Optum Rx®

Monkeypox – Update

- On June 28, 2022, the White House issued a statement on the monkeypox outbreak and outlined the federal government's response. Although Optum Rx does not yet have an official position or resources on monkeypox, the information below may be helpful for increasing awareness and reviewing available management options.

- Monkeypox is an orthopoxvirus that is similar to the smallpox virus, and much of the strategy for monkeypox is based on our understanding of smallpox.

- Monkeypox is spread through close or intimate contact with an infected individual. The virus causes a rash with blisters that appear on the face, inside mouth, or other parts of the body including hands, feet, chest, genitals or anus. Other symptoms include fever, headache, muscle aches, swollen lymph nodes, chills, and exhaustion. Illness typically lasts 2 to 4 weeks. No deaths have been attributed to monkeypox in the U.S. yet.

- The first case was detected in the U.S. on May 18, 2020, and the latest statistics from the Centers for Disease Control and Prevention (CDC), as of July 5, 2022, report 560 cases across 33 states, Washington DC and Puerto Rico.

- Although it is still very early in the current monkeypox outbreak, it is important to note:

    — Testing is available to aid in diagnosis
    — Vaccines exist for prevention
    — Treatments exist for managing infection if needed

- **Testing:** The CDC has worked with state and local public health departments through its Laboratory Response Network to provide increased access to monkeypox testing. Additionally, the CDC has shipped monkeypox tests to five major commercial laboratory companies: Aegis Science, Labcorp, Mayo Clinic Laboratories, Quest Diagnostics and Sonic Healthcare.

- **Vaccines:** Two vaccines exist and are being recommended by the CDC: Jynneos® and ACAM2000®. Both vaccines are part of the U.S. Strategic National Stockpile (SNS) and are being distributed by the Office of the Assistant Secretary for Preparedness & Response (ASPR) to states by the federal government based on existing cases and the proportion of the population at risk for severe disease from monkeypox.

    — Jynneos is a live, attenuated, non-replicating orthopoxvirus vaccine that was approved by the FDA in 2019 for the prevention of smallpox and monkeypox disease in adults 18 years of age and older determined to be at high risk for smallpox or monkeypox infection. Jynneos is administered as two subcutaneous injections given 4 weeks apart. The SNS has 72,000 doses of vaccine immediately available for use, additional supply in reserve, and the Biomedical Advanced Research and Development Authority (BARDA) recently ordered an additional 500,000 doses of Jynneos to be delivered in 2022.

    — ACAM2000 is a live vaccine containing vaccinia virus, a virus in the orthopoxvirus family and similar to monkeypox. ACAM2000 was approved by the FDA in 2007 for the active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. The CDC is allowing ACAM2000 to be used for monkeypox. ACAM2000 is administered as a single dose, via scarification (a percutaneous method of administration

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involving multiple needle punctures into a small area with vaccine). Scarification requires special training before clinicians can administer ACAM2000. The SNS has more than 100 million doses of ACAM2000 available for immediate use.

- **Treatments:** Monkeypox and smallpox are genetically very similar, and the CDC is recommending use of antivirals developed for smallpox be used for monkeypox despite the lack of FDA approval for monkeypox. The CDC has clinical guidance recommendations for the treatment of monkeypox. Many people have a mild, self-limiting disease course. However, individuals should be considered for treatment if they have severe disease, or are at high risk for severe disease, or have involvement of the eyes, mouth, genitals, or anus. Several treatments are available through the SNS including:

  - TPOXX® (tecovirimat) – An antiviral available approved in 2018 for the treatment of human smallpox in adults and pediatric patients weighing at least 3 kg. TPOXX is available as oral capsules and IV injection, and given twice daily for a 14-day course of treatment.
  - CNJ-016 (vaccinia immune globulin [human] sterile solution) – An IGIV product that provides passive immunity. CNJ-016 was approved in 2005 by the FDA for complications of vaccinia vaccinations, but the CDC allows for the treatment of orthopoxviruses (including monkeypox) in an outbreak.
  - Vistide® (cidofovir) – An antiviral approved by the FDA in 1996 for the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS). The CDC has an expanded access protocol that allows for the use of stockpiled cidofovir for the treatment of orthopoxviruses (including monkeypox) in an outbreak.
  - Tembexa® (brincidofovir) – An oral antiviral that is active against orthopoxvirus and was approved by FDA in 2021 for the treatment of human smallpox disease in adults and pediatrics, including neonates. Tembexa is not part of the SNS but the CDC is developing an expanded access protocol for brincidofovir for monkeypox.
  - State and local health authorities interested in monkeypox treatments should contact the CDC Emergency Operations Center (770-488-7100).

- For more information about monkeypox see the CDC's page on monkeypox.

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