NEW YORK CITY DEPARTMENT OF

HEALTH AND MENTAL HYGIENE

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Commissioner

2022 Health Advisory #16: Accessing Tecovirimat for People with Monkeypox

- Many people with monkeypox in New York City (NYC) have developed complications including proctitis, which can progress to become severe and debilitating, and lesions in anatomical sites at risk of scarring or other permanent sequelae. Supportive care, including pain control, is a mainstay of treatment.
- Tecovirimat (TPOXX) is an antiviral medication available through the Centers for Disease Control and Prevention (CDC) that is being used to treat monkeypox infection under CDC's Expanded Access Investigational New Drug (IND) protocol. To date, tecovirimat has been prescribed for over 400 patients in NYC.
- Recently the FDA and CDC simplified this protocol so that treatment with tecovirimat can begin upon obtaining informed consent from the patient. No pre-registration is required and evaluations can be done by telemedicine. Additional forms must be submitted to CDC after initiating treatment.
- Providers are urged to take the necessary steps to prescribe tecovirimat when indicated for the patients that have a positive test result (or are awaiting test results and have a clinically compatible illness). NYC providers who want to prescribe tecovirimat and can adhere to the IND protocol can email MPXtherapeutics@health.nyc.gov for information on free delivery to patients or to request supplies for a pharmacy at their facility.
- For more information about monkeypox, visit the NYC Department of Health and Mental Hygiene's Monkeypox Information for Providers webpage.

August 2, 2022

Dear Colleagues,

The number of people diagnosed with monkeypox continues to rise in New York City (NYC), the US and other countries. On July 23, 2022, the World Health Organization declared MPX a Public Health Emergency of International Concern; on July 28, the New York State Department of Health declared monkeypox an Imminent Threat to Public Health and, on July 29, the State declared a State Disaster Emergency; and on July 30, the NYC Department of Health and Mental Hygiene (Health Department) declared monkeypox a Public Health Emergency, and on August 1, the City declared a State of Emergency.

This Health Advisory provides information on the antiviral tecovirimat (TPOXX) including indications for use and how prescribe it to your patients.

Clinical Experience During the Current Outbreak
During the current global monkeypox outbreak, many individuals with monkeypox have required supportive care including medicines or other clinical interventions to control itching, nausea, vomiting, and pain. In NYC, a high proportion of cases have developed complications requiring prescription medication, including proctitis which can progress to become severe and debilitating, and lesions in anatomical sites (e.g., anal and genitourinary) at risk of scarring or stricture. Prescription medications may include pain relievers and the oral antiviral tecovirimat. See the Health Department's Interim Guidance for Treatment of Monkeypox for detailed guidance regarding care and treatment.

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).

When to Consider Tecovirimat for Patient Management
Tecovirimat is indicated for patients with a positive test result (or patients for whom specimens have been submitted for testing and have a clinically compatible illness) and have:
- Severe disease that may manifest as hemorrhagic disease, sepsis, or encephalitis
- Lesions in anatomical areas at special risk of scarring or stricture, such as those near or directly involving the eye, mouth, rectum, or urethra
- Complications, such as urethritis and proctitis, particularly with tenesmus, challenges in pain control, or rectal bleeding
- High risk of severe disease such as those who are immunocompromised, pregnant or breastfeeding people, have a history or presence of atopic dermatitis or other active exfoliative skin conditions, and children

Experience with Tecovirimat in NYC
Approximately 25% of people diagnosed with monkeypox in NYC have had one or more indications for tecovirimat. The most common indication is severe proctitis. Other indications include painful oral, anal or penile lesions and bacterial superinfection. It has been prescribed for over 400 patients, many of whom have reported significant improvement after just a few days of starting treatment. No significant adverse events have been reported; some patients have reported headache and nausea. There have been severe delays getting tecovirimat to patients given the lack of providers and facilities able to prescribe this medication.

How to Access and Prescribe Tecovirimat

Any provider or health care facility or system can prescribe tecovirimat under the CDC's IND protocol, which was recently simplified, including to allow the use of telemedicine for all patient encounters (initial and follow-up visits) as long as the patient can submit the signed consent form electronically. Tecovirimat is provided at no cost by the federal government and patients should not be charged for the medicine, however providers may bill for the encounter. Providers can prescribe for individual patients as needed from a dedicated NYC supply managed by a partner pharmacy. In planning for future tecovirimat use, providers can also coordinate with the NYC Health Department to request a supply from the strategic national stockpile to have on site at a facility or health system pharmacy.

Follow these steps to prescribe tecovirimat for eligible patients:

1. Have the patient sign the **Informed Consent Form**.
2. Email the NYC Health Department at MPXtherapeutics@health.nyc.gov to receive an automated reply with instructions on how to:
   - Record patient identifiers and indication for treatment in a HIPAA-compliant secure web-based REDCap form; and
   - Arrange to have individual prescriptions delivered to your site or directly to the patient by the NYC pharmacy courier service.
3. Submit to CDC:
   - Enrollment **FDA Form 1572**.
     i. This is a provider/facility enrollment form and is not required for each patient. Only one form is required for each provider or facility and once submitted will cover all prescriptions for that provider, or providers within a facility. Providers and facilities can enroll at any time and submit this form in advance of prescribing tecovirimat to patients.
     ii. If submitting for the first time in order to prescribe tecovirimat for a patient, it should be submitted within 3 days of treatment the patient
   - The two IND forms required for each individual prescription; these forms can be submitted after treatment begins and ideally within 3 days of starting treatment:
     i. The signed and completed **Informed Consent Form**
     ii. **Patient Intake Form**
4. Conduct two follow-up visits: one while the patient is on treatment (ideally between days 7 to 14) and another after treatment completion, and then submit the required **Clinical Outcome Form** to CDC.
5. Report life-threatening or serious adverse events associated with tecovirimat by sending a completed MedWatch Form to regaffairs@cdc.gov within 72 hours of awareness.

Visit CDC's Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox for detailed information about the IND protocol and forms.

Providers or facilities interested in (i) ordering a supply of tecovirimat to maintain at an onsite pharmacy or (ii) requesting instruction and assistance with the IND paperwork or other institutional approvals/review board issues or (iii) interested in serving as a referral site that is set up to prescribe tecovirimat for patients who do not have a primary care provider can email the NYC Health Department at MPXtherapeutics@health.nyc.gov. Providers unable to complete the required IND forms to prescribe tecovirimat can also reach out to this email address for assistance in referring patients to another provider; however, at this time there are prolonged wait times with an insufficient number of providers able to accept external referrals and capacity is limited.

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.

Access to Health Care
Ensuring that all New Yorkers have access to health care when they need it is a top priority of the NYC Health Department. Refer your patients to get free enrollment assistance to sign up for low- or no-cost health insurance, by having them call **311**, text CoveredNYC (SeguroNYC for Spanish) to 877877, or visit nyc.gov/getcoverednyc. To connect with a Health Department Certified Application Counselor, visit nyc.gov/health/healthcoverage.

With appreciation,

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