Table 5c. 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.
- For drug interaction information, please refer to product labels and visit the Liverpool COVID-19 Drug Interactions website.
- For the Panel’s recommendations on using the drugs listed in this table, please refer to the Anti-SARS-CoV-2 Monoclonal Antibodies, Therapeutic Management of Nonhospitalized Adults With COVID-19, and Prevention of SARS-CoV-2 Infection sections of the Guidelines.

<table>
<thead>
<tr>
<th>Dosing Regimens</th>
<th>Adverse Events</th>
<th>Monitoring Parameters</th>
<th>Drug-Drug Interaction Potential</th>
<th>Comments and Links to Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bamlanivimab Plus Etesevimab (Anti-SARS-CoV-2 Monoclonal Antibodies)</strong>&lt;br&gt;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>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose Recommended in FDA EUA for Treatment and PEP of COVID-19 in Adults and Pediatric Patients Weighing ≥40 kg:</strong>&lt;br&gt;• BAM 700 mg plus ETE 1,400 mg as a single IV infusion</td>
<td>• Nausea&lt;br&gt;• Dizziness&lt;br&gt;• Pruritis&lt;br&gt;• Hypersensitivity, including anaphylaxis and infusion-related reactions&lt;br&gt;• These AEs were observed in multiple trials in which participants received either the authorized doses of BAM</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.&lt;br&gt;• Monitor during IV infusion and for ≥1 hour after administration</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></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>&lt;br&gt;• 1–12 kg: BAM 12 mg/kg plus ETE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Availability:</strong>&lt;br&gt;• 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.&lt;br&gt;• HHS Public Health Emergency updates on the distribution of BAM plus ETE are available.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Dosing Regimens

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

<table>
<thead>
<tr>
<th>Dosing Regimen</th>
<th>Adverse Events</th>
<th>Monitoring Parameters</th>
<th>Drug-Drug Interaction Potential</th>
<th>Comments and Links to Clinical Trials</th>
</tr>
</thead>
</table>
| 24 mg/kg as a single IV infusion  
- >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 | and ETE or higher doses of each drug. | infusion is completed. | | • A list of clinical trials is available: Bamlanivimab Plus Etesevimab |

**Bebtelovimab (Anti-SARS-CoV-2 Monoclonal Antibody)**  
*Authorized for the treatment of COVID-19 under FDA EUA.*

| Dose Recommended in FDA EUA for Treatment of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg: | Nausea  
- Vomiting  
- Pruritis  
- Rash  
- 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. | 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 for a list of high-risk conditions.  
- A list of clinical trials is available: Bebtelovimab |
| BEB 175 mg as an IV injection over at least 30 seconds | | Monitor during IV injection and for ≥1 hour after injection is completed. | | |

**Casirivimab Plus Imdevimab (Anti-SARS-CoV-2 Monoclonal Antibodies)**  
*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 CAS plus IMD.*

| Dose Recommended in FDA EUA for Treatment and PEP of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg: | Hypersensitivity, including anaphylaxis and infusion-related reactions  
- These AEs were observed in multiple trials in which participants received CAS 600 mg plus IMD 600 mg or higher doses of each drug.  
- Injection site reactions, including ecchymosis and erythema, in clinical trial participants who received CAS plus IMD as SUBQ injections | 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 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 |
| CAS 600 mg plus IMD 600 mg as a single IV infusion over 1 hour  
- IV infusion is the preferred route of administration. However, when IV infusion is not feasible or would delay treatment, CAS 600 mg plus IMD 600 mg can be administered as 4 SUBQ injections (2.5 mL per injection) at 4 different sites. See | | Monitor during IV infusion or SUBQ injections and for ≥1 hour after infusion or injections are completed. | | |
<table>
<thead>
<tr>
<th>Dosing Regimens</th>
<th>Adverse Events</th>
<th>Monitoring Parameters</th>
<th>Drug-Drug Interaction Potential</th>
<th>Comments and Links to Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Casirivimab Plus Imdevimab (Anti-SARS-CoV-2 Monoclonal Antibodies), continued</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>the <a href="https://www.covid19treatmentguidelines.nih.gov/">FDA EUA</a> for detailed information.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose Recommended in FDA EUA for PEP for Individuals With Ongoing Exposure to SARS-CoV-2:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sotrovimab (Anti-SARS-CoV-2 Monoclonal Antibody)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose Recommended in FDA EUA for Treatment of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| • SOT 500 mg as an IV infusion over 15 minutes for 50 mL bag or over 30 minutes for 100 mL bag | • Rash | • 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 interactions are unlikely between SOT and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers. | **Availability:**
| | • Diarrhea | • Monitor during IV infusion and for ≥1 hour after infusion is completed. | | • 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. |
| | • Hypersensitivity, including anaphylaxis and infusion-related reactions | | | • [HHS Public Health Emergency updates](https://www.covid19treatmentguidelines.nih.gov/) on the distribution of SOT are available. |
| | | | | • A list of clinical trials is available: [Sotrovimab](https://www.covid19treatmentguidelines.nih.gov/) |
| **Tixagevimab Plus Cilgavimab (Evusheld) (Anti-SARS-CoV-2 Monoclonal Antibodies)** | | | | |
| Authorized for PrEP of COVID-19 under FDA EUA. | • Hypersensitivity, including anaphylaxis and injection-related reactions | | | **Availability:**
| **Doses Recommended in FDA EUA for PrEP of COVID-19 in Adults and Pediatric Patients Aged ≥12 Years and Weighing ≥40 kg:** | • Use with caution in individuals with thrombocytopenia or any coagulation disorder. | | • 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](https://www.covid19treatmentguidelines.nih.gov/) for more information.² | |
| • TIX 300 mg plus CIL 300 mg as 2 consecutive 3 mL IM injections | • If a person has received a COVID-19 vaccine, TIX plus CIL should be administered ≥2 weeks after vaccination. | | | |
| | • In 1 clinical trial, cardiac events were reported in participants with cardiac | • Drug-drug interactions are unlikely between | | |
| | | | | |

