Monoclonal Antibody Therapy for COVID-19

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The FDA has given Emergency Use Authorization (EUA) to two drug companies for their versions of novel monoclonal antibody treatments for COVID-19. They are bamlanivimab (Eli Lily) and casirivimab/imdevimab (Regeneron). The treatments are intended for use in patients who have tested positive for SARS-CoV-2, are at high risk for developing severe COVID-19, are early in the onset of symptoms, and do not yet require hospitalization or additional oxygen.

These drugs are in very limited supply at this time. The state of Utah has provided a small number of doses to each hospital system and they have given guidelines for patient selection (see below) that are more restrictive than the general EUA guidance. The State guidelines are intended to direct the limited amount of drug toward treating those individuals who are at the highest risk for needing hospitalization. The intent of treatment is to reduce the number COVID-19 hospitalizations.

Infusion of these drugs involves several complexities related to the risk of adverse reaction including anaphylaxis, and the fact that the individuals being infused are symptomatic with COVID-19.

The Steward Utah hospitals will begin infusing a limited number of high-risk patients who are referred by their primary care providers (PCPs) for novel monoclonal antibody therapy. If after evaluation by a PCP a patient is determined to meet the state requirements (**Risk Stratification Score > 8**), the PCP will call [the hospital] to request an infusion appointment for the patient. If an infusion time is available within a 7-day window from the onset of symptoms, the patient will be scheduled. The PCP will obtain informed consent from the patient and will complete the required consent form, “Attachment D” in the attached Policy. A completed, signed and witnessed informed consent form MUST be sent to the hospital with the Infusion Order. The Infusion Order will include an order for the drug being requested, additional optional medications, and a risk-scoring worksheet. The risk-scoring worksheet MUST be completed by the PCP prior to sending the order. Only after receipt of these documents will the hospital then contact the patient and give further instructions.

To request an infusion appointment for a qualified patient please call **Nursing Supervisor DHMC at 801-807-7008.** Be ready to transmit the completed consent form, order and risk-scoring worksheet.

Please note that the state anticipates there will be more requests for this therapy than there will be capacity to infuse. The hospital will schedule qualified patients as the calls come in from providers. If the hospital receives more than one scheduling request at the same time, each patient will be ranked according to the risk stratification model in the State guidelines. Patients with higher scores will be given priority over those with lower scores. If your patient cannot be scheduled at **Davis Hospital & Medical Center,** you may need to look elsewhere for them.

The Utah State Guidelines and the Steward policy for using these investigational drugs are attached to this email. The policy attachments contain important information you will need when evaluating your patients and giving them informed consent. **Please save them for future reference.**

Thank you for all you do in caring for your patients.

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