GUIDELINE

Title:	COVID-19: Monoclonal Antibody Therapeutic Drug Allocation				
Department/Service Line:	Clinical				
Approver(s):	BSWH CNE; BSWH CMO				
Location/Region/Division:	BSWH				
Document Number:	BSWH.CLN.126.G				
Effective Date:	11/24/2020	**Last Review/ Revision Date:**	11/24/2020	**Origination Date:**	11/13/2020

SCOPE

This document applies to Baylor Scott & White Health including Controlled Affiliates ("BSWH").

DEFINITIONS

When used in this document with initial capital letter(s), the following word(s)/phrase(s) have the meaning(s) set forth below unless a different meaning is required by context. Additional defined terms may be found in the BSWH P&P Definitions document.

None.

GUIDELINE

BSWH seeks to provide a transparent ethical framework based on objective clinical criteria for the responsible allocation of scarce medical resources when demand exceeds supply. This particular guideline focuses on monoclonal antibody therapeutic drugs but may be applied to other limited pharmacologic resources as well if other guidance has not been created.

Application of this guideline and the objective clinical criteria is primarily a physician responsibility and must include: 1) an individualized assessment of each patient's treatment preferences and survival likelihood based on best available, relevant, and objective evidence; and 2) as-needed modification and accommodation of these guidelines and tools based on the individual patient's clinical circumstances including disabilities and/or chronic conditions the individual may have.

Each patient will receive medical treatment delivered with respect, care, and compassion and without regard to basis of race, ethnicity, color, national origin, religion, sex, disability, veteran status, age, genetic information, sexual orientation, gender identity, or any other protected characteristic under applicable law. Further, medical treatment should not be allocated under these Guidelines based on the patient's ability to pay, insurance status, socioeconomic status, immigration status, incarceration status, homelessness, past or future use of resources, perceived self-worth, perceived quality of life, or weight/size.

PROCEDURE

1. Based upon current evidence from current clinical trials and U.S. Food and Drug Administration ("FDA") guidance, qualifying patients may receive an outpatient infusion of monoclonal antibody therapeutic drugs.

2. The responsible treating physician working in conjunction with the pharmacist should apply the following clinical criteria to determine which patients receive these drugs. Either the responsible treating physician or pharmacist may ask the Mass Critical Care Triage Committee for additional advice on guideline compliance, if desired.

3. Allocation decisions should be based on the application of **objective clinical criteria** applied to each individual patient, relying on ability to benefit and priority of need as manifested by clinical criteria. The evaluation should be based upon the individual patient and necessary accommodation for patients with a disability that may impact this evaluation.

Bamlanivimab Clinical Criteria (must meet all six (6)):

1. Adult and pediatric outpatients (i.e., not hospitalized patients) 12 years or older and weighing at least 40 kg;
2. With mild to moderate COVID-19 who are at high risk for progressing to severeCOVID-19 and/or hospitalization with COVID-19;
    a. High risk of progressing to severe COVID-19 and/or hospitalization has been identified in the EUA to include patients that:
        - Have a body mass index (BMI) ≥35
        - Have chronic kidney disease
        - Have diabetes
        - Have immunosuppressive disease
        - Are currently receiving immunosuppressive treatment
        - Are ≥65 years of age
        - Are ≥55 years of age AND have
            - cardiovascular disease, OR
            - hypertension, OR
            - chronic obstructive pulmonary disease/other chronic respiratory disease.
        - Are 12 – 17 years of age AND have
            - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
            - sickle cell disease, OR
            - congenital or acquired heart disease, OR
            - neurodevelopmental disorders, for example, cerebral palsy, OR
            - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
            - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.
3. First positive results of direct COVID-19 viral testing (polymerase chain reaction (PCR) or direct antigen) within the past seven (7) days.
4. After consideration of all clinical factors, the treating physician has come to the reasonable medical judgement that there is potential benefit and that benefit is proportional to the risks and burdens placed upon the patient; and,
5. Patient or surrogate decision-maker provides informed consent after receiving FDA Fact Sheet for Patients and Parents/Caregivers.
6. Lastly, bamlanivimab may only be administered in settings in which health care providers would have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (“EMS”) as necessary.

Casirivimab and Imdevimab Clinical Criteria (must meet all six (6)):

1. Adult and pediatric outpatients (i.e., not hospitalized patients) 12 years or older and weighing at least 40 kg;
2. With mild to moderate COVID-19 who are at high risk for progressing to severeCOVID-19 and/or hospitalization with COVID-19;
    a. High risk of progressing to severe COVID-19 and/or hospitalization has been identified in the EUA to include patients that:
        - Have a body mass index (BMI) ≥35
        - Have chronic kidney disease
        - Have diabetes
        - Have immunosuppressive disease
        - Are currently receiving immunosuppressive treatment

- Are ≥65 years of age
- Are ≥55 years of age AND have
  - cardiovascular disease, OR
  - hypertension, OR
  - chronic obstructive pulmonary disease/other chronic respiratory disease.
- Are 12 – 17 years of age AND have
  - BMI ≥85th percentile for their age and gender based on CDC growth charts, https://www.cdc.gov/growthcharts/clinical_charts.htm, OR
  - sickle cell disease, OR
  - congenital or acquired heart disease, OR
  - neurodevelopmental disorders, for example, cerebral palsy, OR
  - a medical-related technological dependence, for example, tracheostomy, gastrostomy, or positive pressure ventilation (not related to COVID-19), OR
  - asthma, reactive airway or other chronic respiratory disease that requires daily medication for control.

3. First positive results of direct COVID-19 viral testing (polymerase chain reaction (PCR) or direct antigen) within the past seven (7) days.
4. After consideration of all clinical factors, the treating physician has come to the reasonable medical judgement that there is potential benefit and that benefit is proportional to the risks and burdens placed upon the patient; and,
5. Patient or surrogate decision-maker provides informed consent after receiving FDA Fact Sheet for Patients and Parents/Caregivers.
6. Lastly, casirivimab and imdevimab must be administered together and may only be administered in settings in which health care providers would have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system ("EMS") as necessary.

4. Whenever possible, patients with similar clinical criteria within a single institution and across our system should be treated similarly.

5. When two patients qualify equally, but only one treatment course is available, allocation should be based upon the concept of first come, first served or the patient's whose order was placed first.

ATTACHMENTS

None.

RELATED DOCUMENTS

Bamlanivimab Consent and FDA Fact Sheet
Casirivimab and Imdevimab Consent and FDA Fact Sheet

REFERENCES

U.S. FDA Emergency Use Authorization (EUA) of Bamlanivimab, November 9, 2020
U.S. FDA Emergency Use Authorization (EUA) of Casirivimab and Imdevimab, November 21, 2020