Mpox Treatment Drug, Tecovirimat (TPOXX® or ST-246), as a Medi-Cal Pharmacy Benefit

February 13, 2023

What Pharmacy Providers and Prescribers Need to Know

Effective for dates of service (DOS) on or after August 17, 2022, the Department of Health Care Services (DHCS) will reimburse the dispensing fee as a pharmacy benefit for the Mpox treatment drug, Tecovirimat (TPOXX®), when dispensed in accordance with the provisions of the U.S. Food and Drug Administration (FDA) Expanded Access Program and the Centers for Disease Control and Prevention (CDC)'s *Guidance for Tecovirimat Use; Expanded Access Investigational New Drug Protocol During 2022 U.S. Mpox Outbreak*.

Currently, there are no available FDA–approved treatments for Mpox. However, TPOXX is an antiviral drug that is FDA-approved for the treatment of smallpox in adults and pediatric patients. Its use for treatment of Mpox is permitted through an FDA-regulated Expanded Access Investigational New Drug (EA-IND) protocol through CDC, which facilitates access to and use of TPOXX for treatment of Mpox. TPOXX is the recommended first-line treatment for most patients during the current outbreak.

Prior authorization (PA) is not required for reimbursement.

Important Billing Instructions

- The pharmacy must ensure that the prescriber has completed all the required forms for EA-IND, including FDA Form 1572 (or is affiliated with an organization that has completed the form) as specified by CDC.
    - The pharmacy must confirm with the prescriber that the Patient Consent Form has been signed. For additional details, see Expanded Access IND Protocol.

- Note that treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent. Forms requested under the EA-IND can all be returned to CDC after treatment begins.

- Since TPOXX is supplied free by the federal government and made available through public health departments, pharmacies will not be reimbursed for the cost of the drug, but will be reimbursed the professional dispensing fee.

- All eligible retroactive claims for DOS on or after August 17, 2022 will be processed. Pharmacy providers are to submit eligible claims for reimbursement.

- Any concerns regarding delay in reimbursement should not cause pharmacy providers to decline dispensing of TPOXX to patients.

Pharmacy providers may bill for the dispensing of TPOXX NDCs using NCPDP D.0 web, batch, and paper claims according to the table below.

Billable NDCs and billing quantity are both outlined below:

NDC	Label Name	Generic Name	PA required (Y or N)	Minimum Age	Claim Quantity
50072001030	TPOXX	Tecovirimat	N	0	20 ml (200 mg/20 mL in SDV)
50072020042	TPOXX	Tecovirimat	N	0	42 capsules (Each bottle contains 42 x 200 mg capsules)

Product Availability

- TPOXX is available from the U.S. Strategic National Stockpile (SNS). It can be ordered from CDPH and does not need to go through CDC.

- Clinicians and care facility pharmacists requesting TPOXX should contact their local health department for current local availability. Pre-positioned supply may be the fastest route to obtain Tecovirimat.

  - The local health department Medical Health Operational Area Coordinator (MHOAC) will submit a resource request to CDPH, and medications will be shipped to the health care facility.

- CDC can assist in the diagnosis and management of patients with suspected Mpox. If treatment drugs are needed or additional information is required, providers should contact the CDC Emergency Operations Center at 1-770-488-7100, Monday through Friday, 8:00 a.m. to 4:30 p.m. Eastern Time; at other times call 1-404-639-2888.

Resources

- *[TPOXX Package Insert](#)*
- *[Mpox Tecovirimat Treatment Information for Healthcare Providers](#)*
- *[Guidance for Tecovirimat Use; Expanded Access Investigational New Drug Protocol During 2022 U.S. Mpox Outbreak](#)* – CDC guidance regarding TPOXX use.
- *[Information for Healthcare Providers: Tecovirimat (TPOXX) for Treatment of Mpox](#)* – CDC guidance on requesting TPOXX through the SNS.
- *[Expanded Access IND Protocol: Use of Tecovirimat (TPOXX®) for Treatment of Human Non-Variola Orthopoxvirus Infections in Adults and Children](#)*

For population of claim form fields other than those identified in this guidance, review the [Medi-Cal Rx Provider Manual](#).

Additional guidance on Mpox can be found on both the [California Department of Public Health](#) (CDPH) and [CDC](#) websites.

Contact Information

You can call the Medi-Cal Rx Customer Service Center (CSC) at 1-800-977-2273, which is available 24 hours a day, 7 days a week, 365 days per year.

For other questions, email Medi-Cal Rx Education & Outreach at MediCalRxEducationOutreach@magellanhealth.com.