

**Alabama Department of Public Health (ADPH)  
Alabama Emergency Response Technology (ALERT)  
Health Alert Network (HAN)  
September 8, 2021**

**COVID-19 Update on Availability of Monoclonal Antibody Treatment**

HHS has announced that the monoclonal antibodies for treatment of COVID-19 are temporarily under allocation. Providers should order the amount needed for one week. Orders are limited to sites that have HHS Protect accounts (utilization reporting) and the quantity approved will be aligned with utilization, currently estimated at 70% of orders. Only orders utilizing the [smartsheet link](#) will be recognized. Reporting to HHS via teletracking or the hospital reporting system is a requirement to receive product, and a reporting account must be established before the first order or next order is shipped. Contact HHS via email at [hhs-protect@teletracking.com](mailto:hhs-protect@teletracking.com) to request a new account or request assistance with an existing account.

Three products are available under emergency use authorization (EUA): casirivimab/imdevimab (REGEN-COV), bamlanivimab/etesevimab, and sotrovimab.

HHS and CDC have lifted the pause in using bamlanivimab/etesevimab (Lilly) and have granted an extended shelf life for expired bamlanivimab. There is no longer an EUA for bamlanivimab alone; it **must** be given in combination with etesevimab and can be given only by intravenous administration.

Sotrovimab is authorized under an EUA, has an indication similar to the Lilly and Regeneron Products, and is available for purchase. It also can be given only by intravenous administration. Sotrovimab EUA, Fact Sheet, ordering and reimbursement information: <https://www.sotrovimab.com/>

**Primary Prevention Remains the Best Option**

Prevention of any disease, including COVID-19 disease, is always best when it is an available option. The best way to prevent any infectious illness is to avoid being exposed to it. All of the tools in the toolbox need to be used. We are asking for your help in reminding patients that they have the power to protect themselves and their families by reducing the chance of being exposed and of exposing others. Please remind patients of the following:

- Consider the COVID-19 vaccine. (Pfizer mRNA COVID-19 vaccine, Comirnaty, received full FDA approval on August 23 for persons age 16 years and older and remains EUA authorized for children 12-15 years of age. The Moderna mRNA and Janssen J&J vaccines continue to be FDA EUA authorized for persons age 18 and older.)
- Use face masks when in public, especially indoors
- Maintain a distance of at least 6 feet from others not in your household
- Avoid close contact with people who are sick, even with household members inside their homes
- Clean and disinfect frequently used items and touched surfaces often
- Practice good hand and cough hygiene

Additional information for patients can be found on the ADPH website at <https://www.alabamapublichealth.gov/covid19/prevention.html> and at [How to Protect Yourself and Others](#) from the Centers for Disease Control and Prevention (CDC).

## Patient Criteria for Monoclonal Antibody Treatment for COVID-19

As a result of the notification received from the HHS Federal COVID-19 Response Team, current efforts to expand therapy locations have been placed on hold. HHS has placed monoclonal antibodies for treatment of COVID-19 under temporary allocation. To hopefully assure that monoclonal antibodies are available now and in the future for those patients most at risk, providers are reminded that not everyone qualifies for non-hospitalized patient treatment with monoclonal antibodies. As a result of this temporary allocation, Alabama will receive less than the amounts previously ordered. Healthcare providers are asked to review the criteria and to prioritize patients based on their risk of progression to severe COVID-19 disease.

There are currently three monoclonal antibody products under EUA for the treatment of mild to moderate COVID-19. None of these products are authorized for use in persons who are hospitalized due to COVID-19, who require oxygen therapy due to COVID-19 or who require an increase in baseline oxygen flow rate due to COVID-19 in those on chronic oxygen therapy due to underlying non-COVID-19 related comorbidity or who are less than 12 years old.

Consider monoclonal antibody treatment for individuals who:

- Are high risk\* for developing severe COVID-19 **and**
- Have a positive COVID-19 test and have not yet been admitted to the hospital **and**
- Are 12 years of age or older (and at least 88 pounds)

Consider post-exposure preventive monoclonal antibodies for those who have been exposed (consistent with the CDC's close contact criteria) \*\* **and** who are:

- High risk\* for developing severe COVID-19 **and**
- 12 years of age or older (and at least 88 pounds) **and**
- Not fully vaccinated or vaccinated but immunocompromised or on immunosuppressive treatment

It is important to understand that post-exposure preventive monoclonal antibodies are not a replacement for vaccination. It is highly encouraged that everyone who is eligible to be vaccinated, get a COVID-19 vaccine.

Treatment should be given as soon as possible (within 10 days) after a close contact to a positive case of COVID-19, to patients who tested positive for COVID-19 **and** who are at “high risk” for disease progression to severe COVID-19. **Providers are strongly encouraged to consult with pediatric infectious disease specialists when considering treatment of children and teens.**

\*High risk includes any of the following:

- Immunosuppressive disease or weakened immune system such as rheumatoid arthritis, Lupus, cancer, or HIV
- Currently receiving immunosuppressive treatment
- 65 years of age or older
- Overweight (Adult-body mass index over 25, Child-body mass index greater than the 85<sup>th</sup> percentile for age and gender)
- Pregnancy
- Chronic kidney disease

- Diabetes (Type 1 and Type 2)
- Cardiovascular disease/hypertension
- Chronic lung disease such as asthma, or other chronic respiratory disease requiring daily medications for control
- Sickle cell disease
- Neurodevelopmental disorders such as cerebral palsy
- Medical-related technological dependence (for example: tracheostomy, gastrostomy, or positive pressure ventilation not related to COVID-19)

\*\*Close Contact criteria can be found at <https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/appendix.html#contact>

### Three Monoclonal Treatments Available

#### 1. CASIRIVIMAB/IMDEVIMAB (REGEN-COV)

Dose: 600 mg of casirivimab and 600 mg of imdevimab as a one-time dose.

Approved for intravenous infusion and subcutaneous injection when intravenous administration is not feasible and would lead to delay in treatment.

Minimum infusion times for intravenous administration are 20 to 50 minutes, depending on the size of Sodium Chloride bag used.

When giving by subcutaneous injection, four syringes containing 2.5 ml each should be given at four different injections sites into the thigh, back of upper arm, or abdomen, except for 2 inches around the navel, using different quadrants. The waistline should be avoided.

New and existing providers can order REGEN-COV via the AmerisourceBergen C19 Therapies Direct Order Request at no charge:

<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>

#### 2. BAMLANIVIMAB/ETESEVIMAB

Dose: 700 mg of bamlanivimab and 1,400 mg of etesevimab over 21-60 minutes or longer.

The pause on distribution of bamlanivimab/etesevimab (Lilly product) has been lifted and the product is available to order through AmerisourceBergen. A shelf life extension was announced by the FDA and HHS ASPR on August 20, from 12 months to 18 months for the refrigerated Eli Lilly monoclonal antibody, bamlanivimab, which is currently authorized (PDF, 347 KB) for emergency use only when administered together with etesevimab. This product is only approved for intravenous administration.

#### 3. SOTROVIMAB

Dose: 500 mg by intravenous infusion over 30 minutes

Sotrovimab is available **for purchase** directly from AmerisourceBergen using existing AmerisourceBergen accounts or by calling Customer Service (1-800-746-6273) or emailing [c19therapies@amerisourcebergen.com](mailto:c19therapies@amerisourcebergen.com). More information can be found on the sotrovimab website: <https://www.sotrovimab.com/>

<https://app.smartsheet.com/b/form/255d164d67834793b4ab549e160941e8>