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.

Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Bamlanivimab Plus Etesevimab (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 BAM plus ETE.*				
Dose Recommended in FDA EUA for Treatment and PEP of COVID-19 in Adults and Pediatric Patients Weighing ≥40 kg: • BAM 700 mg plus ETE 1,400 mg as a single IV infusion **Doses Recommended in FDA EUA for Treatment and PEP of COVID-19 in Neonates, Infants, Children, and Adolescents Weighing <40 kg:** • *1–12 kg:* BAM 12 mg/kg plus ETE	• Nausea • Dizziness • Pruritis • Hypersensitivity, including anaphylaxis and infusion-related reactions • These AEs were observed in multiple trials in which participants received either the authorized doses of BAM	• 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	• Drug-drug interactions are unlikely between BAM plus ETE and medications that are renally excreted or that are CYP substrates, inhibitors, or inducers.	**Availability:** • **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. • HHS Public Health Emergency updates on the distribution of BAM plus ETE are available.

Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Bamlanivimab Plus Etesevimab (Anti-SARS-CoV-2 Monoclonal Antibodies), continued				
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: • BEB 175 mg as an IV injection over at least 30 seconds	• 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. • Monitor during IV injection and for ≥1 hour after injection is completed.	• 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.[1] See Anti-SARS-CoV-2 Monoclonal Antibodies for a list of high-risk conditions. • A list of clinical trials is available: Bebtelovimab
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: • 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	• 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. • Monitor during IV infusion or SUBQ injections and for ≥1 hour after infusion or injections are completed.	• 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

Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
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.	**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]

Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
Tixagevimab Plus Cilgavimab (Evusheld) (Anti-SARS-CoV-2 Monoclonal Antibody), continued				
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.	risk factors (0.6% in TIX plus CIL arm vs. 0.2% in placebo arm).		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[3] • 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.	• 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.[4] • In patients with impaired cardiac function and heart failure, it may be necessary to reduce the CP volume or decrease the transfusion rate. **Availability:** • Under the FDA EUA, high-titer COVID-19 CP is available for hospitalized patients with COVID-19.[4] See Convalescent Plasma. • A list of clinical trials is available: COVID-19 Convalescent Plasma

Dosing Regimens	Adverse Events	Monitoring Parameters	Drug-Drug Interaction Potential	Comments and Links to Clinical Trials
SARS-CoV-2-Specific Immunoglobulin *Not approved by the FDA and not recommended by the Panel for the treatment of COVID-19. Currently under investigation in clinical trials.*				
Dose in Clinical Trials for Treatment of COVID-19: • Dose varies by clinical trial.	• TRALI • TACO • Allergic reactions • Antibody-mediated enhancement of infection • RBC alloimmunization • Transfusion-transmitted infections[3]	• 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.	• A list of clinical trials is available: SARS-CoV-2 Immunoglobulin

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

1. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for bebtelovimab. 2022. Available at: https://www.fda.gov/media/156152/download.
2. Food and Drug Administration. Fact sheet for healthcare providers: emergency use authorization for Evusheld (tixagevimab co-packaged with cilgavimab). 2022. Available at: https://www.fda.gov/media/154701/download.
3. Marano G, Vaglio S, Pupella S, et al. Convalescent plasma: new evidence for an old therapeutic tool? *Blood Transfus*. 2016;14(2):152-157. Available at: https://www.ncbi.nlm.nih.gov/pubmed/26674811.
4. Food and Drug Administration. Fact sheet for health care providers: emergency use authorization (EUA) of COVID-19 convalescent plasma for treatment of coronavirus disease 2019 (COVID-19). 2021. Available at: https://www.fda.gov/media/141478/download.