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Congress of the United States
House of Representatives
Washington, DC 20515-4606

September 13, 2021

The Honorable Xavier Becerra
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

Dear Secretary Becerra,

I write to you today to inquire about the Department of Health and Human Services' (HHS) recent update to COVID-19 monoclonal antibody (mAb) ordering process for all sites.

As you know, antibody treatments such as bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab were approved under Emergency Use Authorizations (EUA) and have been shown to be effective in treating COVID-19 patients.[1,2] Providers across the country, including providers in Texas, have utilized these treatments, aiding in effective treatment of COVID-19 patients.[3] Unfortunately, numerous doctors and healthcare professionals who serve COVID-19 patients are reportedly being denied or limited orders for these treatments by HHS.

According to a notice of changes announced by the Office of the Assistant Secretary for Preparedness and Response (ASPR) on September 3, 2021, HHS immediately implemented changes to "promote optimal and equitable use of the available supply" of these treatments. Further, the notice also indicates HHS is "limiting immediate orders and shipment only to administration sites with HHSProtect accounts and current utilization reporting" and "Reviewing all orders for alignment with utilization, currently estimated at 70% of orders.[4]

These recent changes have appeared to have an immediate effect on the ability to expeditiously care for and treat COVID-19 patients. It is essential that providers have the freedom to choose what treatments are most suitable for their patients without interference or delays caused by your department.

Please provide answers to the following by October 14, 2021:

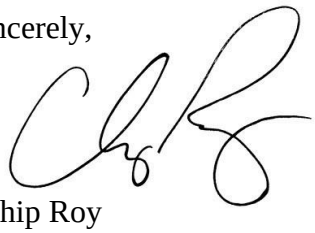
1. For what reasons, and by whom, was this change authorized?
2. Is there a current or expected shortage of any monoclonal antibody treatments in the U.S.?
    a. If so, which treatments?

[1] https://www.fda.gov/media/145801/download
[2] https://www.fda.gov/media/143891/download
[3] https://www.fox4news.com/news/monoclonal-antibodies-can-save-lives-of-sick-covid-19-patients-study-finds
[4] https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Bamlanivimab-etesevimab/Pages/mAb-ordering-update-3Sept2021.aspx

3. Nationally, how many doses of each antibody treatment, including bamlanivimab, bamlanivimab/etesevimab, and casirivimab/imdevimab, are currently available?
4. Your notice indicates this is a temporary change. If this is the case, when does HHS plan to revert to normal procedures for ordering these antibody treatments?
5. Under what regulatory or statutory authority is HHS operating under to limit and review orders or limiting these orders to sites with HHSProtect accounts?
6. Is HHS prioritizing providers with HHSProtect accounts for fulfillment of orders of mAb treatments?
7. Is HHS reviewing all U.S. provider mAb treatment orders?

Thank you for your attention to this important matter.

Sincerely,



Chip Roy
Member of Congress