[Viewed: 9/5/2022](https://www.covid19treatmentguidelines.nih.gov/)
### Dosing Regimens

<table>
<thead>
<tr>
<th>Tixagevimab Plus Cilgavimab (Evusheld) (Anti-SARS-CoV-2 Monoclonal Antibody), continued</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
</tr>
<tr>
<td>- If the initial dose was ≤3 months ago, the second dose should be TIX 150 mg plus CIL 150 mg.</td>
</tr>
<tr>
<td>- If the initial dose was &gt;3 months ago, the second dose should be TIX 300 mg plus CIL 300 mg.</td>
</tr>
</tbody>
</table>

### Adverse Events

- risk factors (0.6% in TIX plus CIL arm vs. 0.2% in placebo arm). |

### Monitoring Parameters

- TIX plus CIL and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers. |\n
### Drug-Drug Interaction Potential

- A list of clinical trials is available: [Tixagevimab Plus Cilgavimab](https://www.covid19treatmentguidelines.nih.gov/)

### Comments and Links to Clinical Trials

- 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. |
- Drug products should not be added to the IV infusion line for the blood product. |
- The decision to use COVID-19 CP for the treatment of COVID-19 in patients aged <18 years should be based on an individualized assessment of risk and benefit. |
- In patients with impaired cardiac function and heart failure, it may be necessary to reduce the CP volume or decrease the transfusion rate. |
- A list of clinical trials is available: [COVID-19 Convalescent Plasma](https://www.covid19treatmentguidelines.nih.gov/)

### 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. |

**Adverse Events:**

- 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 |

**Monitoring Parameters:**

- 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. |

**Availability:**

- Under the FDA EUA, high-titer COVID-19 CP is available for hospitalized patients with COVID-19. See [Convalescent Plasma](https://www.covid19treatmentguidelines.nih.gov/). |
- A list of clinical trials is available: [COVID-19 Convalescent Plasma](https://www.covid19treatmentguidelines.nih.gov/)
### Dosing Regimens

<table>
<thead>
<tr>
<th>SARS-CoV-2-Specific Immunoglobulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not approved by the FDA and not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.</td>
</tr>
</tbody>
</table>

### Dose in Clinical Trials for Treatment of COVID-19:

- Dose varies by clinical trial.

### Adverse Events

- TRALI
- TACO
- Allergic reactions
- Antibody-mediated enhancement of infection
- RBC alloimmunization
- Transfusion-transmitted infections

### Monitoring Parameters

- Monitor for transfusion-related reactions.
- Monitor vital signs at baseline and during and after transfusion.

### Drug-Drug Interaction Potential

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

### Comments and Links to Clinical Trials

- A list of clinical trials is available: [SARS-CoV-2 Immunoglobulin](https://www.covid19treatmentguidelines.nih.gov/)

### Key:

- AE = adverse event
- BAM = bamlanivimab
- BEB = bebetelovimab
- CAS = casirivimab
- CIL = cilgavimab
- CP = convalescent plasma
- CYP = cytochrome P450
- ETE = etesevimab
- EUA = Emergency Use Authorization
- FDA = Food and Drug Administration
- HHS = U.S. Department of Health and Human Services
- IM = intramuscular
- IMD = imdevimab
- IV = intravenous
- the Panel = the COVID-19 Treatment Guidelines Panel
- PEP = post-exposure prophylaxis
- PrEP = pre-exposure prophylaxis
- RBC = red blood cell
- SOT = sotrovimab
- SUBQ = subcutaneous
- TACO = transfusion-associated circulatory overload
- TIX = tixagevimab
- TRALI = transfusion-related acute lung injury
- VOC = variant of concern

### References