

The Commonwealth of Massachusetts

Executive Office of Health and Human Services

Department of Public Health

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# CIRCULAR LETTER: DCP-22-08-114

**To:** MA Practitioners Treating Patients Diagnosed with Monkeypox

**From:** James Lavery, Director, Bureau of Health Professions Licensure

 David Johnson, Director, Drug Control Program

**Date:** August 30, 2022

**Subject:** Controlled Substance Requirements for Practitioners Administering or Dispensing Tecovirimat (TPOXX) for Treatment of Monkeypox pursuant to IND No. 116,039

This Circular Letter is issued by the Drug Control Program (DCP), which is part of the Bureau of Health Professions Licensure, to clarify DCP’s requirements for practitioners working with tecovirimat (TPOXX) to treat patients diagnosed with monkeypox.

Tecovirimat (also known as TPOXX or ST-246) is a Federal Food and Drug Administration (FDA)-approved treatment for human smallpox disease caused by variola virus in adults and children. In Massachusetts, TPOXX is ordinarily a Schedule VI medication in all its forms, as it is not federally scheduled, but requires a prescription when used for treatment of smallpox. However, the FDA has authorized TPOXX for treatment of monkeypox under a specific protocol which designates TPOXX as an Expanded Access-Investigational New Drug (EA-IND) when used for treatment of non-variola orthopoxvirus, including monkeypox. **Practitioners must comply with the protocol (IND No. 116,039) to obtain and administer TPOXX for treatment of monkeypox.**[[1]](#footnote-1)

Massachusetts Controlled Substance Registration

DCP will not require practitioners who have fully complied with IND No. 116,039 to obtain a separate Researcher Massachusetts Controlled Substance Registration (MCSR) to prescribe, administer or delegate administration of TPOXX for treatment of monkeypox. If a practitioner has fully complied with IND No. 116,039, DCP will consider the practitioner’s existing current MCSR as authorizing the practitioner to prescribe, administer or delegate administration of TPOXX to patients for treatment of monkeypox.

Dispensing TPOXX

Licensed clinics and hospitals may dispense TPOXX to non-clinic and non-hospital patients, pursuant to a prescription by any Massachusetts practitioner, despite provisions in CMR 722.000: *Dispensing procedures for clinic and hospital pharmacies*, which limit dispensing only to the clinic or hospital’s own patients and pursuant to prescriptions issued only by clinic and hospital practitioners, because the medication will be handled according to federal rules governing EA-IND treatment protocols, pursuant to a registrant’s authority under IND No. 116,039, rather than the clinic or hospital registration.

A site without an on-site pharmacy (e.g., urgent care or practitioner’s office) and with the appropriate authority pursuant to IND No. 116,039, may receive, stock, administer and dispense TPOXX according to the federal treatment protocol and in compliance with patient specific labelling requirements in M.G.L. c. 94C, § 21. TPOXX must be labeled with the following information:

* date of filling
* pharmacy/hospital/clinic name and address
* filling pharmacist/dispenser initials
* prescription number assigned by pharmacy/dispenser
* name of patient
* name of prescribing practitioner
* name of controlled substance
* expiration date
* directions for use and cautionary statements, if any, and
* number of tablets or capsules in container.

Questions or concerns regarding this Circular Letter should be directed to DCP: dcp.dph@mass.gov

Monkeypox information for clinical providers, including clinical guidance is available here:

<https://www.mass.gov/info-details/monkeypox-information-for-health-care-providers>

For questions regarding patients with known or suspected monkeypox infection, please contact the **24/7 MDPH Epidemiology line at 617-983-6800**

1. For instructions on how to obtain TPOXX, please see the current version of *Information for Healthcare Providers on Obtaining and Using TPOXX (Tecovirimat) for Treatment of Monkeypox* on the CDC website*,*[*https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html*](https://www.cdc.gov/poxvirus/monkeypox/clinicians/obtaining-tecovirimat.html) [↑](#footnote-ref-1)