

Screening Tool for Monoclonal Antibody Treatment

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Introduction

This screening tool should be used for both Eli Lilly Bamlanivimab and Regeneron Casirivimab and Imdevimab monoclonal antibodies (mAbs).

The U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) on Nov. 9, 2020, to permit the emergency use of “the investigational monoclonal antibody therapy bamlanivimab for the treatment of mild-to-moderate COVID-19 in adult and pediatric patients.”¹ On Nov. 21, 2020, a similar EUA was issued to permit the emergency use of “casirivimab and imdevimab” administered together, for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adult and pediatric patients.² Notably, neither of these EUAs authorize the administration of either therapy for “patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19.”^{2, 3}

The U.S. government has secured supplies of these antibody therapies for distribution to states. Shipments are expected weekly. Allocation and administration of these therapies are time-sensitive, as both EUAs specify that infusions be administered as soon as possible after positive COVID-19 test result and within 10 days of symptom onset.³ Health care providers are expected to follow the guidance outlined in the EUAs to equitably and ethically distribute this treatment. The State is providing this tool to assist health care partners in accurately screening positive COVID-19 patients to see if they are eligible to receive treatment. Note: eligibility criteria listed

¹ US Food and Drug Administration (FDA). Nov. 9, 2020. Letter to Christine Phillips, PhD, RAC, Eli Lilly and Company. <https://www.fda.gov/media/143602/download>

² US Food and Drug Administration (FDA). Nov. 21, 2020. Letter to Yunji Kim, PharmD, Regeneron Pharmaceuticals. <https://www.fda.gov/media/143891/download>

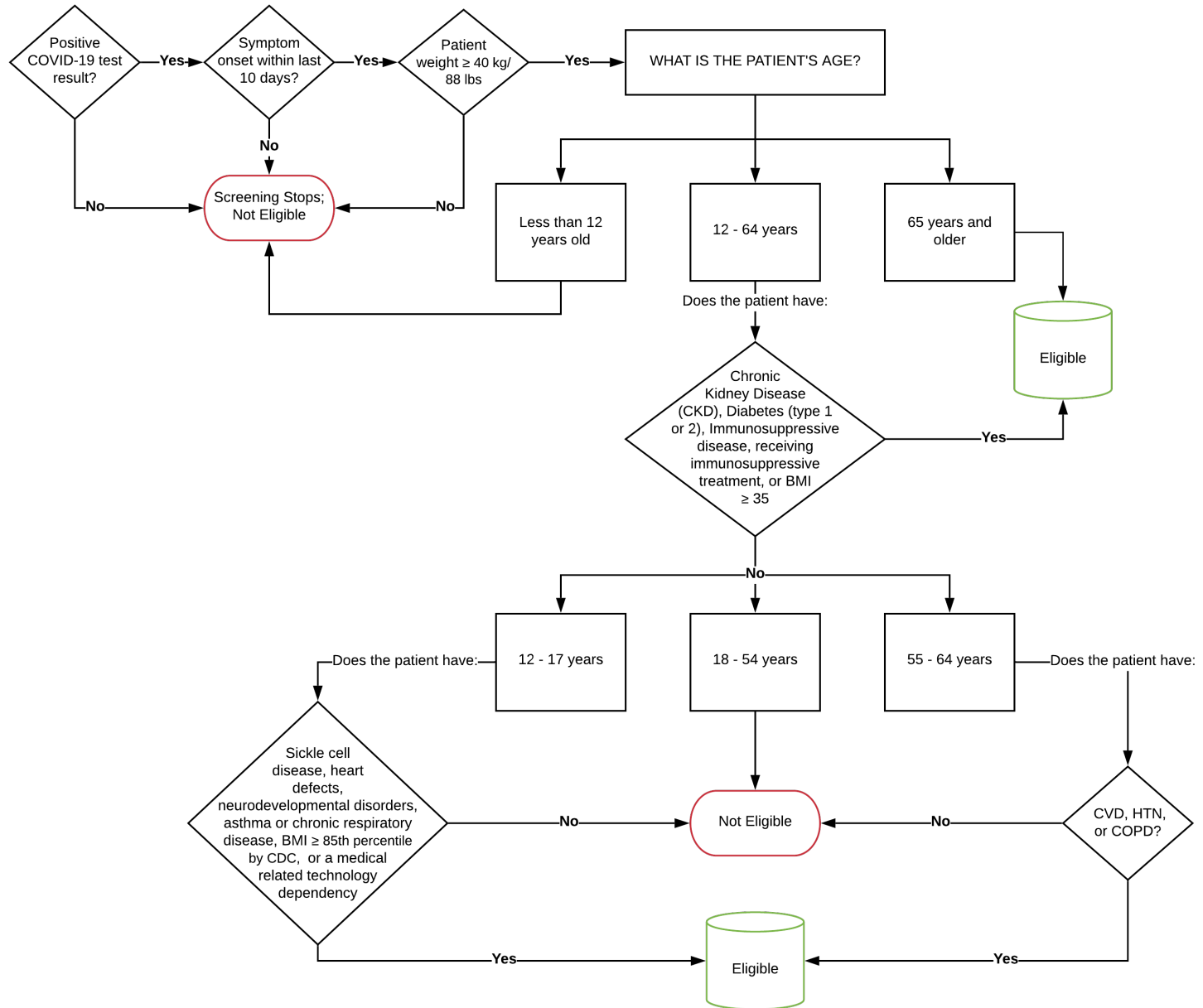
³ FDA. Nov. 9, 2020. Fact Sheet For Health Care Providers Emergency Use Authorization (Eua) Of Bamlanivimab, p.3. <https://www.fda.gov/media/143603/download>

