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Owner:	*Tara Vijayan: Hs Asst Clin Prof-Hcomp*
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Reference Tags:	*Lippincott*
Applicability:	*Ronald Reagan, Resnick, Santa Monica, Ambulatory Care*

Outpatient Use of Monoclonal Antibodies HS 3065

PURPOSE

To provide guidance regarding the use of two investigational SARS-CoV2 monoclonal antibody products.

Policy

In November 2020, the Food and Drug Administration (FDA) issued emergency use authorizations (EUA) for the use of two investigational SARS-CoV2 monoclonal antibody products: a single monoclonal antibody called bamlanivimab (LY-CoV555) manufactured by Eli Lily and company, and a combination monoclonal antibody product called casirivimab and imdevimab manufactured by Regeneron. The drugs can be considered for the treatment of high-risk non-hospitalized patients with mild to moderate COVID-19, who do not require supplemental oxygen therapy or additional oxygen therapy above their baseline.

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To date, only one study (BLAZE-1) has been published on bamlanivimab and no studies have been published to date on casirivimab/imdevimab. The primary outcome for the BLAZE-1 trial was reduction in viral load at 11 days from the date of the positive test. The study did not find this to be a meaningful outcome measure since all patients had a significant decline in their viral load by day 11. The study did demonstrate an absolute reduction in incidence of hospitalizations and emergency room (ER) visits from 6.3% to 1.6%. Adverse events were rare but included: nausea (3%), dizziness (4%), headache (3%), hypersensitivity reactions (1%), and diarrhea (1%).

Per the FDA press release, casirivimab and imdevimab when given together reduced the viral load by day 7 and reduced hospitalizations and ER visits compared with placebo. The effect was most notable for high risk groups, with an absolute reduction in hospitalizations and ER visits from 9% to 3%. Similar adverse events to bamlanivimab were noted.

Procedure

Given the available limited data, two options are available for use through the EUA:

A. A single infusion of bamlanivimab 700mg IV over 60 minutes OR

B. A single infusion of casirivimab 1200mg/imdevimab 1200mg for a total of 2400 mg IV over 60 minutes.

The available monoclonal antibodies may be considered if the following criteria are met for patients with mild-moderate symptoms who are not currently hospitalized.

- Age ≥ 18 years of age

- Not requiring any supplemental O2 or need an increase from their baseline O2
- Confirmed SARS-CoV2 positive test ≤ 7 days prior
- Symptom onset ≤ 7 days prior
- High Risk Category:
  - Age ≥ 65 years of age
  - Age ≥ 55 years of age with cardiovascular disease or hypertension or chronic lung disease
  - Immunocompromised condition or on immunosuppressive medication
  - Diabetes Mellitus
  - Chronic Kidney Disease (CrCl ≤ 60 as measured by Cockcroft Gault for ≥ 3 months)
  - Obesity (BMI ≥ 35)

Individuals coming from a disadvantaged socioeconomic background should be strongly considered given their increased risk of mortality.

Please note the data on the benefit of this drug remain limited and per national guidance, **these drugs should not be considered standard of care and are purely investigational.**

At this time, there are two pathways whereby patients may obtain these investigational drugs:

- Patients who are in the ER and meet the above criteria but do not meet criteria for admission may be given either bamlanivimab or casirivimab. **Please do not refer patients to the ER to receive these drugs given our current surge**.
- Other patients may be able to receive either drug at the designated infusion center after December 10, 2020. There is a centralized process whereby a clinical team will review all outpatients with positive tests who meet criteria. The team will reach out to the ordering clinician to place a referral. Please review the patient fact sheets for both bamlanivimab and casirivimab/imedivimab, which are also available in Spanish, as well as the provider fact sheets. All patients will be given a fact sheet prior to drug administration.

If the demand for these drugs exceeds our ability to administer on any given day, the order time stamp and a point system with measures to account for socioeconomic vulnerability will be included in the allocation process. We will review all referrals at 9:00am and at 12:00pm on each calendar day.

Ongoing trials regarding the efficacy and safety of monoclonal antibodies, including ACTIV-2 here at UCLA, as well as other studies, remain open. Please send a message in Care Connect to the COVID Research Pool for more details.

Hospitalized patients with symptoms may be eligible for remdesivir or other clinical trials. Please contact the infectious disease consultant on call.

You may contact MABTeam@mednet.ucla.edu with questions.

REFERENCES

https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19

Chen P, Nirula A, Heller B, and colleagues on behalf of the BLAZE-1 Investigators. SARS-CoV-Neutralizing Antibody LY-CoV555 in Outpatients wiht Covid-19. N Engl J Med. 2020 Oct 28. doi10.1056/NEJMoa2029849.

Ahmad K, Erqou S, Shah N, Nazir U, Morrison AR, Choudhary G, Wu WC. Association of poor housing conditions wiht COVID-19 incidence and mortality across US counties. PLoS One. 2020Nov 2;15(11):e0241327

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CONTACT

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Attachments

- Patient Fact Sheet Bamlanivimab- Spanish.pdf
- Patient Fact Sheet Bamlanivimab.pdf
- Patient Fact Sheet Casirivimab & Imdevimab.pdf
- Patient Fact Sheet- Spanish Casirivimab & Imdevimab.pdf
- Provider Fact Sheet Bamlanivimab.pdf
- Provider Fact Sheet Casirivimab & Imdevimab.pdf

Approval Signatures

Step Description	Approver	Date
Administration Approval- President and CEO, UCLA Health	Johnese Spisso: Ceo Med Ctr [FD]	02/2021
Ronald Reagan Medical Staff Executive Committee- Chief of Staff	Carlos Lerner: Assoc Prof Of Clin-Hcomp [FD]	02/2021
Santa Monica Medical Staff Executive Committee- Chief of Staff	Roger Lee: Hs Clin Prof-Hcomp [FD]	02/2021
Hospital System Policy Committee Chair	Fiona Dunne: Adm Crd Ofcr [KK]	02/2021
Policy Owner	Tara Vijayan: Hs Asst Clin Prof-Hcomp	01/2021

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