Guardian Consulting Services, Inc.

Consultant Pharmacists for Healthcare Organizations, Industry, and the Community.

Monoclonal Antibody Therapy for COVID-19

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Monoclonal Antibody treatments for COVID-19 are synthetically produced versions of proteins made by the immune system that are known to be active against the SARS COV-2 virus. Antibodies work by attaching to surface protein of the virus, in an attempt to block the virus from invading healthy cells. Compared to vaccines, which may take days or weeks to "teach" the immune system to recognize and fight the virus, when effective, treatment with monoclonal antibodies should provide immediate benefit. As of November 21, 2020, the United States Food and Drug Administration has issued an Emergency Use Authorization (EUA) for two Monoclonal Antibody products: ***Bamlanivimab and Casirivimab/Imdevimab.*** The Full EUA prescribing information for each is available here: https://guardianconsulting.com/covid-19-updates/

Indications for use under the FDA EUA:

- for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

1. ***Bamlanivimab*** **(Eli Lilly/Abcellera)**
   - ***Emergency Use Authorization (EUA) Issued 11/9/2020***
   - May be able to produce as many as 1 million doses by end of year
   - Blaze-1 Trial: 72% risk reduction of progression to serious disease
   - Route of administration: 250ml IV Infusion over 60 minutes

2. ***Casirivimab/Imdevimab*** **(Regeneron/Roche)**
   - ***Emergency Use Authorization (EUA) Issued 11/21/2020***
   - Combination of two monoclonal antibodies, targeting non-competing sites
   - May be able to produce up to 300,000 doses by end of January 2021
   - REGN-COV2 Trials: Hospitalizations/ER visits 9% in placebo group, 3% in treatment arms.
   - Route of administration: 250ml IV Infusion over 60 minutes

Limitations of use under the FDA EUA:

- These treatments are not authorized for use in patients: who are hospitalized due to COVID-19, OR who require oxygen therapy due to COVID-19, OR who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity.