



610 10th Street NW, Ste 300
Washington, DC 20001

August 10, 2021

Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8013
Baltimore, MD 21244-8013

Re: National Coverage Determination Analysis for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

The Infusion Providers Alliance (IPA) is pleased to provide comments regarding the Center for Medicare and Medicaid Services (CMS) National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease.

Background on the Infusion Providers Alliance

The IPA has become the leading voice for in-office and freestanding ambulatory infusion providers, with nearly 1,000 community-based, non-hospital sites across 43 states. Our members are committed to preserving the integrity of the provider-patient relationship in a manner that delivers exceptional care to patients and value to the health care system, typically saving Medicare more than 50 cents on the dollar per infusion compared to hospital administration. Our facilities are major access points of care for patients with complex and chronic health conditions, including Alzheimer's disease in communities, large and small. The IPA's mission is to serve as a thought leader and to educate on issues critical to safeguarding, supporting, and strengthening provider-directed, patient-focused access to infused medications. More information about IPA can be found on our website:

www.infusionprovidersalliance.org.

Addressing CMS's NCD Questions

We wish to comment specifically on Question 5: In what setting should treatments of care be given?

IPA members are focused primarily on providing the highest-quality care at the lowest total cost for patients suffering from complex chronic conditions and requiring infusion or injection therapy. It is important to note, however, that members of the IPA do not directly diagnose, develop treatment plans or write orders; rather, as infusion providers, our role is to ensure a patient receives their medication in a clinically safe, reliable and efficient manner once a treatment plan has been developed by a patient's specialist.

As such, IPA will focus its comments on the appropriateness of the clinic-based setting of care should a qualified specialist order such medication for his/her patient. In that context, IPA believes its setting of care offers the optimal mix of cost, quality and access for Medicare beneficiaries.

From a cost standpoint, Medicare pays hospitals substantially more for infusions of identical drugs using identical staff time and skills as physician offices and freestanding ambulatory infusion centers, all of which are paid on the Physician Fee Schedule. Based on the relative complexity of the infusion, we would expect to bill Medicare CPT Code 96413 or 96365 to infuse Aduhelm and other complex medications. Our in-office and ambulatory infusion centers are paid approximately 45 percent of the hospital rate: \$309.56 vs \$142.55 for 96413 and provide a similar level of savings to Medicare for CPT code 96365.

Similarly, we do believe patient access and health equity will be critical issues in the context of any new Alzheimer's treatment. With that in mind, we believe that it is critical that Alzheimer's treatments not be restricted to large academic centers given their existing capacity issues and relatively limited geographic footprint. Moreover, the lack of adequate coverage in rural areas and the capacity limitations to accommodate urban and minority patients in need of treatment has the potential to meaningfully impact beneficiaries' ability to access appropriate care.

A recent Rand Corporation report modeled three potential infrastructure capacity constraints with respect to Alzheimer's patients: availability of dementia specialists, access to amyloid detection testing, and access to infusion centers for treatment. It found that current trends in these infrastructure constraints could delay treatment for more than 18 months for patients in need.¹ Our focus is ensuring that the "right" patients, once identified and properly diagnosed, have access to the infusions they are prescribed.

The IPA looks forward to working with CMS and other stakeholders to ensure the right patient gets the right treatment for his or her medical condition. Please contact John McManus, President of The McManus Group at jmcmanus@mcmanusgrp.com should you have any questions or require additional information on this matter.

Sincerely,



Doug Ghertner
President Infusion Providers Alliance

¹ Liu Jodi, et al. "Assessing the preparedness of the U.S. health care system infrastructure for an Alzheimer's treatment". *RAND Corporation*, 2017. https://www.rand.org/pubs/research_reports/RR2272.html