Communicable Disease Epidemiology and Immunization Section
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Health Advisory: Update on Managing Monkeypox (Mpox) in Patients Receiving Therapeutics, November 30, 2022

Action Requested

- **Be aware that the Centers for Disease Control and Prevention (CDC) has confirmed the presence of tecovirimat-resistant monkeypox (mpox) in two patients.**
  - Note that no transmission of tecovirimat-resistant mpox virus has been documented so far.
  - Vaccination with JYNNEOS remains an important tool to prevent mpox in at-risk patients.
- **Continue to consider tecovirimat (also known as TPOXX or ST-246) as first-line therapy for eligible patients with mpox.**
  - Recognize that patients who either have or are at high risk for severe disease may require longer courses (>14 days) of tecovirimat, and additional therapies, until their immune systems can effectively clear the virus**.**
    - These include patients who have HIV with CD4 counts <350 cells/mm^3 and patients with other severely immunocompromising conditions.
    - Additional therapeutics include cidofovir (intravenous), brincidofovir (oral), and Vaccinia Immune Globulin Intravenous (VIGIV).
  - Counsel patients about the critical importance of taking oral tecovirimat with fatty meals to ensure adequate gastrointestinal absorption and maximize serum levels of the medication. Inadequate serum levels could promote resistance.
- **Consider testing lesion swab specimens for tecovirimat resistance and plasma pharmacokinetic sample collection for any patient who, after completing 14 days of tecovirimat treatment, experiences persistent or newly emergent mpox lesions.**
  - Perform resistance testing and pharmacokinetic testing to determine if any cases of confirmed resistance are associated with drug levels below target concentrations.
  - CDC provides detailed instructions for collecting and submitting specimens for resistance testing and pharmacokinetic testing. Pharmacokinetic testing is not performed at CDC.
  - Report possible tecovirimat resistant mpox cases to Public Health at the time of suspicion and/or testing (206-296-4774)
- **Providers prescribing tecovirimat, consider first seeking access through enrollment in the AIDS Clinical Trials Group (ACTG) Study of Tecovirimat for Human Mpox Virus (STOMP) trial, which is evaluating the efficacy of tecovirimat.**
  - For patients not eligible for the STOMP trial or who decline to participate, contact Public Health – Seattle & King County using this request form to receive information regarding CDC's Tecovirimat Expanded Access-IND.

Background

The Centers for Disease Control and Prevention (CDC) issued a Health Update via the CDC Health Alert Network on November 17, 2022, to provide new information about the presence of tecovirimat-resistant viruses in two patients. CDC was notified of one patient with persistent mpox whose viral isolates demonstrated tecovirimat resistance. Isolates from this patient demonstrated genotypic changes in F13L associated with tecovirimat resistance. In addition, CDC confirmed phenotypic resistance to tecovirimat in

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cell culture. CDC also confirmed tecovirimat resistance in another patient who was tested due to poor response to tecovirimat treatment. Genotypic and phenotypic testing subsequently confirmed resistance.

Both patients were severely immunocompromised, with disseminated and progressive mpox infection despite prolonged treatment (>14 days) with tecovirimat. These are the first known cases of mpox with laboratory-confirmed tecovirimat resistance in the United States. No transmission of resistant strains has been documented to date.

Additional resources

- For guidance on how and when to administer different mpox treatment options including treatment of possible tecovirimat resistant mpox cases, consultation is available through the **CDC Emergency Operations Center (EOC) at 770-488-7100** (Possible tecovirimat resistant mpox cases should still be reported to Public Health – Seattle & King County, 206-296-4774)
- Mpox Treatment Information for Healthcare Professionals
- Information on the AIDS Clinical Treatment Group (ACTG) STOMP trial
- Resistance testing & pharmacokinetic testing
- CDC HAN – Update on Managing Mpox in Patients Receiving Therapeutics, 11/17/2022
- CDC HAN – Severe Manifestations of Mpox among People who are Immunocompromised Due to HIV or Other Conditions, 9/29/2022