The SARS-CoV-2 genome encodes 4 major structural proteins: spike (S), envelope (E), membrane (M), and nucleocapsid (N), as well as nonstructural and accessory proteins. The spike protein is further divided into 2 subunits, S1 and S2, that mediate host cell attachment and invasion. Through its receptor-binding domain (RBD), S1 attaches to angiotensin-converting enzyme 2 (ACE2) on the host cell; this initiates a conformational change in S2 that results in virus-host cell membrane fusion and viral entry. Anti-SARS-CoV-2 monoclonal antibodies (mAbs) that target the spike protein have been shown to have clinical benefit in treating SARS-CoV-2 infection (as discussed below). Some anti-SARS-CoV-2 mAbs have been found to be effective as post-exposure prophylaxis (PEP) after a potential exposure to SARS-CoV-2 in a household setting and during SARS-CoV-2 outbreaks in skilled nursing and assisted living facilities. Other anti-SARS-CoV-2 mAbs have been shown to reduce the risk of infection when used as pre-exposure prophylaxis (PrEP).

Anti-SARS-CoV-2 Monoclonal Antibodies That Have Received Emergency Use Authorizations From the Food and Drug Administration

Four anti-SARS-CoV-2 mAb products have received Emergency Use Authorizations (EUAs) from the Food and Drug Administration (FDA). Bamlanivimab plus etesevimab, casirivimab plus imdevimab (REGEN-COV), and sotrovimab received EUAs for the treatment of mild to moderate COVID-19 in nonhospitalized patients with laboratory-confirmed SARS-CoV-2 infection who are at high risk for progressing to severe disease and/or hospitalization. However, the distribution of bamlanivimab plus etesevimab and casirivimab plus imdevimab has been paused because the products have reduced activities against the B.1.1.529 (Omicron) variant of concern (VOC). Sotrovimab is expected to retain efficacy against the Omicron variant. The FDA has issued an EUA for tixagevimab plus cilgavimab (Evusheld), a long-acting anti-SARS-CoV-2 mAb combination. The EUA allows this combination to be used as SARS-CoV-2 PrEP for individuals who do not have SARS-CoV-2 infection, who have not been recently exposed to an individual with SARS-CoV-2 infection, AND who are at risk for an inadequate immune response to COVID-19 vaccination OR have a documented history of severe adverse reaction to an available COVID-19 vaccine or any of its components (see Prevention of SARS-CoV-2 Infection for more information). The issuance of an EUA does not constitute FDA approval.

These authorized anti-SARS-CoV-2 mAb products are listed alphabetically as follows:

- **Bamlanivimab plus etesevimab**: These are neutralizing mAbs that bind to different, but nonoverlapping, epitopes in the spike protein RBD of SARS-CoV-2. The broad distribution of bamlanivimab plus etesevimab has been paused in the United States because the Omicron variant has markedly reduced in vitro susceptibility to bamlanivimab and etesevimab, and, therefore, this regimen is not expected to provide clinical benefit for patients with Omicron infection.

- **Casirivimab plus imdevimab**: These are recombinant human mAbs that bind to nonoverlapping epitopes of the spike protein RBD of SARS-CoV-2. The broad distribution of casirivimab plus imdevimab has been paused in the United States because the Omicron variant has markedly reduced in vitro susceptibility to casirivimab and imdevimab, and, therefore, this regimen is not expected to provide clinical benefit for patients with Omicron infection.

- **Sotrovimab**: This mAb was originally identified in 2003 from a survivor of SARS-CoV infection.
It targets an epitope in the RBD of the spike protein that is conserved between SARS-CoV and SARS-CoV-2. Sotrovimab retains in vitro activity against the Omicron variant.8

- *Tixagevimab plus cilgavimab:* These are recombinant human anti-SARS-CoV-2 mAbs that bind to nonoverlapping epitopes of the spike protein RBD of SARS-CoV-2. Although available in vitro data suggest that the Omicron variant remains susceptible to this combination, more data are needed to fully assess the activity of this regimen when the Omicron variant is circulating at high frequency.4,9,10

The FDA has issued an EUA for tixagevimab plus cilgavimab that allows the combination to be used as SARS-CoV-2 PrEP. Before the pause in distribution of bamlanivimab plus etesevimab and casirivimab plus imdevimab, the FDA had expanded the product EUAs to allow the regimens to be used as PEP for certain individuals who are at high risk of acquiring SARS-CoV-2 infection and, if infected, are at high risk of progressing to serious illness. For more information, see the FDA EUA fact sheets for *bamlanivimab plus etesevimab* and *casirivimab plus imdevimab* and *Prevention of SARS-CoV-2 Infection*.

**Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19**

The recommendations and discussion below pertain only to the use of the authorized anti-SARS-CoV-2 mAb products for the treatment of COVID-19. For recommendations and discussion regarding the use of anti-SARS-CoV-2 mAb products as PEP or PrEP, see *Prevention of SARS-CoV-2 Infection*.

The Omicron VOC has become the dominant SARS-CoV-2 variant in the United States.11 This variant, which includes numerous mutations in the spike protein, has markedly reduced in vitro susceptibility to several anti-SARS-CoV-2 mAbs, especially bamlanivimab plus etesevimab and casirivimab plus imdevimab. Sotrovimab retains in vitro activity against the Omicron variant.

**Recommendations**

- The COVID-19 Treatment Guidelines Panel (the Panel) recommends using *sotrovimab 500 mg* as a single intravenous (IV) infusion, administered as soon as possible and within 10 days of symptom onset, to treat nonhospitalized patients (aged ≥12 years and weighing ≥40 kg) with mild to moderate COVID-19 who are at high risk of clinical progression (AIIa) (see the EUA criteria for use of the product and the related discussion below).

  - Because the Omicron VOC has become the dominant variant in the United States and real-time testing to identify currently rare, non-Omicron variants is not routinely available, the Panel recommends against using *bamlanivimab plus etesevimab* or *casirivimab plus imdevimab* (AIII).

  - Treatment with anti-SARS-CoV-2 mAbs should be started as soon as possible after SARS-CoV-2 infection is confirmed by an antigen test or a nucleic acid amplification test (NAAT) and within 10 days of symptom onset.

  - Treatment with anti-SARS-CoV-2 mAbs should be considered for patients with mild to moderate COVID-19 who are hospitalized for a reason other than COVID-19 if they otherwise meet the EUA criteria for outpatient treatment.

  - Anti-SARS-CoV-2 mAbs are not currently authorized for use in patients who are hospitalized with severe COVID-19; however, the products may be available through expanded access programs for patients who either have not developed an antibody response to SARS-CoV-2 infection or are not expected to mount an effective immune response to infection.

  - When logistical or supply constraints make it impossible to offer available therapeutics to all
eligible nonhospitalized patients, see Therapeutic Management of Nonhospitalized Adults With COVID-19 for further guidance.

- There are no data on the combined use of antiviral agents and anti-SARS-CoV-2 mAbs for the treatment of nonhospitalized patients with COVID-19. Clinical trials are needed to determine whether this combination therapy has a role in the treatment of COVID-19.
- Severely immunocompromised patients may have prolonged SARS-CoV-2 replication leading to more rapid viral evolution. There is a theoretic concern that using a single anti-SARS-CoV-2 mAb in these patients may result in emergence of resistant virus. Additional studies are needed to assess this risk. The role of sotrovimab plus antiviral therapy in treating COVID-19 is not yet known.

Rationale

In randomized placebo-controlled trials in nonhospitalized patients who had mild to moderate COVID-19 symptoms and certain risk factors for disease progression, the use of anti-SARS-CoV-2 mAb products reduced the risk of hospitalization and death (see Table 3a). These studies were conducted before the widespread circulation of the Delta and Omicron VOCs. The potential impact of these variants and their susceptibility to different FDA-authorized anti-SARS-CoV-2 mAbs are discussed below.

Sotrovimab

Sotrovimab retains in vitro activity against the Omicron variant and is expected to provide clinical benefit in patients with Omicron infection. The data that support the EUA for sotrovimab are from the Phase 3 COMET-ICE trial, which included outpatients with mild to moderate COVID-19 who were at high risk for progression to severe disease and/or hospitalization. A total of 583 participants were randomized within 5 days of symptom onset to receive sotrovimab 500 mg IV (n = 291) or placebo (n = 292). The primary endpoint was the proportion of participants who were hospitalized for ≥24 hours or who died from any cause by Day 29. Endpoint events occurred in 3 of 291 participants (1%) in the sotrovimab arm and 21 of 292 participants (7%) in the placebo arm (P = 0.002), resulting in a 6% absolute reduction and an 85% relative reduction in hospitalizations or death associated with sotrovimab.

Bamlanivimab Plus Etesevimab

The broad distribution of bamlanivimab plus etesevimab has been paused in the United States because the Omicron variant has markedly reduced in vitro susceptibility to this mAb regimen. Prior to the spread of the Omicron variant, the Phase 3 BLAZE-1 trial had demonstrated a clinical benefit of bamlanivimab plus etesevimab in people with mild to moderate COVID-19 who are at high risk for progression to severe disease and/or hospitalization (see Table 3a).

Casirivimab Plus Imdevimab

The broad distribution of casirivimab plus imdevimab has been paused in the United States because the Omicron variant has markedly reduced in vitro susceptibility to this mAb regimen. Prior to the spread of the Omicron variant, the FDA had authorized the use of casirivimab 600 mg plus imdevimab 600 mg administered as a single IV infusion for the treatment of people with mild to moderate COVID-19 who are at high risk for progression to severe disease and/or hospitalization. The FDA also authorized subcutaneous (SQ) injection of the regimen if an IV infusion is not feasible or would delay treatment. SQ administration of casirivimab plus imdevimab requires 4 injections (2.5 mL per injection) at 4 different sites (see the FDA EUA for details).

The recommendation for using the lower dose of casirivimab 600 mg plus imdevimab 600 mg IV is based on data from a Phase 3, double-blind randomized placebo-controlled trial in outpatients with mild to moderate COVID-19. This trial evaluated different doses of casirivimab plus imdevimab administered...
as a single IV infusion. The modified full analysis set included participants aged ≥18 years who had a positive SARS-CoV-2 polymerase chain reaction result at randomization and who had ≥1 risk factors for progression to severe COVID-19. The results demonstrated a 2.2% absolute reduction and a 70% relative reduction in hospitalization or death with receipt of casirivimab 600 mg plus imdevimab 600 mg. The results for the higher dose of casirivimab plus imdevimab are comparable: a 3.3% absolute reduction and a 71% relative reduction in hospitalization or death among the patients who received casirivimab 1,200 mg plus imdevimab 1,200 mg. See Table 3a for additional details from the trial.

The recommendation for administering casirivimab plus imdevimab by SQ injections is based on safety data from the Phase 1 R10933-10987-HV-2093 study (ClinicalTrials.gov Identifier NCT04519437). This double-blind randomized placebo-controlled trial compared casirivimab plus imdevimab administered by SQ injection to placebo in healthy volunteers who did not have SARS-CoV-2 infection. Injection site reactions were observed in 12% of the 729 casirivimab plus imdevimab recipients and in 4% of the 240 placebo recipients. According to the FDA EUA for casirivimab plus imdevimab, there were similar reductions in viral load in the IV and SQ arms in a different trial that evaluated the anti-SARS-CoV-2 combination in symptomatic participants.13 However, because the safety and efficacy data for casirivimab plus imdevimab administered by SQ injection are limited, this route of administration should only be used when IV infusion is not feasible or would lead to a delay in treatment (BIII).

Criteria for Using Anti-SARS-CoV-2 Monoclonal Antibodies Under the Emergency Use Authorizations

The FDA EUAs for anti-SARS-CoV-2 mAbs include a list of specific conditions that place patients at high risk for clinical progression. On May 14, 2021, the FDA revised the EUAs to broaden these criteria.12,13 Notable changes included lowering the body mass index (BMI) cutoff from ≥35 to >25 and adding other conditions and factors (e.g., pregnancy, race or ethnicity). Other than being aged ≥12 years, there are no longer any age criteria restricting the use of these products in patients with the following conditions: sickle cell disease, neurodevelopmental disorders, medical-related technological dependence, asthma, cardiovascular disease, hypertension, and chronic lung disease.

When logistical or supply constraints make it impossible to offer available therapeutics to all eligible nonhospitalized patients, see Therapeutic Management of Nonhospitalized Adults With COVID-19 for further guidance.

Recommendations

The strength of the evidence for using anti-SARS-CoV-2 mAbs varies depending on the medical conditions and other factors that place patients at high risk for progression to severe COVID-19 and/or hospitalization. The ratings for the recommendations for the use of anti-SARS-CoV-2 mAbs as treatment are based on the FDA EUA criteria for identifying high-risk individuals. These criteria include the following conditions and other factors.

Medical Conditions or Other Factors That Were Represented in Patients in Clinical Trials That Evaluated Anti-SARS-CoV-2 Monoclonal Antibodies

- Aged ≥65 years (AIIa)
- Obesity (BMI >30) (AIIa)
- Diabetes (AIIa)
- Cardiovascular disease (including congenital heart disease) or hypertension (AIIa)
- Chronic lung diseases (e.g., chronic obstructive pulmonary disease, moderate-to-severe asthma, interstitial lung disease, cystic fibrosis, pulmonary hypertension) (AIIa)
Other Conditions or Factors That Had Limited Representation in Patients in Clinical Trials but Are Considered Risk Factors for Progression to Severe COVID-19 by the Centers for Disease Control and Prevention

- An immunocompromising condition or immunosuppressive treatment (AIII). Many experts strongly recommend therapy for patients with these conditions, despite their limited representation in clinical trials.
- Being overweight (BMI 25–30) as the sole risk factor (BIII)
- Chronic kidney disease (BIII)
- Pregnancy (BIII)
- Sickle cell disease (BIII)
- Neurodevelopmental disorders (e.g., cerebral palsy) or other conditions that confer medical complexity (e.g., genetic or metabolic syndromes and severe congenital anomalies) (BIII)
- Medical-related technological dependence (e.g., tracheostomy, gastrostomy, or positive pressure ventilation that is not related to COVID-19) (BIII)
- Infants aged <1 year. Although bamlanivimab plus etesevimab is authorized for use in this high-risk group, the Panel recommends against using this mAb regimen (AIII) because it has markedly reduced activity against Omicron, the dominant VOC in the United States.

It is important to note that the likelihood of developing severe COVID-19 increases when a person has multiple high-risk conditions or comorbidities. Medical conditions or other factors (e.g., race or ethnicity) that are not listed in the mAb EUAs may also be associated with high risk for progression to severe COVID-19. The current EUAs state that the use of anti-SARS-CoV-2 mAbs may be considered for patients with high-risk conditions and factors that are not listed in the EUAs. For additional information on medical conditions and other factors that are associated with increased risk for progression to severe COVID-19, see the CDC webpage People With Certain Medical Conditions. The decision to use anti-SARS-CoV-2 mAbs for a patient should be based on an individualized assessment of risks and benefits.8

Using Anti-SARS-CoV-2 Monoclonal Antibodies in Patients Hospitalized for COVID-19

The anti-SARS-CoV-2 mAbs available through FDA EUAs are not authorized for use in the following patients:

- Those hospitalized for COVID-19; or
- Those who require oxygen therapy due to COVID-19; or
- Those who are on chronic oxygen therapy due to an underlying non-COVID-19-related comorbidity and who require an increase in oxygen flow rate from baseline because of COVID-19.

The FDA EUAs do permit the use of these products in patients who are hospitalized for a diagnosis other than COVID-19, provided they have mild to moderate COVID-19 and are at high risk for progressing to severe disease.21-23

Anti-SARS-CoV-2 mAbs have been evaluated in hospitalized patients with severe COVID-19. A substudy of the ACTIV-3/TICO trial randomized patients who were hospitalized for COVID-19 to receive bamlanivimab 7,000 mg or placebo, each in addition to remdesivir. On October 26, 2020, study enrollment was halted after a prespecified interim futility analysis indicated a lack of clinical benefit for bamlanivimab.24,25
Prior to the spread of the Omicron variant, there were data that supported the use of anti-SARS-CoV-2 mAbs in hospitalized patients with COVID-19 who are seronegative for the anti-spike protein antibody and/or with evidence of ongoing viral replication. In a subset analysis of the ACTIV-3 trial, 153 of the 314 participants (49%) were negative for the anti-spike endogenous neutralizing antibody. The subhazard ratio (sHR) comparing bamlanivimab to placebo for sustained recovery (i.e., defined as discharge home and remaining at home for ≥14 days through Day 90) was 1.24 among the participants who were seronegative (CI, 0.90–1.70) versus 0.74 among those who were seropositive (CI, 0.54–1.00). Further, the difference for sustained recovery between bamlanivimab and placebo was even greater among the seronegative participants who had high viral loads (sHR 1.89; CI, 1.23–2.91). However, these results are limited due to the trial’s early termination for futility and small sample size.26

The ACTIV-3/TICO trial also randomized hospitalized patients with COVID-19 to receive sotrovimab 500 mg IV, an anti-SARS-CoV-2 mAb combination of BRII-196 1,000 mg IV plus BRII-198 1,000 mg IV, or placebo, each in addition to remdesivir. On March 1, 2021, study enrollment was halted after a prespecified interim futility analysis indicated a lack of clinical benefit for sotrovimab or BRII-196 plus BRII-198.27 A subset analysis did not suggest efficacy for sotrovimab in those with or without endogenous antibodies.

In the RECOVERY study, hospitalized patients with COVID-19 were randomized to receive standard of care with casirivimab 4,000 mg plus imdevimab 4,000 mg IV or standard of care alone. There was no difference in 28-day all-cause mortality between the casirivimab plus imdevimab arm and the standard of care arm; 944 of 4,839 patients (20%) in the casirivimab plus imdevimab arm died versus 1,026 of 4,946 patients (21%) in the standard of care arm (rate ratio 0.94; 95% CI, 0.86–1.03; \( P = 0.17 \)). However, in the subgroup of patients who were seronegative for the anti-spike protein antibody, there was a significant reduction in 28-day all-cause mortality in the casirivimab plus imdevimab arm (396 of 1,633 casirivimab plus imdevimab recipients [24%] died vs. 451 of 1,520 standard of care recipients [30%]; rate ratio 0.80; 95% CI, 0.70–0.91; \( P = 0.001 \)).28 Under the current EUA, this higher dose of casirivimab plus imdevimab is not available, and the lower dose is only authorized for use in nonhospitalized patients with COVID-19. In addition, rapid serology testing that can identify seronegative individuals in real time is currently not widely available.

Anti-SARS-CoV-2 mAbs may be available through expanded access programs for the treatment of immunocompromised patients who are hospitalized because of COVID-19. It is not yet known whether these mAb products provide clinical benefits in people with B cell immunodeficiency or other immunodeficiencies.

**SARS-CoV-2 Variants and Their Susceptibility to Anti-SARS-CoV-2 Monoclonal Antibodies**

In laboratory studies, some SARS-CoV-2 variants that harbor certain mutations have markedly reduced susceptibility to a number of the authorized anti-SARS-CoV-2 mAbs.29 The clinical relevance of reduced in vitro susceptibility of select variants to anti-SARS-CoV-2 mAbs is under investigation.

Some of the key SARS-CoV-2 variants that have been identified are:

- **B.1.1.7 (Alpha):** This variant retains in vitro susceptibility to all the anti-SARS-CoV-2 mAbs that are currently available through FDA EUAs.12,13,30
- **B.1.351 (Beta):** This variant has markedly reduced in vitro susceptibility to bamlanivimab and etesevimab.12,30 In vitro studies also suggest that the Beta variant has markedly reduced susceptibility to casirivimab, although the combination of casirivimab and imdevimab appears to retain activity against the variant. Sotrovimab also appears to retain activity against the variant.8,13
• **P.1 (Gamma):** This variant has markedly reduced in vitro susceptibility to bamlanivimab and etesevimab.\textsuperscript{12,31} The Gamma variant also has reduced susceptibility to casirivimab; however, the combination of casirivimab plus imdevimab appears to retain activity against the variant. Sotrovimab also appears to retain activity against the Gamma variant.\textsuperscript{8,13}

• **B.1.617.2, non-AY.1/AY.2 (Delta):** This VOC retains in vitro susceptibility to all the anti-SARS-CoV-2 mAbs that are currently available through FDA EUAs.\textsuperscript{12,13}

