November 6, 2020

Hon. Alex Azar
Secretary
Department of Health and Human Services
Washington, DC

Dear Secretary Azar,

We are grateful for the Federal government’s rapid actions in developing vaccines and therapeutics in responding to the COVID-19 crisis. In particular, we strongly believe that monoclonal antibody (mAb) therapy holds great promise to save lives and reduce suffering in our nursing home population.

AMDA – The Society for Post-Acute and Long-Term Care Medicine is the only national medical specialty society representing the community of over 50,000 medical directors, physicians, nurse practitioners, physician assistants, and other practitioners working in the various post-acute and long-term care (PALTC) settings. The Society’s 5,500 members work in skilled nursing facilities, long-term care and assisted living communities, CCRCs, home care, hospice, PACE programs, and other settings.

While we are very much in support of giving appropriate nursing home residents access to mAbs, we are writing today to express concerns regarding the allocation of mAbs for COVID-19 to nursing homes and other PALTC settings, which may be approved by the FDA in an Emergency Use Authorization (EUA) in the next weeks.

As we understand it, this therapy would be for outpatients, within three days of a COVID-19 diagnosis, and involves a one-hour infusion with a two-hour post-infusion observation period. Nursing homes are not equipped to provide large-scale infusion therapy, so these services would need to be brought into the facilities.

In addition, we urge you to delay distribution of mAb for non-clinical trial use pending further controlled studies, with sufficient enrollment of the nursing home population to ascertain a magnitude of clinical benefit. We also ask that the Department urgently develop and disseminate national guidance on how the allocation of this therapy is to be prioritized, administered, and paid for.

Specifically, we ask the Department to respond to these key questions:

1. How many doses of mAb will be available, and when do you anticipate scaled distribution to begin? How will access to this therapy be prioritized?
2. Which segment(s) of the patient population have you determined will benefit most from this therapy, and on what basis have you made that determination?
3. How do you intend to address the many logistical challenges of mAb distribution and administration? Specifically, effective administration of mAb requires an IV
infusion with qualified staff that requires up to three hours, targeted to high-risk (as yet undefined), symptomatic, PCR+ individuals within three days of their test. If nursing facilities are being considered as a location to perform these infusions, it will require significant additional staff time for monitoring.

If patients who do not already reside in the nursing home are being considered to receive infusions in the facility, that would involve essentially inviting COVID-19 positive patients at the height of their infectivity into a facility with many frail, vulnerable residents. Also, given that PCR testing turnaround times are still up to three days or more in many parts of the country, prompt identification of suitable candidates for the mAb will be very challenging.

In terms of skilled nursing facilities, as you know, most are doing surveillance testing with point-of-care antigen devices, and many patients with positive results aren’t symptomatic at the time of diagnosis.

4. What expected benefits should recipients of mAb infusions expect? Clinical studies to date seem to indicate a modest benefit in reducing viral load and slight improvement in symptoms. There may also be a reduction in hospitalization rates, which would be a significant benefit if shown to be causally related (https://www.nejm.org/doi/full/10.1056/NEJMoa2029849).

5. How will DHHS address the serious financial/payment issues of mAb distribution and administration in light of the fragmented patchwork of coverage that is the operating reality for the nation’s nursing homes? Although the federal government will likely purchase initial doses of mAbs, states will need to work with providers and payers to ensure that administration costs and copays do not serve as a barrier to access. Without a way to address this challenge, these costs will be unsustainable for nursing homes to carry.

To date, based on current research on mAb therapy, it is not clear that there is a demonstrated benefit for the frail, medically complex population in nursing homes. In addition, using prescribed medication widely in this setting would remove potential subjects from needed clinical studies; without these trials we cannot be sure what the potential risks or harms to our patients might be.

Finally, in any distribution of mAbs to nursing homes, the medical director will need to be engaged to provide physician oversight and careful supervision of the medication administration, to ensure that adverse reactions can be minimized and residents kept safe. Engaging the medical director should be an integral part of any plan to make mAb therapy widely available to nursing homes.

Thank you for your consideration of our concerns. The Society is grateful for the Department’s ongoing response to the COVID-19 crisis and stands ready to continue to assist in those efforts.

Sincerely,

David A. Nace, MD, MPH, CMD
President

Christopher E. Laxton, CAE
Executive Director