Alabama Department of Public Health (ADPH)
Alabama Emergency Response Technology (ALERT)
Health Alert Network (HAN)
January 25, 2022

FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID 19 Due to the Omicron Variant

Key points:

1. BAM/ETE and Regeneron are not currently authorized for use in the United States due to the prevalence of Omicron.
2. NIH Guidance has updated outpatient therapeutic options, and the guidance lists nonhospital therapeutics in order of preference. Information is included on outpatient use of remdesivir.
3. Therapeutic options for COVID 19 will remain in limited supply, but efforts are underway at the federal level to increase supply of therapeutics.

The following information is being sent to monoclonal antibody providers, ALAHA, MASA, and APA on January 25, 2022:

Dear Provider,

HHS announced yesterday evening that "as a result of the extremely high prevalence of Omicron and recent guidance from FDA and NIH, [they] will not include bamlanivimab plus etesivimab and casirivimab plus imdevimab (REGEN-COV)" in this week's allocations for COVID-19 therapeutics. These "two treatments are **not currently authorized for use anywhere in the U.S**., due to the prevalence of Omicron. The Emergency Use Authorization (EUA) fact sheets for bamlanaivimab plus etesivimab and REGEN-COV have been updated to reflect these changes. For this reason, any orders placed for these two products will not be fulfilled. Please see the full guidance from HHS, including the links to the new FDA and NIH guidelines for treatment of COVID-19, below.

"The prevalence of COVID-19 variants remains dynamic, and the U.S. Department of Health and Human Services (HHS) actively assesses data on a continuous basis to adjust COVID-19 therapeutics allocation guidelines as required.

When we learned of Omicron, we immediately reviewed our existing monoclonals and available data on whether they would work against the new variant, and learned that two of them – bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) – are not effective against Omicron. Subsequently, both Lilly and Regeneron have said their products are not likely to be effective against Omicron, and several independent studies have shown this as well.

CDC data released last week confirms that Omicron is the overwhelmingly dominant variant of concern (VOC) in the United States at a prevalence of greater than 97.8% in all regions and nationally greater than 99%. Private sector data points to Omicron's dominance as well. For example, Walgreens estimates that every state is above 95% Omicron. HHS has also communicated with many state health officials over the past week, who have shared this is the reality they are seeing on the ground as well.

In light of these facts, the FDA today updated the Emergency Use Authorization (EUA) fact sheets for two COVID-19 monoclonal antibody treatments: Lilly's bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV). FDA now says these two treatments are not currently authorized for use anywhere in the U.S., due to the prevalence of Omicron. FDA is encouraging

healthcare providers to choose authorized treatment options with activity against circulating variants in their state, territory, or U.S. jurisdiction. This follows action last week by the National Institutes of Health (NIH) to update its clinical guidelines to recommend against the use of bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) at this time.

As a result of the extremely high prevalence of Omicron and recent guidance from FDA and NIH, ***we will not include bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV) in today's allocations for COVID-19 therapeutics.***

Jurisdictions, providers and patients should be aware that we have more treatments that do work against Omicron available than ever before, including oral and IV antivirals in addition to the GSK/Vir monoclonal antibody (Sotrovimab). Sotrovimab, Evusheld, Paxlovid and Molnupiravir are included in today's allocations; attached are the jurisdiction-by-jurisdiction allocated amounts.

We are committed to making sure that, if Americans get sick with COVID-19, they are offered treatments that work. It is critically important we are giving effective therapies to patients, and HHS will continue to provide effective treatments to states at no cost."

- For information on where to find the oral antivirals, Paxlovid and molnupiravir, and the pre-exposure prophylaxis monoclonal product, Evusheld, visit the HHS COVID-19 Therapeutics Locator Tool at: https://covid-19-therapeutics-locator-dhhs.hub.arcgis.com/.

- If you are interested in becoming a provider for the long acting monoclonal antibody for pre-exposure prophylaxis, Evusheld, please email pharmacy@adph.state.al.us with the following information: Facility name, facility address, facility county, contact name, contact email, contact phone number, and capacity (# of courses requesting, minimum of 24 courses).

For additional information:

https://www.covid19treatmentguidelines.nih.gov/about-the-guidelines/whats-new/

https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/

PDF of New England Journal Article Regarding Remdesivir

https://www.nejm.org/doi/pdf/10.1056/NEJMoa2116846?articleTools=true

FDA Fact Sheets:

Bamlanivimab/etesevimab (Eli Lilly)
https://www.fda.gov/media/145802/download

Casirivimab/imdevimab (REGEN-COV/Regeneron
https://www.fda.gov/media/145611/download

Sotrovimab (Xevudy/GlaxoSmithKline),
https://www.fda.gov/media/149534/download

Nirmatrelvir/ritonavir (Paxlovid/Pfizer)
https://www.fda.gov/media/155050/download

Molnupiravir (Merck)
https://www.fda.gov/media/155054/download

Tixagevimab/cilgavimab (Evushield/AstraZeneca)
https://www.fda.gov/media/154701/download