**Table 3c. Characteristics of SARS-CoV-2 Antibody-Based Products**

_Last Updated: April 8, 2022_

- The information in this table is based on data from investigational trials evaluating these products for the treatment or prevention of COVID-19. The table includes dose recommendations from the FDA EUAs for patients who meet specified criteria.
- There are limited or no data on dose modifications for patients with organ failure or those who require extracorporeal devices. Please refer to product labels, when available.
- There are currently not enough data to determine whether certain medications can be safely coadministered with therapies for the treatment or prevention of COVID-19. When using concomitant medications with similar toxicity profiles, consider performing additional safety monitoring.
- The potential additive, antagonistic, or synergistic effects and the safety of using combination therapies for the treatment or prevention of COVID-19 are unknown. Clinicians are encouraged to report AEs to the [FDA Medwatch program](https://www.fda.gov/medwatch).
- For drug interaction information, please refer to product labels and visit the [Liverpool COVID-19 Drug Interactions website](https://covid19-druginteractions.org/).
- For the Panel’s recommendations on using the drugs listed in this table, please refer to the [Anti-SARS-CoV-2 Monoclonal Antibodies](https://covid19treatmentguidelines.nih.gov/ actionable_monoclonals), [Therapeutic Management of Nonhospitalized Adults With COVID-19](https://covid19treatmentguidelines.nih.gov/ nonhospitalized_adults), and [Prevention of SARS-CoV-2 Infection](https://covid19treatmentguidelines.nih.gov/ prevention) sections of the Guidelines.

<table>
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<tr>
<th>Dosing Regimens</th>
<th>Adverse Events</th>
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<tr>
<td><strong>Bamlanivimab Plus Etesevimab (Anti-SARS-CoV-2 Monoclonal Antibodies)</strong></td>
<td></td>
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<tr>
<td>Authorized for the treatment and PEP of COVID-19 under FDA EUA, but distribution has paused because the Omicron VOC has markedly reduced in vitro susceptibility to BAM plus ETE.</td>
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<tr>
<td><strong>Dose Recommended in FDA EUA for Treatment and PEP of COVID-19 in Adults and Pediatric Patients Weighing ≥40 kg:</strong></td>
<td>Nausea</td>
<td>Only for administration in health care settings by qualified health care providers who have immediate access to emergency medical services and medications to treat severe infusion reactions.</td>
<td>Drug-drug interactions are unlikely between BAM plus ETE and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.</td>
<td><strong>Availability:</strong></td>
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<tr>
<td>• BAM 700 mg plus ETE 1,400 mg as a single IV infusion</td>
<td>Dizziness</td>
<td>• These AEs were observed in multiple trials in which participants received either the authorized doses of BAM and ETE or higher doses of each drug.</td>
<td></td>
<td>• Distribution of BAM plus ETE has paused because the Omicron VOC has markedly reduced in vitro susceptibility to BAM plus ETE, and this regimen is not expected to provide clinical benefit.</td>
</tr>
<tr>
<td><strong>Doses Recommended in FDA EUA for Treatment and PEP of COVID-19 in Neonates, Infants, Children, and Adolescents Weighing &lt;40 kg:</strong></td>
<td>Pruritus</td>
<td>• Monitor during IV infusion and for ≥1 hour after infusion is completed.</td>
<td></td>
<td>• HHS Public Health Emergency updates on the distribution of BAM plus ETE are available.</td>
</tr>
<tr>
<td>• 1–12 kg: BAM 12 mg/kg plus ETE 24 mg/kg as a single IV infusion</td>
<td>Hypersensitivity, including anaphylaxis and infusion-related reactions</td>
<td></td>
<td></td>
<td>• A list of clinical trials is available: <a href="https://www.covid19treatmentguidelines.nih.gov/">Bamlanivimab Plus Etesevimab</a>.</td>
</tr>
</tbody>
</table>
### Dosing Regimens

**Bamlanivimab Plus Etesevimab (Anti-SARS-CoV-2 Monoclonal Antibodies), continued**

- **>12 kg to 20 kg:** BAM 175 mg plus ETE 350 mg as a single IV infusion
- **>20 kg to <40 kg:** BAM 350 mg plus ETE 700 mg as a single IV infusion

**Bebtelovimab (Anti-SARS-CoV-2 Monoclonal Antibody)**

- **Dose Recommended in FDA EUA for Treatment of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:** BEB 175 mg as an IV injection over at least 30 seconds
- **Adverse Events:** Nausea, Vomiting, Pruritis, Rash, Hypersensitivity, including anaphylaxis and infusion-related reactions
- **Monitoring Parameters:** Only for administration in health care settings by qualified health care providers who have immediate access to emergency medical services and medications to treat severe infusion reactions.
- **Drug-Drug Interaction Potential:** Drug-drug interactions are unlikely between BEB and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.
- **Availability:** Under the FDA EUA, BEB is available for the treatment of high-risk outpatients with mild to moderate COVID-19. See [Anti-SARS-CoV-2 Monoclonal Antibodies](https://www.covid19treatmentguidelines.nih.gov/) for a list of high-risk conditions.
- **HHS Public Health Emergency updates** on the distribution of CAS plus IMD are available.
- **A list of clinical trials is available:** Bebtelovimab

