

# 7. Anti-SARS-CoV-2 Antibody Products

Last Updated: April 29, 2022

## Summary Recommendations

The COVID-19 Treatment Guidelines Panel's (the Panel) recommendations for the use of anti-SARS-CoV-2 monoclonal antibodies (mAbs) are based on current knowledge of the in vitro activities of available products against the circulating SARS-CoV-2 variants and subvariants. These recommendations remain fluid and depend on the prevalence of resistant variants.

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

- 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 Food and Drug Administration (FDA) Emergency Use Authorization (EUA) criteria for outpatient treatment.
- The risk for progression to severe COVID-19 in high-risk patients is substantially greater for those who are not vaccinated or those who are vaccinated but not expected to mount an adequate immune response to the vaccine due to an underlying immunocompromising condition. When the available therapies cannot be offered to all eligible patients, see [Prioritization of Anti-SARS-CoV-2 Therapies for the Treatment and Prevention of COVID-19 When There Are Logistical or Supply Constraints](#) for the Panel's recommendations.
- At this time, the Panel's anti-SARS-CoV-2 mAb recommendations are for the treatment of nonhospitalized patients with mild to moderate COVID-19 who are at high risk of progressing to severe disease.

### Bebtelovimab

- The Panel recommends using **bebtelovimab 175 mg** intravenous injection in patients aged  $\geq 12$  years as an alternative therapy **ONLY** when ritonavir-boosted nirmatrelvir (Paxlovid) and remdesivir are not available, feasible to use, or clinically appropriate (**CIII**). Treatment should be initiated as soon as possible and within 7 days of symptom onset. See [Therapeutic Management of Nonhospitalized Adults With COVID-19](#) for further guidance.
- Bebtelovimab should be administered in a setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed. Patients should be monitored during the injection and observed for at least 1 hour after injection.

### Bamlanivimab Plus Etesevimab, Casirivimab Plus Imdevimab, and Sotrovimab

- Because the Omicron (B.1.1.529) variant of concern (VOC) and its subvariants have become dominant in the United States, the Panel **recommends against** using **bamlanivimab plus etesevimab, casirivimab plus imdevimab, or sotrovimab** for the treatment of COVID-19 (**AIII**).

### Anti-SARS-CoV-2 Monoclonal Antibodies as Post-Exposure Prophylaxis for SARS-CoV-2 Infection

- The Panel **recommends against** the use of **bamlanivimab plus etesevimab** and **casirivimab plus imdevimab** for SARS-CoV-2 post-exposure prophylaxis (PEP), as the Omicron VOC, which is not susceptible to these agents, is currently the dominant SARS-CoV-2 variant circulating in the United States (**AIII**).

### Anti-SARS-CoV-2 Monoclonal Antibodies as Pre-Exposure Prophylaxis for SARS-CoV-2 Infection

- The Panel recommends using **tixagevimab 300 mg plus cilgavimab 300 mg (Evusheld)** administered as 2 consecutive 3-mL intramuscular injections (**BIII**) as SARS-CoV-2 pre-exposure prophylaxis (PrEP) for adults and adolescents (aged  $\geq 12$  years and weighing  $\geq 40$  kg) 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 moderately to severely immunocompromised and may have an inadequate immune response to COVID-19 vaccination; *or*
  - Are not able to be fully vaccinated with any available COVID-19 vaccines due to a history of severe adverse reactions to a COVID-19 vaccine or any of its components.
- For individuals who previously received a dose of tixagevimab 150 mg plus cilgavimab 150 mg, the FDA EUA states that a second dose should be administered as soon as possible:
  - If the initial dose was administered  $\leq 3$  months ago, the second dose should be tixagevimab 150 mg plus cilgavimab 150 mg.
  - If the initial dose was administered  $> 3$  months ago, the second dose should be tixagevimab 300 mg plus cilgavimab 300 mg.

### Summary Recommendations, continued

- **Tixagevimab plus cilgavimab is not a substitute for COVID-19 vaccination and should not be used in unvaccinated individuals for whom COVID-19 vaccination is recommended and who are anticipated to have an adequate response.**
- If supplies of tixagevimab plus cilgavimab are limited, priority for use as PrEP should be given to those who are at the highest risk for severe COVID-19 (see [Prioritization of Anti-SARS-CoV-2 Therapies for the Treatment and Prevention of COVID-19 When There Are Logistical or Supply Constraints](#)).

#### COVID-19 Convalescent Plasma

- The Panel **recommends against** the use of COVID-19 convalescent plasma (CCP) that was collected prior to the emergence of the Omicron VOC for the treatment of COVID-19 **(AIII)**.
- The Panel **recommends against** the use of CCP for the treatment of COVID-19 in hospitalized, immunocompetent patients **(AI)**.
- There is insufficient evidence for the Panel to recommend either for or against the use of high-titer CCP that was collected after the emergence of the Omicron VOC for the treatment of immunocompromised patients and nonhospitalized, immunocompetent patients with COVID-19.

#### Anti-SARS-CoV-2-Specific Immunoglobulins

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

**Rating of Recommendations:** A = Strong; B = Moderate; C = Weak

**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