep your updated form, CDC does not require updated forms. You are now an approved TPOXX provider.
- B. Once Form 1572 has been signed, provide to ADPH (Burnestine.taylor@adph.state.al.us and Pharmacy@adph.state.al.us) shipping information. (You may want to list as your Primary POC a pharmacist, as this person will receive and, likely, store your medication). Having this shipping information on file ASAP will assure prompt delivery of medication to your facility.
- A. Shipping address for TECOVIRIMAT (can put Attention Pharmacy if applicable, or any special delivery instructions); No PO Boxes
- B. Receiving POC#1 at shipping address (please indicate if Pharmacist) (name, email and 24/7 monitored Phone #)
- C. Receiving POC #2 at shipping address (please indicate if Pharmacist) (name, email and 24/7 monitored Phone #)
- D. Jurisdiction HD POC (health department POC)(please indicate if Pharmacist) (name, email and 24/7 monitored Phone #)- can list Dr. Taylor (ADPH) if you are not affiliated with a Health Department
- E. Days/times the shipping address location is/is not available to receive a shipment
- C. Order request for oral TPOXX can be made through Pharmacy@adph.state.al.us. Minimum order is 6 courses/12 bottles. IV TPOXX can be requested from the same source. Further details on IV TPOXX will be available through the same source, if needed.
- D. Once you are an approved provider, your TPOXX **inventory should be updated weekly (every Monday before COB)** with ADPH via email : Pharmacy@adph.state.al.us with the following information:
1. Inventory on hand at depot for each site (if multiple) in bottles (not courses)
 2. Number of bottles administered since last report on inventory
 3. Number of incomplete therapy (patient did not complete)
 4. Reporting POC name and name of Institution
- E. Once you have TPOXX on hand, it will be your clinical decision to administer TPOXX. Neither ADPH nor CDC has to be consulted for this decision. The treating entity is, however, responsible for obtaining and **Informed Consent form** and **Patient Intake Form** and sending to CDC via email (regaffairs@cdc.gov). ADPH does not require copies of patient forms. The treating entity is also responsible for reporting any serious adverse events, if any. The patient diary and clinical outcome forms are optional, but CDC would appreciate information on special groups (pregnant, children, etc.) to help formulate future guidelines. The treating entity can decide to have in-person or virtual visits during therapy.
- F. Familiarize yourself with
- a. TPOXX protocol- treatment guidelines: <https://www.cdc.gov/poxvirus/monkeypox/pdf/Tecovirimat-IND-Protocol-CDC-IRB.pdf>
 - b. TPOXX HPOP Attestation (you cannot sell TPOXX, etc.): <https://www.alabamapublichealth.gov/monkeypox/assets/tpoxx-distribution-attestation.pdf>
- G. You can also become a Jynneos Vaccine Provider. If you are not enrolled in ImmPrint, you can become enrolled. You must meet storage requirements. Sign the Vaccine Provider Agreement and forward to Denise.strickland@adph.state.al.us and she will contact you with further information. The amount of vaccine distributed will be assessed on a case-by-case basis depending on allotment available and amount you utilize, as displayed in ImmPrint. <https://www.alabamapublichealth.gov/monkeypox/assets/mpx-vax-provider-agreement.pdf> <https://www.cdc.gov/poxvirus/monkeypox/pdf/Storage-and-Handling-Summary.pdf>

For additional questions, contact: Burnestine.taylor@adph.state.al.us

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