State of Utah

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Governor

DEIDRE M. HENDERSON
Lieutenant Governor

Utah Department of Health
Executive Director's Office

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Interim Executive Director

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Deputy Director

12/29/2021

Dear Provider,

The landscape for COVID-19 therapeutics is rapidly evolving and this letter offers several critical updates. We encourage you to read this letter in its entirety. This letter complements a previous letter dated 12/20/2021 where specific details on emerging therapeutics and supply constraints were described.

First, effective Thursday, 12/30/21, our Utah Department of Health (UDOH) monoclonal antibody (mAb) treatment sites, partner sites, and all health systems will be discontinuing the use of REGEN-COV and bamlisivimab / etesivimab. The rapid advance of the omicron variant has expedited this transition. National Institute of Health (NIH) guidelines indicate that when omicron reaches 80% prevalence that we move to sotrovimab or remdesivir. While there is a lag in whole genome sequencing data due to processing times, S-gene target failures (SGTF) on PCR now represent at least 70% of PCR tests performed on the Thermo Fisher TaqPath assay in Utah. 100% of recent PCR samples with SGTF able to be sequenced at the Utah Public Health Laboratory (UPHL) are omicron. The UDOH monoclonal antibody infusion strike team (MIST) will continue to administer REGEN-COV and bamlisivimab / etesivimab, including REGEN-COV for post-exposure prophylaxis, to mitigate long-term care facility and other congregate setting outbreaks when confirmation of the presence of the S-gene target can be determined by testing at UPHL.

Second, effective immediately, the guidelines around which patients qualify for mAb treatment in Utah will be changing. In addition, eligibility for Paxlovid, a new oral antiviral, will be aligned with that of mAb. These changes are necessitated by both the emergence of omicron as the dominant strain of COVID-19 and the exceedingly scarce supply of therapeutics proven effective in preventing hospitalizations due to omicron. Based on their superior efficacy, Sotrovimab and Paxlovid will be limited to the treatment of patients at highest risk of hospitalization from COVID-19. Utah has benefited greatly from a risk calculator that can dial eligibility criteria up and down depending on the available supply of effective therapeutics and the system capacity to administer them. Taken together, the supply of Sotrovimab and Paxlovid will be less than half of the number of mAb treatments we have been providing weekly as a state (520 vs. 1100).
To adjust to these conditions of scarcity amidst increased demand for therapeutics related to the emergence of omicron, individuals who are unvaccinated must now have a risk score of 6.5 or higher and individuals who are vaccinated must have a risk score of 8.5 or higher to receive Sotrovimab or Paxlovid so long as they meet other emergency use authorization (EUA) criteria. Patients with certain immunocompromising conditions also automatically qualify. Pregnant persons who are not vaccinated automatically qualify for Sotovimab only. Paxlovid is not recommended during pregnancy and in people who can become pregnant and are not using contraception. These changes were recommended by the Scarce Medications Allocation Subcommittee of the Utah Crisis Standards of Care Workgroup to ensure the limited supply of effective treatments are prescribed to patients who are most likely to be at highest risk of poor outcomes, including

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hospitalization and death. The criteria closely match the characteristics of patients who are currently being admitted to Utah hospitals for COVID-19.

Patients and health care providers may determine eligibility for mAb treatment using an online risk score calculator or by calling 1-800-456-7707. The risk calculator has been updated to reflect the new eligibility criteria for mAb. Within the next 1-2 weeks the risk calculator will be retooled to dually assess eligibility to mAb and Paxlovid. In the meantime, please use the mAb risk calculator for access to both Sotovimab and Paxlovid. The COVID-19 treatments website will also undergo continued revisions to reflect the rapidly changing therapeutics landscape.

Third, related to the scarce supply of Sotrovimab, and in an effort to continue to ensure geographic equity, effective Thursday, 12/30/2021, the UDOH St. George and UDOH partner Davis Hospital high-volume mAb treatment sites will be closed. In these geographic areas, mAb will continue to be administered at other sites that have previously administered mAb. **Fourth, to leverage the existing infrastructure for mAb treatment and ensure timely access to effective therapeutics, we want all providers to be aware of where Sotrovimab and Paxlovid are available.** Published lists of treatment locations will not be immediately available to the general public to prevent an undue burden on providers of these therapeutics from demand outpacing supply. We appreciate your support of your patients in navigating this challenging landscape and the COVID-19 hotline is prepared to support you and members of the public by calling 1-800-456-7707.

Sotrovimab is available beginning Thursday, 12/30/21 at the following treatment locations, with doses available noted to demonstrate the extremely limited supply. We will have an additional allocation of 360 doses arriving in Utah next week but do not expect any more doses for at least 2 weeks. Allocations are based on utilization patterns over the last month. Additional information on how to access these treatment sites is available in the provider section of the website.

LOCATION	DOSES AVAILABLE
Intermountain Healthcare (45 sites)	150
UDOH Millcreek	135
UDOH MIST	80
Nomi Orem	50
University of Utah Health (2 sites)	40
Steward Health Care (5 sites)	35
Ogden Regional Medical Center	20

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Hurricane Family Pharmacy	10
Gunnison Valley Hospital	10
Ashley Regional Medical Center	10
Castleview Hospital	10
Central Valley Medical Center	10
Moab Regional Hospital	5
San Juan Hospital	5
Beaver Valley Hospital	5
Blue Mountain Hospital	5
Kane County Hospital	5

Paxlovid has been allocated to clinical care sites prepared to deliver a test-to-dispense model to ensure meeting the 5-day eligibility window from symptom onset and is expected to arrive in Utah within 1-5 days. A majority of the supply will be available through Intermountain Healthcare in urgent care sites across the state as well as through an open access telemedicine and home medication delivery model accessible by emailing monoclonal.antibodies@imail.org. A clinical assessment and knowledge of available supply of both Sotrovimab and Paxlovid will support access to these therapeutics for as many referred patients as possible.

LOCATION	TREATMENT COURSES AVAILABLE
Intermountain Healthcare (13 sites)	320
University of Utah Health (2 sites)	40
Blanding Family Pharmacy	20
Moab Regional Hospital	20
Ashley Regional Medical Center	20
Walgreens Pharmacy in Tooele	20

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Finally, I would like to draw your attention to molnupiravir as a treatment option when more effective alternative COVID-19 treatment options authorized by the FDA are not accessible or clinically appropriate. 2,060 doses of molnupiravir are expected to arrive in Utah within 1-5 days and will be distributed to federal retail pharmacy partner sites at CVS, Kroger, and Walgreens and selected other sites where federal pharmacy access points were not available geographically. Please refer to the following list of locations prepared to dispense molnupiravir with a valid prescription and review the EUA closely before prescribing. Additional information on molnupiravir has been prepared by the UDOH pharmacy team and is accessible here.

The evolving situation with the Omicron variant may alter recommendations regarding all available therapeutics. Our goal remains the same - to optimize limited resources by focusing available treatments on the highest risk patients who are most likely to benefit. 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.

Thank you for all you do in protecting Utahns during this challenging time.

Kindest regards,

Michelle Hofmann, MD, MPH, MHCDS
Deputy Director and Chief Medical Advisor, Utah Department of Health