Yale NewHaven Health

TO: **YNHHS MEDICAL STAFF**

FROM: **YNHHS COVID-19 TREATMENT TEAM, YNHHS ANTIMICROBIAL STEWARDSHIP COMMITTEE**

SUBJECT: **Revised Criteria for Bamlanivimab & Casirivimab/Imdevimab for the Treatment of COVID-19 in Outpatients**

DATE: **MARCH 10, 2021**

Situation:
On November 9, 2020 and then on November 21 ,2020, The US Food and Drug Administration (FDA) granted Emergency Use Authorization (EUA) for bamlanivimab and casirivimab/imdesivimab which are monoclonal antibodies to treat mild to moderate COVID-19 in outpatients.

Background:
Bamlanivimab and casirivimab/imdevimab are potent anti-spike neutralizing monoclonal antibodies that binds with high affinity to the receptor-binding domain of SARS-CoV-2. Both medications reduced the rate of hospitalization for COVID-19 when compared to placebo in outpatients with mild to moderate COVID-19 infection.

Assessment:
Based the above information the YNHHS COVID-19 Treatment Team and YNHHS Antimicrobial Stewardship Committee have developed YNHHS Criteria for bamlanivimab and casirivimab/imdevimab based on the FDA EUA criteria, the limited availability of these medications, and the mortality risk stratified by co-morbidities.

Recommendations:
With the increased availability of these medications as well as additional sites for infusion, the YNHHS criteria for bamlanivimab and casirivimab/imdesivimab have been revised as follows:

Patient must 12 years of age and older and weighing at least 40kg and have a documented positive result of a direct SARS CoV-2 viral test within the last 7 days AND who meet the following clinical criteria listed below:

a) Patients ≥ 65 years of age
b) Patients ≥ 55 years of age AND have one of the following comorbidities:
    a. Chronic obstructive pulmonary disease/other chronic respiratory disease
c) Patient less than 65 years of age AND have one of the following co-morbidities:
    1) Diabetes mellitus
    2) BMI ≥ 35 kg/m^2
    3) Chronic Kidney Disease or ESRD
    4) Congestive Heart Failure
    5) Cirrhosis
    6) Immunosuppressed status due to an underlying immunocompromising condition or use of immunosuppressive therapy
    7) Sickle cell disease
    8) Parkinson's disease
    9) Patient aged 12-17 with one of the following:
        a) Congenital or acquired heart disease
        b) Neurodevelopmental disorders
        c) Medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19)
        d) Chronic respiratory disease excluding asthma

Exclusion Criteria:

Bamlanivimab and casirivimab/imdesivimab are not authorized for use in the following patients:

1) Hospitalized due to COVID-19
   Monoclonal antibodies, such as bamlanivimab or casirivimab/imdesivimab, may be associated with worse clinical outcomes when administered to hospitalized patients with COVID-19 requiring high flow oxygen or mechanical ventilation.
   OR
2) Patients 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.

Referring Patients for Bamlanivimab and Casirivimab/Imdesivimab:

To initiate evaluation of an outpatient for possible casirivimab/imdevimab, enter an ambulatory referral in EPIC for "COVID Antibody Infusion Therapy".

If you do not have access to initiate the referral via EPIC, please use the attached referral form which can be faxed to 475-246-9923.

The above documents are located on the YNHHS COVID-19 Resources for Medical Staff under the "Outpatient Clinical Resources—Medications" which is located at:
https://www.ynhhs.org/patient-care/covid-19/for-employees/for-employees.aspx

References:

1. Anonymous. Full Emergency Use Authorization (EUA) Prescribing Information for Bamlanivimab. Available at: http://pi.lilly.com/eua/bamlanivimab-eua-factsheet-hcp.pdf.
2. Anonymous. Full Emergency Use Authorization (EUA) Prescribing Information for Available at: https://www.regeneron.com/sites/default/files/treatment-covid19-eua-fact-sheet-for-hcp.pdf
3. Chen P et al. SARS-CoV-2 Neutralizing Antibody LY-CoV555 in Outpatients with Covid-19. N Engl J Med 2021: 384(3):229-237.
4. Weinreich DM et al. REGN-COV2, a Neutralizing Antibody Cocktail, in Outpatients with Covid-19. N Engl J Med 2021; 384(3):238-251.