State of Utah

SPENCER J. COX
Governor

DEIDRE M. HENDERSON
Lieutenant Governor

Utah Department of Health
Executive Director's Office

Nate Checketts, M.P.A.
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Deputy Director

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Deputy Director

12/20/2021

Dear Provider,

The landscape for COVID-19 therapeutics is rapidly evolving and this letter offers several critical updates. We encourage every provider in Utah to read this letter in its entirety.

First, the guidelines around which patients qualify for monoclonal antibody (mAb) treatment in Utah were updated in late November. These changes were recommended by the Scarce Medications Allocation Subcommittee of the Utah Crisis Standards of Care Workgroup to ensure mAb treatment is prescribed fairly and to patients who are most likely to benefit from it. **Individuals 65 or older who test positive for COVID-19 who are currently symptomatic and within 10 days of symptom onset now automatically qualify for mAb treatment if they meet other emergency use authorization (EUA) criteria.** Pregnant women and those with certain immunocompromising conditions also automatically qualify. Other patients may qualify based on underlying medical conditions. **mAb is a pre-hospital therapeutic and patients with a new or increasing oxygen need do not qualify under the EUA.**

As before, patients may determine their eligibility for mAb treatment using an online risk score calculator or by calling 1-800-456-7707. Monoclonal antibody infusion sites are located across the state. The Utah Department of Health operates two sites (Millcreek (1141 E 3900 S) and St. George (544 E 400 S)). Treatment provided at the UDOH infusion center is free; insurance will not be billed.

Second, on December 3, 2021, the Food and Drug Administration (FDA) gave EUA for some of the mAb treatments to be used in children younger than 12, depending on the child's risk for severe illness. For questions or to arrange treatment for patients aged 15 and younger, please send an email to Pediatric.MonoclonalAntibodies@imail.org.

Third, we anticipate decreased efficacy of the monoclonal antibodies REGEN-COV (casirivimab/imdevimab) and bamlanivimab/etesevimab with the Omicron variant; however, early *in vitro* data suggests sotrovimab does retain activity against the Omicron variant. In late November, the federal government paused shipment of sotrovimab and we have 55 doses currently available in Utah. Ordering was reopened to states by the federal government on December 17 and Utah has been allocated 540 doses with no further allocations expected in 2021. We are meeting this week with the Scarce Medications Allocation Subcommittee to seek further guidance on distribution of sotrovimab in Utah. Until Omicron is the dominant variant in Utah, we will be administering our supply of other monoclonal antibody products.

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Finally, we are closely monitoring advances related to other novel therapeutics to treat patients with COVID-19 and creating plans for their distribution in Utah. We anticipate all of these new treatments will be in scarce supply on initial release. While our goal is to transition to a more typical medical model of clinician prescribing and pharmacy dispensing, it will likely be several months before this becomes possible.

The first of these new medications to receive EUA is Evusheld (tixagevimab/cilgavimab). Evusheld is an intramuscular injection for the pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals (12 years of age and older weighing at least 40 kg) who are not currently infected and who have not been exposed to COVID-19, and have moderate to severe immunocompromise or are unable to be vaccinated due to severe allergic reaction. Evusheld may be effective for pre-exposure prevention for up to six months. **On December 17, Utah received its first allocation of 504 doses of Evusheld, which will be distributed to 10 geographically dispersed clinical sites specializing in cancer treatment.** We anticipate allocations of Evusheld every two weeks and expanding eligibility and access as supply allows.

Two oral antiviral medications are pending EUA: molnupiravir and paxlovid. The U.S. Food and Drug Administration's (FDA) Antimicrobial Drugs Advisory Committee (AMDAC) recommended the FDA consider EUA for molnupiravir with a vote of 13-10. The FDA is not bound by AMDAC's guidance, and as of today has not issued an EUA. Based on available efficacy and safety data, the Scarce Medications Allocation Subcommittee advised against broad distribution of molnupiravir in a public health model. We remain uncertain if and when the FDA will issue an EUA for molnupiravir. Healthcare providers will need to weigh the benefits and risks of the molnupiravir should the FDA authorize its use. Monoclonal antibody treatment is superior to molnupiravir in terms of efficacy and safety.

Preliminary evidence with paxlovid suggests it is more effective than molnupiravir and does not pose the same risk of damaging human DNA that molnupiravir may. EUA for paxlovid is anticipated as soon as the end of December or in early 2022. We plan to supply molnupiravir and paxlovid to dispensing locations that request it and will dispense it from select federally contracted pharmacies to individuals with prescriptions from their providers.

The evolving situation with the Omicron variant may alter recommendations regarding all available therapeutics. Please check https://coronavirus.utah.gov/noveltherapeutics/ for updates and for a posted copy of this letter.

If you or your facility are interested in becoming a provider for any of these therapeutic options please fill out this survey to let the Department know of your interest.

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Thank you for all you do in protecting Utahns during this challenging time. We look forward to serving your patients.

Kindest regards,

Michelle Hofmann, MD, MPH, MHCDS

Deputy Director and Chief Medical Advisor, Utah Department of Health