December 15, 2020

Dear Colleagues,

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) for two monoclonal antibodies – bamlanivimab, by Eli Lilly, and casirivimab/imdevimab, by Regeneron. Both drugs work by binding the spike protein of the SARS-CoV-2 virus, thus reducing the viral load and its replicating capacity. EUA specifies these therapies are a treatment option for outpatients who are at highest risk for hospitalization. An individual must be within 10 days of symptom onset and must have a documented positive COVID-19 test and meet EUA criteria to be considered appropriate for therapy. Treatment is NOT authorized for patients hospitalized for COVID-19, those who require oxygen therapy due to COVID-19, or those who require an increase in their baseline oxygen flow rate due to COVID-19. Please review the accompanying referral form for criteria to determine eligibility to receive the treatment.

These drugs are a reasonable treatment option if, after consultation with a medical provider and informed decision-making, the patient puts a high value on the uncertain benefits and a low value on uncertain adverse events. Early studies suggest a potential clinical benefit of monoclonal antibodies for outpatients with mild to moderate COVID-19. However, the relatively small number of participants and the low number of hospitalizations or emergency department visits make it difficult to draw definitive conclusions about the clinical benefit of these therapies. If you have a patient that you believe would be an appropriate candidate for one of these therapies, please fill out a copy of the attached referral forms. Fax the completed forms, along with a copy of the patient’s test result, including the patient’s name and the date of the test, to (907) 349-1920. If demand is greater than the available supply, the patient will be placed on a wait list until they reach day 10 from symptom onset. If the patient is selected, they will be contacted with a date, time, and details about receiving the infusion. It is imperative to provide the best contact phone number for patients.

Finally, the EUA requires the reporting of adverse reactions, hospitalizations, and deaths. If one of your patients receives the treatment, it is requested that you send a follow up note to the fax number provided above. This should be provided for all patients who received the infusion, not just those who experience an adverse reaction. Please document any patient who experiences an adverse event(s) within 30 days of receiving the infusion.

Thank you for all that you do in serving your community and providing great care to your patients.

Sincerely,

[Signature]

Anne Zink, MD, FACEP
Chief Medical Officer, State of Alaska