STOMP Study of Tecovirimat for Mpox

California PTC

What is STOMP and why refer?

- **STOMP (www.stomptpoxx.org) is a clinical trial of oral tecovirimat (TPOXX) safety and efficacy.**
- It is the preferred strategy for clinicians and local health jurisdictions to access oral TPOXX.
- Enrollment is critical to show TPOXX efficacy against mpox for FDA approval and commercial availability.

Who qualifies?

- Any patient with *presumptive or laboratory-confirmed* mpox disease, of any severity, whose symptoms began ≤ 14 days prior to enrollment, and who have ≥1 active lesion(s).
- Patients without prior use of oral or IV TPOXX, and not likely to need IV TPOXX as therapy.
- Persons with HIV not planning to initiate cabotegravir/rilpivirine (Cabenuva®) during or within 2 weeks of study completion.

What to say?

Participation can be in-person and/or 100% remote via video. Travel is not required.

Participants will be compensated with cash and/or gift card(s).

Pregnant people, children and participants with severe mpox, immunosuppression, or specific skin conditions (e.g. eczema) receive TPOXX.

Participants with mild to moderate mpox are randomized to receive TPOXX or placebo, 2:1. Neither the clinical study team nor the participant will be notified of randomization (double-blinded). If symptoms worsen, participants may be switched to TPOXX open-label study.

Participants are monitored via in-person or video appointments, questionnaires, and symptom diaries.

Participants usually receive TPOXX/ placebo within 24 hours after enrollment.

How to help patients enroll?

1. **Order/collect confirmatory human mpox virus PCR testing** a positive test result is required for continued participation following enrollment.
2. **Call the Mpox Study Hotline +1 (855) 876-9997** together with your patient or provide the number directly to your patient.

Language services are not available through the hotline, consider using in-clinic interpretation services. Most study sites can enroll Spanish-speaking participants. Other languages are enrolled in accordance with IRB-approved procedures.

What else for patients?

- Offer JYNNEOS® vaccination as post-exposure prophylaxis (PEP) to all patients exposed to mpox who do not yet have symptoms contributable to mpox. It is most effective if provided <14 days of exposure.
- Provide the patient with return precautions in the case that STOMP enrollment is unsuccessful and symptoms continue.

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Scan to visit the STOMP website