TO: YNHHS MEDICAL STAFF

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

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

DATE: December 18, 2020

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/imdevimab 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 were compared to placebo in outpatients with mild to moderate COVID-19 infection. Bamlanivimab reduced the rate of hospitalization from 6.3% (9/143) [placebo] to 1.6% (5/309). Similarly, casirivimab/imdevimab reduced hospitalization from 2% (8/434) [placebo] to 4% (10/231) to 2% (8/434).

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:
Based on the increased availability of these medications, the YNHHS criteria for bamlanivimab and casirivimab/imdevimab 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) Patient less than 65 years of age AND have one of the following co-morbidities:
   1) Diabetes mellitus
   2) BMI ≥ 40 kg/m²
   3) Chronic Kidney Disease, Stage III or higher or receiving dialysis
   4) Congestive Heart Failure NYHA Class III or higher
   5) Severe pulmonary disease defined as one of the following:
      a) COPD with continuous home oxygen, pulmonary hypertension/pulmonary fibrosis, or cystic fibrosis
      b) Cirrhosis—Child Class B or C
   7) Immunosuppressed status due to an underlying immunocompromising condition or use of immunosuppressive therapy
   8) Sickle cell disease
   9) Parkinson’s disease
10) 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”.

For more information on the “COVID Antibody Infusion Therapy” outpatient referral, please review the accompanied “Tips & Tricks” document.

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

Sites for Bamlanivimab and Casirivimab/Imdesivimab Infusion Across YNHHS:
1) Lawrence + Memorial Hospital:
   Monoclonal antibody infusions will be given at the outpatient infusion department.

2) Westerly Hospital:
   Monoclonal antibody infusions will be given in the ED Fast Track area.

3) Bridgeport Hospital:
   Monoclonal antibody infusions will be given at MedEase, 267 Grant St. starting December 22, 2020.

4) Greenwich Hospital:
   Monoclonal antibody infusions will be given in the bronchoscopy suite.
   Patients will enter via the north side of the building where the prior tent for SARS CoV-2 testing was located.

5) Yale-New Haven Hospital:
   Monoclonal antibody infusions will be given at Smilow Rapid Evaluation Clinic on NP-1.

References: