



Health Alert Network Message 21-53: Anti-SARS-CoV-2 Antibody Products

Origination Date:
July 27, 2021

Revision Dates (List All Revision Dates):

Anti-SARS-CoV-2 Antibody Products

The National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel has issued updated guidance for the use of Anti-SARS-CoV-2 Antibody Products. Given the recent surge in COVID-19 cases in Louisiana, the Office of Public Health wanted to remind clinicians of the indications for Anti-SARS-CoV-2 Antibody Products.

Detailed treatment guidance can be found at:

<https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>

Updated: July 8, 2021

Anti-SARS-CoV-2 Monoclonal Antibodies

The COVID-19 Treatment Guidelines Panel (the Panel) recommends using one of the following anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the Emergency Use Authorization (EUA) criteria:

- **Casirivimab plus imdevimab; or**
- **Sotrovimab.**

At this time, the Panel **recommends against** using **bamlanivimab plus etesevimab (AIII)** because the P.1 (Gamma) and B.1.351 (Beta) variants of concern, which have reduced susceptibility to both bamlanivimab and etesevimab, represent an increasing proportion of the circulating variants in the United States. See the [Centers for Disease Control and Prevention's \(CDC\) COVID Data Tracker](#) for the latest information on variant proportion by region of the United States.

The quality of the evidence that supports the Panel's recommendations for the use of anti-SARS-CoV-2 monoclonal antibodies differs based on the criteria used to define high risk of progression to severe COVID-19. Consequently, the Panel weighed the strength of the recommendations based on the evidence for the risk of progression (see the [Panel's Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19](#)). Treatment is recommended based on the FDA EUA criteria for:

- Patients with high-risk conditions that were represented in clinical trials (**AIIa**), and

- Patients with other medical conditions and factors that had limited representation in clinical trials (**BIII**) ; however, in cases where the patient has an immunocompromising condition or is receiving immunosuppressive therapy, the rating for the recommendation is **AIII** .

Treatment should be started as soon as possible after the patient receives a positive result on a SARS-CoV-2 antigen or nucleic acid amplification test and within 10 days of symptom onset. The Panel **recommends against** the use of **anti-SARS-CoV-2 monoclonal antibodies** for patients who are hospitalized because of COVID-19, except in a clinical trial (**AIIa**) . However, their use should be considered for persons with mild to moderate COVID-19 who are hospitalized for a reason other than COVID-19 but who otherwise meet the EUA criteria.

COVID-19 Convalescent Plasma

The Panel **recommends against** the use of **low-titer COVID-19 convalescent plasma** for the treatment of COVID-19 (**AIIb**). Low-titer COVID-19 convalescent plasma is no longer authorized through the convalescent plasma EUA.

- For hospitalized patients with COVID-19 who do not have impaired immunity:
 - The Panel **recommends against** the use of **COVID-19 convalescent plasma** for the treatment of COVID-19 in mechanically ventilated patients (**AI**).
 - The Panel **recommends against** the use of **high-titer COVID-19 convalescent plasma** for the treatment of COVID-19 in hospitalized patients who do not require mechanical ventilation, except in a clinical trial (**AI**).
- For hospitalized patients with COVID-19 who have impaired immunity:
 - There is insufficient evidence for the Panel to recommend either for or against the use of high-titer COVID-19 convalescent plasma for the treatment of COVID-19.
- For non-hospitalized patients with COVID-19:
 - There is insufficient evidence for the Panel to recommend either for or against the use of high-titer COVID-19 convalescent plasma for the treatment of COVID-19 in patients who are not hospitalized.

Anti-SARS-CoV-2 Specific Immunoglobulin

There is insufficient evidence for the Panel to recommend either for or against the use of anti-SARS-CoV-2 specific immunoglobulin for the treatment of COVID-19

Rating of Recommendations: A = Strong; B = Moderate; C = Optional

Rating of Evidence: I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion

In laboratory studies, some SARS-CoV-2 variants of concern or interest harboring certain mutations have shown reduced susceptibility to some agents (see the [CDC website](#) for more information). Based on the degree of reduced susceptibility and the proportion of these variants in a region, some regimens may be preferred over others in certain settings. See [Anti-SARS-CoV-2 Monoclonal Antibodies](#) and the [Panel's Statement on the Emergency Use Authorizations of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19](#) for recommendation ratings, dosing of the regimens, and additional information. Updates on the distribution of bamlanivimab plus etesevimab are available from the [Department of Health and Human Services Bamlanivimab/Etesevimab website](#).

See the [Panel's Statement on the Updated Emergency Use Authorization of the Anti-SARS-CoV-2 Monoclonal Antibody Combination Casirivimab Plus Imdevimab](#) for the Treatment of COVID-19 for dosing and administration information.

Medical conditions or other factors that were represented in clinical trials evaluating anti-SARS-CoV-2 monoclonal antibodies:

- Older age (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 clinical trials, but are considered risk factors for progression to severe COVID-19 by the [CDC](#):

- An immunocompromising condition or immunosuppressive treatment **(AIII)** (based on theoretic considerations, many experts strongly recommend therapy for patients who are immunosuppressed despite their limited representation in clinical trials).
- 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 [not related to COVID-19]) **(BIII)**

It is important to note that the likelihood of developing severe COVID-19 is increased when a person has multiple high-risk conditions or comorbidities. Other factors (e.g., race or ethnicity) or medical conditions may also place individual patients at high risk for progression to severe COVID-19. The current EUAs state that anti-SARS-CoV-2 monoclonal antibodies may be considered for many of these other patients **(BIII)**. For additional information on medical conditions and factors associated with increased risk for progression to severe COVID-19, see the CDC webpage [Extra Precautions: People With Certain Medical Conditions](#). Health care providers should consider the benefits and risks of using anti-SARS-CoV-2 monoclonal antibodies for each individual patient.

Where Providers Can Get Monoclonal Antibodies

Providers can find potential treatment sites located near them by using this link. <https://www.phe.gov/emergency/events/COVID19/therapeutics/Pages/default.aspx>

There is adequate supply of RGN-COV (casirivimab and imdevimab) according to HHS. It can be ordered at no charge directly from Amerisource Bergen. If the facility does not have an account, they can email: c19therapies@amerisourcebergen.com

Sotrovimab is a commercially available product and can be purchased via the usual pharmaceutical purchasing channels.