

## **Expanded Access to Tecovirimat (TPOXX) for Monkeypox**

August 26, 2022

Dear Colleagues:

The number of people diagnosed with monkeypox continues to rise in Maricopa County (MC). Most cases of monkeypox are self-limited and only require supportive care to fully recover. Those cases that are severe or at risk of progressing to severe disease are eligible for treatment with tecovirimat (TPOXX). So far during the 2022 outbreak in MC, about 20% of cases have met eligibility for treatment with TPOXX. With increasing demand for TPOXX, MCDPH has partnered to ensure equitable and efficient access to TPOXX.

### **Staging TPOXX**

MCDPH has staged TPOXX supply at outpatient clinics that see high numbers of high-risk patients for monkeypox. TPOXX supply has also been staged at major healthcare systems across the county for both inpatient and outpatient prescribing. If you are a clinician who cares for high-risk patients and are affiliated with a large healthcare system, inquire internally regarding access to TPOXX prescribing.

### **Expanding TPOXX Consultation Capacity**

In partnership with the Banner Poison and Drug Information Center (BPDIC), clinicians without access to staged TPOXX supply can now call BPDIC at 602-747-7111 to obtain TPOXX. BPDIC will review clinical eligibility based on CDC criteria with the prescribing clinician and when appropriate submit an order for dispensing to MCDPH. MCDPH will arrange for the TPOXX course to be delivered to the prescriber.

### **TPOXX Prescribing Eligibility**

According to CDC, prescribers should consider treating patients with highly suspect or laboratory-confirmed monkeypox infection AND one of the following:

- Severe disease (e.g., hemorrhagic disease, confluent lesions, sepsis, encephalopathy)
- Hospitalization for monkeypox or other co-morbidities

- Compromised immune system [e.g., HIV<sup>1</sup>, active cancer diagnosis/treatment, immunotherapy]
- Age < 8 years
- Pregnancy or breastfeeding
- Mucous membrane involvement (e.g., eyes, mouth, anus or genitals)
- Significant facial lesions at-risk for permanent scarring
- Secondary complications (e.g., bacterial infection, diarrhea, dehydration, concurrent disease, severe pain)

More information regarding TPOXX treatment can be found in [CDC's Guidance for TPOXX Use](#) and [Clinical Considerations for Treatment and Prophylaxis of Monkeypox Virus Infection in People with HIV](#)

### **Streamlined EA-IND Process for Prescribers**

The FDA and CDC have streamlined the [process for ordering TPOXX](#). Prescribers must obtain informed consent, complete FDA form 1572 and complete the patient intake form. All required forms can be found on the CDC [website](#). Interval follow-up and the clinical outcome form are no longer required.

### **Background on Tecovirimat**

Tecovirimat is an antiviral medication approved by the United States Food and Drug Administration (FDA) for the treatment of smallpox, and is now being used to treat monkeypox infection under an Expanded Access Investigational New Drug (IND) protocol from the Centers for Disease Control and Prevention (CDC). It is available for children and adults as an oral capsule and IV formulation. While data are not available on the effectiveness of tecovirimat in treating monkeypox infections in people, animal studies have shown it is effective in treating disease and reducing the risk of death from Orthopoxviruses. Clinical trials in people have shown the drug is safe with only minor side effects. One case report describes a shortened duration of illness and viral shedding in a patient who received tecovirimat (Adler, 2022).

### **Experience with Tecovirimat in Maricopa County**

Approximately 20% of people diagnosed with monkeypox in Maricopa County have been treated with TPOXX. Frequent indications include painful oral, anal or penile lesions and bacterial superinfection. It has been prescribed for about 40 patients, many of whom have reported significant improvement after just a few days of starting treatment. There have been delays getting tecovirimat to patients given the lack of providers and facilities willing and able to prescribe this medication.

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<sup>1</sup> Treatment strongly encouraged for HIV pts with CD4 <350, [uncontrolled or](#) unknown viral load or poor compliance with treatment

Monkeypox is a painful, often debilitating illness. Prompt initiation of tecovirimat can lessen suffering and reduce the risk of complications. We urge facilities and providers to take steps to be able to prescribe tecovirimat to ensure timely treatment for their patients. For more information, including information about supportive care for monkeypox, visit the [NYC Health Department's Monkeypox Information for Providers](#) webpage.



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