# Anti-SARS-CoV-2 Antibody Products

Last Updated: August 18, 2022

# **Summary Recommendations**

The COVID-19 Treatment Guidelines Panel's (the Panel) recommendations for the use of anti-SARS-CoV-2 antibody products are based on current knowledge of the in vitro activities of available products against the circulating SARS-CoV-2 variants and subvariants.

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

- For nonhospitalized adults aged ≥18 years with mild to moderate COVID-19 who are at high risk of progressing to severe disease, the Panel recommends using **bebtelovimab 175 mg** intravenous injection as an alternative therapy <u>ONLY</u> when both 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 the Centers for Disease Control and Prevention webpage <u>People With Certain Medical Conditions</u> for information on medical conditions that are associated with an increased risk of progression to severe COVID-19 and <u>Therapeutic Management of Nonhospitalized Adults With COVID-19</u> for further guidance on the use of bebtelovimab.
- Bebtelovimab should be administered in a setting where severe hypersensitivity reactions, such as anaphylaxis, can be managed. Patients should be monitored for at least 1 hour after injection.
- Bebtelovimab is 1 of the treatment options that can be considered for adults aged ≥18 years 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.
- There is insufficient evidence for the Panel to recommend either for or against the use of bebtelovimab for the treatment of COVID-19 in children aged 12 to 17 years who have mild to moderate COVID-19 and who are at the highest risk of progression to severe COVID-19.
- Because the Omicron variant of concern (VOC) and its subvariants have become the dominant SARS-CoV-2 variants
  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 post-exposure prophylaxis (PEP), as the Omicron VOC and its subvariants, which are not susceptible to these agents, are currently the dominant SARS-CoV-2 variants 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 (IM) injections **(BIIb)** as SARS-CoV-2 pre-exposure prophylaxis (PrEP) for adults and adolescents (aged ≥12 years and weighing ≥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.
- The Panel recommends repeat dosing of **tixagevimah 300 mg plus cilgavimah 300 mg** administered as IM injections every 6 months (BIIb).
- The FDA EUA states that individuals who received tixagevimab 150 mg plus cilgavimab 150 mg should be given a second dose as soon as possible.
  - If the initial dose was administered ≤3 months prior, the second dose should be tixagevimab 150 mg plus cilgavimab 150 mg.

## **Summary Recommendations**, continued

- If the initial dose was administered >3 months prior, the second dose should be tixagevimab 300 mg plus cilgavimab 300 mg.
- 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.
- 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 <u>Prioritization of Anti-SARS-CoV-2 Therapies for the Treatment and Prevention of COVID-19 When There Are Logistical or Supply Constraints</u>).

#### **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.

# SARS-CoV-2-Specific Immunoglobulins

• There is insufficient evidence for the Panel to recommend either for or against the use of 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