Official websites use .gov A .gov website belongs to an official government organization in the United States. Secure .gov websites use HTTPS A lock ( ) or https:// means you've safely connected to the .gov website. Share sensitive information only on official, secure websites. Oral tecovirimat for treatment of mpox is primarily available through the National Institutes of Health’s Study of Tecovirimat for Mpox (STOMP). Healthcare providers should either contact the STOMP call center (1-855-876-9997) or their state/territorial health department to inquire about any remaining, prepositioned supply of oral tecovirimat available within their jurisdiction. Any remaining supply can be used for EA-IND eligible patients. State/local/territorial health departments should request TPOXX on behalf of providers caring for patients with mpox by calling the CDC Emergency Operations Center (770-488-7100) or poxvirus@cdc.gov (during regular business hours). The expanded access IND (EA-IND) eligibility criteria for tecovirimat treatment for patients with mpox has been revised. The current version of the EA-IND protocol [494 KB, 28 pages] is version 6.4 dated June 5, 2024. Refer to Section 2.0 of the protocol for the full list of eligibility criteria. The CDC Institutional Review Board (IRB) approved the protocol amendment on June 5, 2024 (see the approval letter [372 KB, 2 pages]). Oral tecovirimat for treatment of mpox is primarily available through enrollment in the Study of Tecovirimat for Mpox (STOMP). Researchers and clinicians do not know whether tecovirimat is effective or how safe it is in treating mpox. The STOMP trial is designed to collect data to help answer these scientific questions. Providers with patients who are ineligible for STOMP’s open-label arm (e.g., illness ≥ 14 days or prior TPOXX receipt) but meet EA-IND eligibility for tecovirimat treatment for mpox should contact their state, local, or territorial health departments to see if any oral TPOXX remains available within their jurisdiction from prior prepositioned supply. While the large-scale prepositioning of stockpiled oral tecovirimat stopped on February 27, 2023, by ASPR, some of the deployed supply still remains within expiry. Any remaining supply can be used for EA-IND eligible patients. If there is no local supply, state, local, or

territorial health departments should request oral TPOXX on providers' behalf by calling the CDC Emergency Operations Center (EOC) at (770) 488-7100 (24×7) or poxvirus@cdc.gov. (This email box is monitored from 9 a.m. to 4 p.m. U.S. Eastern time on non-holiday weekdays). For patients who require intravenous TPOXX treatment and meet treatment eligibility under the EA-IND protocol, providers, in conjunction with jurisdictional health departments, can contact the CDC EOC or e-mail poxvirus@cdc.gov to make the request; a clinical consultation with a CDC clinical duty officer regarding management of hospitalized patients can also be requested. To facilitate access to tecovirimat, CDC holds an expanded access IND (EA-IND) protocol for the treatment of non-variola orthopoxvirus infections, including mpox, in adults and children. Use of tecovirimat under this EA-IND protocol is for patients with laboratory-confirmed or suspected mpox who meet the eligibility criteria as outlined in Section 2.0 of the protocol [494 KB, 28 pages]. This includes: Patients with mpox who meet the above-mentioned EA-IND eligibility for tecovirimat treatment may also be eligible for oral tecovirimat through the open-label tecovirimat arm of NIH's STOMP study. The EA-IND eligibility criteria are closely aligned with the STOMP open-label arm's eligibility criteria regarding those with severe immunocompromise, people who are pregnant or lactating, and children. However, the definition of protracted or life-threatening manifestations of mpox listed above for tecovirimat treatment under the EA-IND protocol are narrower than STOMP's definition of severe disease. CDC's EA-IND provides umbrella regulatory coverage so that clinicians and facilities do not need to request and obtain their own INDs. To be covered under the EA-IND, the providers and affiliated facilities must register online as participating providers/sites. Tecovirimat use under the EA-IND is also covered under the Public Readiness and Emergency Preparedness (PREP) Act, which provides liability immunity to qualified providers and compensation to eligible patients via the Countermeasures Injury Compensation Program (CICP). Providers and affiliated facilities must be registered online as participating

providers/sites under the CDC-held expanded access IND (EA-IND) protocol for tecovirimat. The tecovirimat IND Online Registry allows for convenient, time-efficient, and secure completion and return of required EA-IND forms to CDC. View this Fact Sheet [521 KB, 8.5″ x 11″] for an overview of the tecovirimat IND online registry process.

Source URL: https://www.cdc.gov/poxvirus/mpox/clinicians/tecovirimat-ea-ind.html