Treatment and Vaccine Update

PrEP4All's M-Pox Alert is a weekly bulletin containing key information for activists, advocates and impacted communities on the evolving response to the monkeypox in the United States and worldwide. We will issue our alerts weekly, updating key data points and progress on action steps.

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prep4all.org/monkeypox

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PrEP4All M–Pox Community Monitoring Project

PrEP4All has a community monitoring project focused on access to monkeypox testing, vaccines, and treatments in the United States; we encourage activists and impacted people in diverse communities in the US and in other countries to reach out to share tools, information and updates as we track this outbreak.

Treatment Update

In late July, following sustained pressure from PrEP4All, clinicians and gay health activists, the US Centers for Disease Control and Prevention (CDC) finally announced that it was simplifying the onerous paperwork required for people with monkeypox to access the antiviral tecovimirat (brandname TPOXX, manufactured by SIGA Pharmaceuticals) in the United States. According to an update issued on July 22, health providers no longer need to fill out and file paperwork or provide samples and photographs of lesions to the CDC prior to obtaining TPOXX for a client. The paperwork has been simplified and people can start tecovimirat before it has can be submitted.

Before this shift, the CDC required paperwork that took an hour or more to complete and which offered "male" and "female" as the only options for gender identity on the informed consent form. The changes should make it simpler to obtain this crucial drug. At PrEP4All's recent monkeypox town hall and via our community monitoring project, we have heard consistently that TPOXX resolves symptoms quickly and safely and, importantly, provides relief from the often-excruciating pain associated with monkeypox lesions.

If you or someone you know needs tecovimirat:

- Your provider can prescribe it and you can start it right away—there is no paperwork pre-requisite for you receiving the medication.

- Any provider can prescribe it—they do not need to be affiliated with a research institution.

While this is a welcome development, it is not the change that activists have demanded. Providers still must fill out paperwork, albeit simplified, and clients still must complete an informed consent. This is because tecovimirat is considered a "non-research Expanded Access Investigational New Drug (EA-IND)" by the US Centers for Disease Control and Prevention.

Classifying a drug as an EA-IND is a way of saying that more data needs to be collected about the medication before it can be prescribed freely, without reporting back to the CDC or other regulatory authorities.

PrEP4All believes strongly that all people, including marginalized and under-served populations, have the right to health care including safe, effective, rigorously evaluated and high-quality medications, vaccines and tests. However, in this instance, PrEP4All and many other activists and providers feel that this EA-IND classification is unnecessary and presents a barrier to immediate access for an urgently needed drug.

Here's why:

- Tecovimirat was approved by the FDA in 2018 for treatment of smallpox. The FDA has already said there is data in animals that confirm this drug is effective. Those data come from animal studies of monkeypox in non-human primates and rabbitpox in rabbits. Because variola virus (the virus that causes smallpox) cannot be reliably propagated in non-human animals, no smallpox data was used by the FDA to approve the drug. The FDA approval was based on studies in animals (this is called approval via "the animal rule.") The FDA approved via the animal rule because there was no way to ethically conduct a human trial of the medication since smallpox has been eradicated in humans. Smallpox is from the same family of viruses as monkeypox. The studies looked at how the drug worked against monkeypox infection in non-human primates as the basis for approval. While the efficacy of the drug could not be studied in humans, the safety of the drug could be. Importantly, the safety of the drug was studied extensively in healthy humans. The drug was found to be very safe, with minimal adverse events reported.

- The Europeans Medicine Agency has already approved tecovimirat for use in individuals with monkeypox. The EMA is the European equivalent of the US Food and Drug Administration. Both are what the World Health Organization calls 'stringent regulatory authorities.' They operate by the same high standards and are recognized as reliable and authoritative.

- The real and measurable harms of withholding tecovimirat outweigh the theoretical risks. People with monkeypox experience symptoms with varying degrees of severity. For some people, the pain is excruciating and overwhelming. Proper, adequate and timeline pain management is a key part of monkeypox care. But painkillers do not tackle the virus itself. Tecovimirat does. It reduces symptoms, appears to speed the healing of lesions, and may make people less infectious. Its benefits outweigh the risks.

Treatment: Key Points on Access and Activism

ACCESS

People with monkeypox should be able to receive tecovimirat as soon as they are diagnosed if they and their provider think treatment is needed. The CDC has made it easier for providers to order tecovimirat from the Strategic National Stockpile.

- Your provider can prescribe it and you can start it right away—there is no paperwork pre-requisite for you receiving the medication.
- Any provider can prescribe it—they do not need to be affiliated with a research institution.
- If you are having any challenges with access, please alert PrEP4All via our community monitoring project at www.prep4all.org/monkeypox.

ACTIVISM

Contact your member of Congress, HHS, CDC (click here for twitter handles) and let them know:

- Simplified paperwork for an EA-IND is still onerous. The CDC should rescind the EA-IND immediately to further accelerate treatment access
  and/or
- Xavier Becerra, the Secretary of the Department of Health and Human Services, can declare that an Emergency Use Authorization (EUA) is appropriate, allowing the FDA to authorize unapproved uses for approved or unapproved medical products to treat diseases, like monkeypox.

US Vaccine Status Report

On July 27, the Food and Drug Administration announced that it had cleared 786,000 doses of the JYNNEOS vaccine manufactured by Bavarian Nordic . This announcement came after months of egregious, preventable and misleadingly described delays (see M-Pox Alert #1 for more details). On July 28, the Department of Health and Human Services Administration for Strategic Preparedness and Response (ASPR) announced the allocations of new doses . This is a crucial moment in what has been a grievously inadequate process. Up until now, vaccines have arrived in states unpredictably and without coordinated state- and citywide communication about availability.

- ASPR/HHS must immediately issue a clear schedule and retrospective history of the dates that vaccines will arrive (and have arrived) in the US and their onward distribution at city and state levels.
- ASPR/HHS must also track, share and respond to evolving need, allocations and orders. A recent review of jurisdictional requests for existing doses—prior to the release of the new doses—found that while some states are not requesting their full allocation, the demand has exceeded supply. Allotments to date have been made based on a government algorithm that uses population estimates of gay men and other men who have sex with men and reported cases to gauge need. As monkeypox continues to spread within and beyond LGBTQ populations, including in prisons and jails, the formula for allotments and the pace of distribution will need to change.
- Funding for communication about vaccine availability, appointment scheduling and a range of other monkeypox related public health activities is urgently needed. The federal government must launch a broad, national communications campaign notifying individuals of how and where to access vaccines within their communities.

Global Activism Alert

As we work to expand access in the US, activists in the US and in Europe must also work in solidarity with LGBT communities and others to ensure global access to treatment, vaccines and tests. The World Health Organization has now declared monkeypox a global public health emergency and has called for countries with capacity to scale up manufacturing of medications and treatments to do so. Most cases of monkeypox to date have happened in Europe and North America, however all of the deaths have occurred in Africa, where cases are also climbing. Recently, the US State Department sent an unclassified cable to PEPFAR countries alerting them that the programs can communicate to local governments that "PEPFAR-supported infrastructure is available to prevent and respond to monkeypox." This cable includes no information about additional funding for a rapid response if needed and/or for available commodities including vaccines and treatments. Without a rapid, funded and strategic global response led by WHO and supported by US and European governments, a global equity crisis is inevitable. PrEP4All is committed to working in solidarity with LGBT communities and allies to mobilize access to drugs, vaccines, tests, community literacy materials and rights-based services. This will be the focus of an upcoming M-Pox Alert.