• **Omicron:** This is the predominant VOC circulating in the United States. This variant, which includes numerous mutations in the spike protein, has markedly reduced in vitro susceptibility to some anti-SARS-CoV-2 mAb products, including bamlanivimab plus etesevimab and casirivimab plus imdevimab.\textsuperscript{9} Sotrovimab retains in vitro activity against this variant.\textsuperscript{9,10} In vitro studies have reported a moderate reduction in the susceptibility of Omicron to tixagevimab plus cilgavimab, although this mAb regimen is expected to provide clinical benefit for SARS-CoV-2 PrEP.\textsuperscript{9,10,32}

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<tr>
<th>WHO Label</th>
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<th>CDC Variant Class</th>
<th>Notable Mutations</th>
<th>BAM Plus ETE In Vitro Susceptibility\textsuperscript{a}</th>
<th>Anticipated Clinical Activity</th>
<th>CAS Plus IMD In Vitro Susceptibility\textsuperscript{a}</th>
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<th>SOT In Vitro Susceptibility\textsuperscript{a}</th>
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<td>Moderate reduction\textsuperscript{c}</td>
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\textsuperscript{a} Based on the fold reduction in susceptibility reported in the FDA EUAs.\textsuperscript{4,8,12,13}

\textsuperscript{b} Marked change for CAS and no change for IMD. The combination of CAS plus IMD appears to retain activity against the variant.

\textsuperscript{c} Despite moderately reduced in vitro susceptibility, TIX plus CIL is expected to retain activity against the Omicron variant.

**Key:** BAM = bamlanivimab; CAS = casirivimab; CIL = cilgavimab; CDC = Centers for Disease Control and Prevention; ETE = etesevimab; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; IMD = imdevimab; SOT = sotrovimab; TIX = tixagevimab; VBM = variant being monitored; VOC = variant of concern; WHO = World Health Organization

Ongoing population-based genomic surveillance of the types and proportions of circulating SARS-CoV-2 variants, as well as studies on the susceptibility of different variants to available anti-SARS-CoV-2 mAbs, will be important in defining the utility of specific mAbs in the future.
Clinical Trials
See Table 3a for information on the clinical trials that are evaluating the safety and efficacy of anti-SARS-CoV-2 mAbs in patients with COVID-19.

Monitoring
Sotrovimab should be administered by IV infusion and should only be administered in health care settings by qualified health care providers who have immediate access to emergency medical services and medications that treat severe infusion-related reactions.

Patients should be monitored during the IV infusion and for at least 1 hour after the infusion is completed.

Adverse Effects
Hypersensitivity, including anaphylaxis and infusion-related reactions, has been reported in patients who received anti-SARS-CoV-2 mAbs. Rash, diarrhea, nausea, dizziness, and pruritis have also been reported.8,13,23

Drug-Drug Interactions
Drug-drug interactions are unlikely between the authorized anti-SARS-CoV-2 mAbs and medications that are renally excreted or that are cytochrome P450 substrates, inhibitors, or inducers (see Table 3c).

Considerations in Pregnancy
The use of anti-SARS-CoV-2 mAbs can be considered for pregnant people with COVID-19, especially those who have additional risk factors for severe disease (see the EUA criteria for the use of these products above).

As immunoglobulin (Ig) G mAbs, the authorized anti-SARS-CoV-2 mAbs would be expected to cross the placenta. There are no pregnancy-specific data on the use of these mAbs; however, other IgG products have been safely used in pregnant people when their use is indicated. Therefore, authorized anti-SARS-CoV-2 mAbs should not be withheld during pregnancy. When possible, pregnant and lactating people should be included in clinical trials that are evaluating the use of anti-SARS-CoV-2 mAbs for the treatment and/or prevention of COVID-19.

Considerations in Children
Please see Special Considerations in Children for therapeutic recommendations for children with COVID-19.

Drug Availability
Bamlanivimab plus etesevimab, casirivimab plus imdevimab, and sotrovimab are available through FDA EUAs. The broad distribution of bamlanivimab plus etesevimab and casirivimab plus imdevimab has been paused in the United States because the Omicron variant has reduced susceptibility to bamlanivimab and etesevimab, and casirivimab and imdevimab.6,7 Efforts should be made to ensure that communities most affected by COVID-19 have equitable access to these anti-SARS-CoV-2 mAbs.

References