**Casirivimab Plus Imdevimab (Anti-SARS-CoV-2 Monoclonal Antibodies)**

- **Dose Recommended in FDA EUA for Treatment and PEP of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:** CAS 600 mg plus IMD 600 mg as a single IV infusion over 1 hour
- **Adverse Events:** Hypersensitivity, including anaphylaxis and infusion-related reactions
- **Monitoring Parameters:** Only for administration in health care settings by qualified health care providers who have immediate access to emergency medical services and medications to treat severe infusion reactions.
- **Drug-Drug Interaction Potential:** Drug-drug interactions are unlikely between CAS plus IMD and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.
- **Availability:** Distribution of CAS plus IMD has paused because the Omicron VOC has markedly reduced in vitro susceptibility to CAS plus IMD, and this regimen is not expected to provide clinical benefit.
- **HHS Public Health Emergency updates** on the distribution of CAS plus IMD are available.
- **A list of clinical trials is available:** Casirivimab Plus Imdevimab

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### Dosing Regimens

**Casirivimab Plus Imdevimab (Anti-SARS-CoV-2 Monoclonal Antibodies), continued**

The FDA EUA for detailed information.

Dose Recommended in FDA EUA for PEP for Individuals With Ongoing Exposure to SARS-CoV-2:
- After initial dose, repeat dosing of CAS 300 mg plus IMD 300 mg by SUBQ injections or IV infusion every 4 weeks for duration of ongoing exposure.

**Sotrovimab (Anti-SARS-CoV-2 Monoclonal Antibody)**

Authorized for the treatment of COVID-19 under FDA EUA, but distribution has paused in the United States because the Omicron BA.2 subvariant has markedly reduced in vitro susceptibility to SOT.

Dose Recommended in FDA EUA for Treatment of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:
- SOT 500 mg as an IV infusion over 15 minutes for 50 mL bag or over 30 minutes for 100 mL bag
- Rash
- Diarrhea
- Hypersensitivity, including anaphylaxis and infusion-related reactions
- Only for administration in health care settings by qualified health care providers who have immediate access to emergency medical services and medications to treat severe infusion reactions.
- Monitor during IV infusion and for ≥1 hour after infusion is completed.
- Drug-drug interactions are unlikely between SOT and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.

### Adverse Events

- Rash
- Diarrhea
- Hypersensitivity, including anaphylaxis and infusion-related reactions

### Monitoring Parameters

- Only for administration in health care settings by qualified health care providers who have immediate access to emergency medical services and medications to treat severe infusion reactions.
- Monitor during IV infusion and for ≥1 hour after infusion is completed.

### Drug-Drug Interaction Potential

- Drug-drug interactions are unlikely between SOT and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.

### Comments and Links to Clinical Trials

Availability:
- Distribution of SOT has paused because the Omicron BA.2 subvariant has markedly reduced susceptibility to SOT, and SOT is not expected to provide clinical benefit.
- HHS Public Health Emergency updates on the distribution of SOT are available.
- A list of clinical trials is available: Sotrovimab

**Tixagevimab Plus Cilgavimab (Evusheld) (Anti-SARS-CoV-2 Monoclonal Antibodies)**

Authorized for PrEP of COVID-19 under FDA EUA.

Doses Recommended in FDA EUA for PrEP of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:
- TIX 300 mg plus CIL 300 mg as 2 consecutive 3 mL IM injections
- Hypersensitivity, including anaphylaxis and injection-related reactions
- In 1 clinical trial, cardiac events were reported in participants with cardiac
- Use with caution in individuals with thrombocytopenia or any coagulation disorder.
- Monitor for ≥1 hour after injection.
- If a person has received a COVID-19 vaccine, TIX plus CIL should be administered ≥2 weeks after vaccination.
- Drug-drug interactions are unlikely between

Under the FDA EUA, TIX plus CIL for PrEP of COVID-19 is available for certain patients at high risk of infection. See Prevention of SARS-CoV-2 Infection for more information.²
For patients who previously received a dose of TIX 150 mg plus CIL 150 mg, administer a second dose per the following criteria as soon as possible:

- If the initial dose was ≤3 months ago, the second dose should be TIX 150 mg plus CIL 150 mg.
- If the initial dose was >3 months ago, the second dose should be TIX 300 mg plus CIL 300 mg.

TIX plus CIL and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.

- A list of clinical trials is available: Tixagevimab Plus Cilgavimab

### COVID-19 Convalescent Plasma
**Authorized for the treatment of COVID-19 under FDA EUA.**

**Dose Recommended in FDA EUA for Treatment of COVID-19:**
- Per the EUA, consider starting clinical dosing with 1 high-titer COVID-19 CP unit (about 200 mL), with administration of additional CP units based on the prescribing provider’s medical judgment and the patient’s clinical response.
- TRALI
- TACO
- Allergic reactions
- Anaphylactic reactions
- Febrile nonhemolytic reactions
- Hemolytic reactions
- Hypothermia
- Metabolic complications
- Transfusion-transmitted infections
- Thrombotic events
- Theoretical risk of antibody-mediated enhancement of infection and suppressed long-term immunity
- Before administering CP to patients with a history of severe allergic or anaphylactic transfusion reactions, the Panel recommends consulting a transfusion medicine specialist who is associated with the hospital blood bank.
- Monitor for transfusion-related reactions.
- Monitor vital signs at baseline and during and after transfusion.

**Drug products should not be added to the IV infusion line for the blood product.**

**Availability:**
- A list of clinical trials is available: COVID-19 Convalescent Plasma
## References


