Dear Stakeholder,

Thank you for your continued partnership in the distribution and administration of COVID-19 monoclonal antibody therapeutics.

As you are likely aware, the recent increase in the prevalence of the Delta variant of COVID-19 has caused a substantial surge in the utilization of monoclonal antibody drugs, particularly in areas of the country with low vaccination rates. It is our goal to ensure continued availability of these drugs for current and future patients. As such, we are immediately implementing the following changes to help promote optimal and equitable use of the available supply of monoclonal antibodies while we continue efforts to procure additional product:

- Limiting immediate orders and shipment only to administration sites with HHSProtect accounts and current utilization reporting
- Reviewing all orders for alignment with utilization, currently estimated at 70% of orders

Please note that this is a temporary change. We will continue to monitor product utilization rates, variant prevalence, and overall availability of monoclonal antibody therapeutics to determine when we will shift back to the normal direct ordering process. In the meantime, your cooperation in this effort will help ensure that, to the extent feasible, current and future patients receive monoclonal antibodies as needed.

Should you have any questions regarding this update in ordering and distribution procedures, please email the Federal COVID-19 Response Team at COVID19therapeutics@hhs.gov. If a site needs to establish an HHSProtect account for weekly utilization reporting, please email hhs-protect@teletracking.com.

Regards,
Federal COVID-19 Response Team

Please note the email below from the Federal COVID-19 Response Team regarding the availability of monoclonal antibody drugs from HHS. HHS has purchased supplies of two monoclonal antibodies for outpatient use = REGEN-COV (Regeneron) and Bam/Ete (Lilly products). Therefore, my assumption is that HHS's email refers to these two medications.

Please note that a third monoclonal antibody drug, Sotrovimab, has not been purchased by HHS and is available on the open market. Sotrovimab (GlaxoSmithKline) has an FDA EUA indication for the treatment of patients with mild to moderate Covid-19 who meet the EUA criteria for its use (i.e. are not hospitalized for Covid-19, do not require supplemental oxygen, are >= 12 years of age, are high-risk for the progression to severe Covid-19, etc.). Sotrovimab does NOT have an indication for Covid-19 post exposure prophylaxis. Therefore, Sotrovimab may be an option for practitioners or facilities who are looking for a mAb indicated for the treatment of outpatients with mild to moderate Covid-19. More information about Sotrovimab can be found

on the FDA website. Information about how to order Sotrovimab can be found on GSK's website.