Anti-SARS-CoV-2 Antibody Products

Last Updated: August 18, 2022

<table>
<thead>
<tr>
<th>Summary Recommendations</th>
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<td>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.</td>
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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 ONLY 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 People With Certain Medical Conditions for information on medical conditions that are associated with an increased risk of progression to severe COVID-19 and Therapeutic Management of Nonhospitalized Adults With COVID-19 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 tixagevimab 300 mg plus cilgavimab 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 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.

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