Best Practices for Use of Monoclonal Antibodies to Treat COVID-19 In PALTC
August 31, 2021

Monoclonal Antibody Treatment for Patients with Active COVID-19

For treatment of mild to moderate COVID-19 positive patients 12 years of age and older, with laboratory confirmed COVID-19 (SARS-CoV-2 antigen or nucleic acid amplification test (NAAT)) who do NOT require hospitalization or supplemental oxygen AND who are at high risk for progression to severe COVID-19:

Emergency Use Authorized monoclonal antibodies for treatment:

- **REGEN-COV** 1200 mg (Regeneron): casirivimab 600 mg + imdevimab 600 mg given by IV infusion (**preferred, but not required**) or by 4 subcutaneous injections. No cost, [may be ordered directly from AmerisourceBergen](https://www.amerisourcebergen.com/)
  For more info: [REGEN-COV Healthcare Provider Fact Sheet](https://www.regen-cov.com/fact-sheet)

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- **Sotrovimab**: 500 mg IV infusion x 1 dose
  Commercially available through GlaxoSmithKline: [https://www.sotrovimab.com/](https://www.sotrovimab.com/)
  For more info: [Sotrovimab Healthcare Provider Fact Sheet](https://www.sotrovimab.com/fact-sheet)

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- **Bamlanivimab/etesevimab**: After a temporary pause, the EUA now authorizes the use of bamlanivimab and etesevimab, administered together, **only in states, territories, and U.S. jurisdictions in which recent data shows the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%**. Bamlanivimab/etesevimab are expected to retain activity against the Delta variant (B.1.617.2) and are **not** expected to retain activity against the SARS-CoV-2 P.1/Gamma variant, the B.1.351/Beta variant, the AY.1 and AY.2 variants/Delta[+K417N] (Delta plus), and the B.1.621 variant. [Document outlining changes to EUA](https://www.fda.gov/drugs/information-approved-drug-products-briefing-documents-drug-and-biologics- approvals)

REGEN-COV can be used in asymptomatic, SARS-CoV-2 positive patients.

Vaccination status should **NOT** affect treatment decisions, including the use and timing of monoclonal antibody treatments. However, any further dose of vaccine should be deferred for 90 days after infusion including the booster/additional third dose.

Administration:

- One-time drug administration as soon as possible after positive laboratory test (**no later than 10 days** post symptom onset).
- One-hour patient observation period post-dose completion for an allergic reaction.
• Minimum available emergency supplies in case of allergic reaction: epinephrine, H1 agonist (e.g., diphenhydramine or cetirizine), and BP monitor.

COVID-19 vaccination post monoclonal antibody treatment:

COVID-19 vaccination should be delayed for 90 days after treatment with monoclonal antibodies including booster doses or 3\textsuperscript{rd} dose.

Selected Clinical Data:

Anti-SARS-CoV-2 Monoclonal Antibodies: Selected Clinical Data: https://www.covid19treatmentguidelines.nih.gov/tables/table-3a/

**Monoclonal Antibody Treatment for Post-Exposure Prophylaxis (PEP)**

On July 30, 2021, the Food and Drug Administration (FDA) issued Emergency Use Authorization for the use of the monoclonal antibody combination of casirivimab and imdevimab (REGEN-COV) for post-exposure prophylaxis against COVID-19.

REGEN-COV EUA letter for PEP

Post-exposure prophylaxis is recommended for:

Individuals who are 12 years of age and older and who are at high risk for progression to severe COVID-19, including hospitalization or death, and are:

- Not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) AND
- Have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per CDC OR
- Who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of COVID-19 infection in other individuals in the same institutional setting, such as nursing homes

Under the EUA, “High Risk for progression to severe COVID-19” applies to the majority of those living in PALTC:

- Older age
- Obesity or being overweight
- Chronic kidney disease
- Diabetes
- Immunosuppressive disease or immunosuppressive treatment
- Cardiovascular disease (including congenital heart disease) or hypertension
- Chronic lung disease

The vision of AMDA – The Society for Post-Acute and Long-Term Care Medicine is a world in which all post-acute and long-term care patients and residents receive the highest-quality, compassionate care for optimum health, function, and quality of life.
Post-exposure prophylaxis is **NOT** a substitute for vaccination. If administered, vaccination should be delayed for 90 days.

**Administration:**

- REGEN-COV can be given by IV infusion (600 mg casirivimab + 600 mg imdevimab) OR by 4 subcutaneous injections as soon as possible after exposure. Note that during the research trials for post-exposure prophylaxis, subcutaneous injections were used. There is **NO preference regarding route.**
- Medication should be given “as soon as possible following exposure to SARS-CoV-2”.
- Patient should be observed for one hour after dose administration for allergic reaction.
- Minimum available emergency supplies in case of allergic reaction: epinephrine, H1 agonist (e.g., diphenhydramine or cetirizine), and BP monitor.
- For individuals in whom repeat dosing is determined to be appropriate for ongoing exposure to SARS-CoV-2 for longer than 4 weeks and who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination, then REGEN-COV can be given by IV infusion or subcutaneous injection (no preference) at half the original dose on a monthly basis = REGEN-COV 600 mg

REGEN-COV is **NOT** approved for pre-exposure prophylaxis

**Links to Additional Resources:**

Frequently Asked Questions on EUA of REGEN-COV: [https://www.fda.gov/media/143894/download](https://www.fda.gov/media/143894/download)


The Monoclonal Antibody Project from the Nebraska Antimicrobial Stewardship Assessment and Promotion Program (ASAP): [https://asap.nebraskamed.com/monoclonal-antibody-project/](https://asap.nebraskamed.com/monoclonal-antibody-project/)

Intravenous bamlanivimab use associates with reduced hospitalization in high-risk patients with mild to moderate COVID-19: [https://www.jci.org/articles/view/151697](https://www.jci.org/articles/view/151697)