in this screening tool are taken from both EUAs, which list specific criteria and limitations of authorized use.

For more information, including provider fact sheets, reference [Eli Lilly: Bamlanivimab for COVID-19 \(www.lilly.com/news/media/media-kits/bamlanivimab-covid19\)](https://www.lilly.com/news/media/media-kits/bamlanivimab-covid19) and FDA news release for Casirivimab and Imdevimab at [Coronavirus \(COVID-19\) Update: FDA Authorizes Monoclonal Antibodies for Treatment of COVID-19 \(https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-mono-clonal-antibodies-treatment-covid-19\)](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-mono-clonal-antibodies-treatment-covid-19).

Screening tool

Patients who are terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice) are only eligible if mAbs are considered to be in sufficient supply (e.g., when the number of doses received meets or exceeds MDH's projection of need). MDH will notify facilities whether mAbs are in sufficient or scarce supply at the time of each week's shipment.



Screening worksheet

1. Patient Name (First, Last): _____
2. Date of Birth (mm/dd/yyyy): _____
3. Positive COVID-19 test result (circle one): Yes / No
 - If **no**, screening stops; Not eligible to receive treatment
4. Symptom onset within last 10 days (circle one): Yes / No
 Date (mm/dd/yyyy): _____
 - If **no**, screening stops; Not eligible to receive treatment
 - If **yes**, continue to question 4.
 - **NOTE: Please allow sufficient time between screening date and scheduling infusion date to remain within 10 days of symptom onset per the EUA**
5. Patient weight: _____ lbs / kgs
 - If weighs less than 40 kg (88 lbs), screening stops; Not eligible to receive treatment
6. Patient Age: _____ years
 - If **65 years or older**, patient is *eligible*; Screening stops, follow facility policy to schedule
 - If **less than 12 years old**, screening stops; Not eligible to receive treatment
7. Does the patient have any of the following:
 - Chronic Kidney Disease (CKD) (see appendix)
 - Diabetes (type 1 or type 2)
 - Immunosuppressive disease (see appendix)
 - Receiving Immunosuppressive treatment (chemotherapy, transplant immunosuppressants, immune modulators such as Rituximab, etc.)
 - Body Mass Index (BMI) ≥ 35 Height: _____ ft / m Weight: _____ lbs / kg
 BMI = Weight in **kilograms** / [Height in **meters**]²
 Calculator: https://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmicalc.htm
 BMI = _____
 - If any of the above are true, patient is *eligible*; Screening stops, follow facility policy to schedule
 - If the patient is **18-54 years old** and does **not** have any of the above, screening stops; Not eligible to receive treatment

