Background: There is a multi-country outbreak of monkeypox in non-endemic countries including the US. The current circulating strain of monkeypox has been to date limited to the West African clade, which tends to cause milder disease. Most patients have mild disease and recover without medical intervention. Patients with severe monkeypox disease or who are at high risk for severe disease should be considered for treatment.

Currently there is no treatment approved specifically for monkeypox virus infections. However, antivirals developed for use in patients with smallpox may prove beneficial against monkeypox. The following clinical guidelines and FAQs are to support clinicians obtain and use tecovirimat. For information on other therapies see CDC Monkeypox Treatment Information. Visit the LAC DPH Healthcare Provider Monkeypox Hub for current guidance including monkeypox testing, treatment, vaccination.

Tecovirimat (also known as TPOXX or ST-246) is an FDA-approved antiviral medication for the treatment of human smallpox disease. The CDC holds an expanded access Investigational New Drug (EA-IND) protocol that allows for the use of stockpiled tecovirimat to treat monkeypox disease during an outbreak. Tecovirimat is available for use in Los Angeles County for patients who meet the CDC clinical criteria (see LAC DPH TPOXX Treatment Algorithm below). Informed consent is required for all patients treated with tecovirimat. Tecovirimat is available in oral and intravenous formulations.

Data are not available on the effectiveness of tecovirimat in treating monkeypox infections in people, but studies using a variety of animal species have shown that tecovirimat is effective in treating disease caused by orthopoxviruses. Clinical trials in people showed the drug was safe and had only minor side effects.

### LAC DPH TPOXX Treatment Algorithm

<table>
<thead>
<tr>
<th>Has the patient tested positive for monkeypox?</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the patient have severe disease as defined by one of the following*:</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>Does the patient meet criteria as at risk for severe monkeypox as defined by one of the following*:</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td>1. Immunocompromise (e.g. poorly controlled HIV, active cancer, organ transplant, immune suppressing medications)</td>
<td>2. Age &lt;8 years of age</td>
<td>3. Pregnant or breastfeeding women</td>
</tr>
</tbody>
</table>

Healthcare providers should speak to their patient regarding monkeypox treatment-see FAQs below. Providers can treat using the CDC IND protocol*. To obtain tecovirimat call the DPH healthcare provider line at 213-240-7941 (this line is reserved only for providers and not patients or the public).

Algorithm footnotes:
+ Adapted from CDC Interim clinical guidance for treatment of monkeypox
* See the LAC DPH Monkeypox Provider Hub for the most current vaccination recommendations.
# Please refer to CDC treatment considerations for tecovirimat. Patient selection for treatment is at the discretion of the treating clinician under the EA-IND.
^ CDC IND protocol information
Obtaining and Using Tecovirimat: Healthcare providers who determine that their patients require treatment can call the DPH healthcare provider line 213-240-7941 to obtain tecovirimat and providers can treat following the CDC IND protocol forms which will be emailed to them. Providers will need to submit required documents necessary for the IND protocol directly to the CDC. If further orthopoxvirus testing is deemed necessary, at discretion of the treating clinician according to the IND protocol, LAC DPH can coordinate specimen submission to the CDC.

Immediate need – Patient urgently needs Tecovirimat

If a provider has a patient in urgent need of treatment, the provider may proceed with tecovirimat treatment once informed consent has been obtained. Paperwork does not need to be completed to initiate treatment.

The use of tecovirimat for monkeypox is under the EA-IND which has been CDC IRB-approved and authorized by FDA to proceed. Patient-level approval is not required from FDA in order to initiate treatment (except for pediatric patients, if a pediatric patient is in need of treatment at this time, CDC requires use of a single-patient IND, which would require patient-level FDA authorization prior to administration).

To obtain additional information and required forms to start the treatment process, please call the DPH healthcare provider line 213-240-7941.

Frequently Asked Questions about Monkeypox Treatment with Tecovirimat

What drugs are available in Los Angeles County for the treatment of monkeypox?

Tecovirimat (TPOXX) is an investigational new drug available for the treatment of monkeypox and is available in Los Angeles County if the patient meets treatment criteria as per CDC clinical guidance. TPOXX is an antiviral medication available through an expanded access Investigational New Drug (EA-IND) protocol for the treatment of monkeypox infection. Informed consent is required for all patients treated with tecovirimat. Tecovirimat is available in oral and intravenous formulations. Other drugs (brincidofovir, vaccinia immune globulin) are potentially available, but are considered second-line drugs.

How effective is tecovirimat for the treatment of monkeypox?

Experience with and data for tecovirimat treatment for monkeypox is currently very limited. Animal studies suggest mortality benefit. The oral drug has been well tolerated in the people who have received it this far and appears to be effective in laboratory studies, but the drug is still considered an investigational new drug. Safety and side effects have not been studied in pregnancy, breastfeeding, and pediatrics.

How do I refer my patient for treatment of monkeypox?

If your patient is a candidate for treatment of monkeypox, you should reach out to LAC DPH provider line at 213-240-7941. Patient calls are not accepted by the LAC DPH provider line and only healthcare providers can obtain TPOXX for use following the CDC EA-IND protocol.

What can my patient expect if they start treatment with tecovirimat?

Standard adult oral dosing of tecovirimat is 600mg every 12 hours for 14 days. For most adults, this will require taking 3 pills every 12 hours. Tecovirimat capsules should be taken within 30 minutes after a full meal containing moderate or high fat. Co-administration of the diabetes drug repaglinide may increase the risk of hypoglycemia. IV formulations are available for the drug if needed for hospitalized patients.
Patients who start tecovirimat need to consent for use of an investigational new drug and will need to follow-up with their provider according to the CDC’s EA-IND protocol which may include blood tests if the patient’s clinical condition necessitates performing clinical labs. Required and optional items for healthcare providers using TPOXX following CDC’s EA-IND protocol can be found [here](#).

**What are the side effects of tecovirimat?**

Tecovirimat is generally well tolerated and side effects were fairly rare and mild. There was a small increase in headache (12%) and nausea (5%) for patients taking tecovirimat as compared to placebo (8% and 4% respectively).

**If my patient is not a candidate for pharmacological treatment of monkeypox, what other treatments are recommended?**

Most patients with monkeypox have mild disease and should recover without medical intervention. Supportive and symptomatic care such as fluids, antipyretics and pain control is recommended. If the patient’s monkeypox disease worsens, they should be re-assessed for tecovirimat therapy.

**What are the isolation instructions for patients with monkeypox?**

For individuals with monkeypox, isolation precautions should be continued until all lesions have resolved, the scabs have fallen off, and a fresh layer of intact skin has formed. See CDC monkeypox infection control in [healthcare settings](#) and [at home](#) for more details.