Question or request:
1. How should bamlanivimab be distributed to New Mexico healthcare facilities.
2. Which patients should be prioritized for treatment with bamlanivimab?

Recommendations in bullet form:
1. Bamlanivimab should be distributed to centers with the capacity for intravenous administration and monitoring of outpatients who meet criteria of administration under the FDA Emergency Use Authorization (EUA).
2. It is intended for outpatient treatment of mild to moderate coronavirus disease 2019 (COVID-19) in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age and older weighing at least 40 kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.
3. Bamlanivimab should be given as soon as possible after positive results of direct SARS-CoV-2 viral testing and within 10 days of symptom onset.
4. High risk is defined as patients who meet at least one of the following criteria: Body Mass Index (BMI) >35; chronic kidney disease; diabetes; immunosuppression; are >65 years of age; are ≥55 years of age and have cardiovascular disease or hypertension or chronic obstructive pulmonary disease (COPD) or other chronic respiratory disease; or 12-17 years of age and have BMI ≥85th percentile or sickle cell disease or congenital or acquired heart disease or neurodevelopmental disorders such as cerebral palsy, a medical-related technological dependence such as tracheostomy, gastrostomy or positive pressure ventilation not related to COVID, or asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
5. It is not authorized for use in patients who are hospitalized or require oxygen therapy from COVID-19 (new or increase from baseline), or mechanical ventilation.
6. Dosage is with a single IV infusion of 700 mg bamlanivimab administered over at least 60 minutes via pump or gravity followed by observation for at least 1 hour. Administration should occur at a facility that is able to recognize and treat anaphylaxis and infusion-related reactions. The 700mg dose must be prepared using 0.9% sodium chloride and must be equilibrated to room temperature prior to preparation. IV solutions are intended for immediate patient administration. If immediate administration is not possible, diluted bamlanivimab infusion solution can be stored for up to 24 hours at refrigerated temperature (2°C to 8°C) or up to 7 hours at room temperature including infusion time. If refrigerated, allow to equilibrate to room temperature for ~20 minutes prior to administration.
7. No dosage adjustments are recommended in pregnant or lactating women, geriatric patients, patients with renal impairment or patients with mild hepatic impairment. It has not been studied in patients with moderate or severe hepatic impairment.
8. Administration of Bamlanivimab requires documentation of patient consent (including Fact sheet) and reporting of adverse events to FDA MedWatch, following the requirements under Emergency Use Authorizations.
Assessment:

1. Bamlanivimab is a neutralizing monoclonal antibody that binds to the receptor binding domain (RBD) of the spike protein of SARS-CoV-2.1-3
2. Bamlanivimab may be effective in reducing severity of symptoms and may reduce risk of hospitalization or visit to an emergency department in outpatients with mild to moderate COVID-19 who are at high risk of progressing to severe COVID-19 and/or hospitalization.1-3 In preliminary analysis of an ongoing, randomized, double-blinded trial comparing three doses of study drug to placebo, there was a possible treatment effect in analysis of symptoms on day 3.3 Combining all three bamlanivimab dosage groups, the risk of hospitalization or emergency room visits was 1.6% (5/309) compared to 6.3% (9/156) in placebo-treated patients.3 In those ≥65 years of age or BMI≥35, the same risk was 4.2% in bamlanivimab-treated subjects versus 14.6% in the placebo group.3
3. The most frequently reported adverse event was nausea (3.9%) and infusion-related reactions were reported in 2.3% of the patients receiving LY-CoV555 (7/309 all dose groups). Infusion reactions were reported as mild in severity and in some cases, antihistamines were administered to help resolve symptoms.3
4. Difficulty in identifying outpatient clinical settings where bamlanivimab can be safely administered to COVID patients may limit use.
5. There is no adequate, approved and available alternative to bamlanivimab for the emergency use for this indication.

Red flags and concerns:

1. Infusion-related reactions have been observed and there is potential for severe reactions, including anaphylaxis.1-3 Bamlanivimab may only be administered in settings in which health care providers have immediate access to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS).2
2. Use of bamlanivimab under this EUA includes limiting use to outpatients that meet the inclusion/exclusion requirements; documentation of provision of the patient fact sheet,4 discussion of alternatives and disclosure that it is an unapproved drug; and reporting requirements that include reporting of medication errors and serious adverse events to the FDA.1,2
3. Monoclonal antibodies such as bamlanivimab may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high-flow oxygen or mechanical ventilation.
4. The U.S. Department of Health and Human Services/Operation Warp Speed has released guidance on the use of monoclonal antibody products.5

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Resources/Reference:
2. Fact Sheet for Health Care Providers Emergency Use Authorization (EUA) of Bamlanivimab https://www.fda.gov/media/143603/download