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8. If the patient is **55-64 years** do they have any of the following:

- Cardiovascular disease (CVD) (see appendix)
- Hypertension (HTN)
- Chronic obstructive pulmonary disease (COPD) or other chronic respiratory disease (see appendix)
- If any of the above are true, patient is *eligible*; Screening stops, follow facility policy to schedule
- If **no**, screening stops; Not eligible to receive treatment

9. If the patient is **12-17 years** do they have any of the following:

- Sickle cell disease
- Congenital or acquired heart disease
- Neurodevelopmental diseases (e.g. cerebral palsy) (see appendix)
- Asthma, reactive airway or other chronic respiratory disease requiring daily medication
- A medical-related technological dependence (e.g. tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)
- A BMI \geq 85th percentile for their age
 - Boys: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm#males
 - Girls: https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm#females
- If any of the above are true, patient is *eligible*; Screening stops, follow facility policy to schedule
- If **no**, screening stops; Not eligible to receive treatment

Appendix

Eligible medical conditions (including though not limited to):

Chronic Kidney Disease

- Chronic kidney disease (CKD)/ Chronic renal insufficiency (CRI)
- Dialysis (HD)
- End stage renal disease (ESRD)
- Glomerulonephritis (GN)
- Nephrotic syndrome
- Polycystic kidney disease (PCKD)

Immunosuppressive disease

- AIDS or CD4 count < 200
- Complement deficiency
- Grafts-Vs-Host disease (GVHD)
- HIV infection
- Immunoglobulin deficiency/ Immunodeficiency
- Immunosuppressive therapy (within the last 12 months)
- Leukemia
- Lymphoma (Hodgkins/ Non-Hodgkins (NHL))
- Metastatic cancer
- Multiple Myeloma
- Solid organ malignancy
- Steroid therapy (within past 2 weeks)
- Bone marrow transplant (BMT) or peripheral stem cell transplant (PSCT)
- Solid organ transplant

Cardiovascular disease

- Aortic aneurysm
- Valvular heart disease or valve replacement
- Atherosclerotic cardiovascular disease (ASCVD)
- Atrial fibrillation (AFib)
- Atrioventricular (AV) blocks
- Automated implantable devices (AID/AICD) / Pacemaker

- Bundle branch block (BBB, LBBB, RBBB)
- Cardiomyopathy
- Carotid stenosis
- Stroke
- Congenital heart disease
- Coronary artery bypass grafting (CABG)
- Coronary artery disease (CAD)
- Deep vein thrombosis (DVT)
- Congestive heart failure (CHF)
- Myocardial infarction (MI)
- Peripheral artery disease (PAD)
- Peripheral vascular disease (PVD)
- Pulmonary embolism (PE)
- Pulmonary hypertension (PHTN)
- Transient ischemic attack (TIA)
- History of Ventricular fibrillation (VF, VFib)
- History of Ventricular tachycardia (VT, VTach)

Chronic respiratory disease

- Active Tuberculosis (TB)
- Asbestosis
- Asthma/Reactive airway disease
- Bronchiectasis
- Bronchiolitis obliterans
- Chronic bronchitis
- Chronic respiratory failure
- Cystic Fibrosis (CF)
- Emphysema/Chronic obstructive pulmonary disease (COPD)
- Interstitial lung disease (ILD)
- Obstructive sleep apnea (OSA)
- Oxygen (O₂) dependent
- Pulmonary fibrosis
- Restrictive lung disease

- Sarcoidosis

Neurodevelopmental diseases

- Cerebral palsy
- Down Syndrome/ Trisomy 21
- Edward's syndrome/ Trisomy 18
- Epilepsy/ Seizure/ Seizure disorder
- Mitochondrial disorder
- Muscular dystrophy
- Neural tube defects/ Spina bifida



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