The National Home Infusion Association (NHIA) appreciates the opportunity to provide feedback on the proposed National Coverage Analysis (NCA) decision memorandum, "Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease" (CAG-00460N), issued by the Centers for Medicare & Medicaid Services (CMS) on January 11, 2022.[1] NHIA is a trade association that represents companies that provide infusion therapy to patients in their homes, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and alternate site infusion community, we write to share our comments regarding the proposed decision.

NHIA is concerned that in order to gain access to monoclonal antibodies directed against amyloid for the treatment of Alzheimer's Disease, patients would have to participate in a CMS-approved or NIH-supported clinical trial exclusively offered in a hospital outpatient setting. NHIA believes this requirement to limit infusions to hospital settings is unnecessary and inconsistent with the inclusivity goals of CMS. If CMS intends to ensure the diversity and representativeness of populations in Coverage with Evidence Development (CED trials), then the agency should remove this requirement and allow infusions in a wide range of settings, including the home. Limiting the site of care for conducting such trials disenfranchises patients who do not live near a study facility, are not physically able to travel, or simply could not otherwise participate due to situational constraints. During the COVID-19 pandemic, many companies, including those studying monoclonal antibodies for the treatment of Alzheimer's Disease, successfully modified their clinical trial protocols to include administration of study drugs in the home setting. Collecting real-world data from settings other than the hospital outpatient centers reduces enrollment barriers and contributes valuable insights that improve the final product. NHIA strongly urges CMS to reconsider this requirement if the CED is finalized.

If CMS does not move forward with the CED process, NHIA reiterates its previous recommendations for ensuring that monoclonal antibodies for the treatment of Alzheimer's disease are accessible to Medicare beneficiaries in the home. NHIA encourages CMS to ensure that all eligible patients have the option to receive infusions in the home setting. Currently, Medicare only offers coverage of home-based drug administration services for a limited subset of drugs – about 30 medications that require an external infusion pump to administer. These limited services are covered under the Medicare Part B DMEPOS benefit. For drugs that do not require a pump for administration – such as monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease – there is no Medicare coverage for home administration of the drugs. As a result, Medicare beneficiaries will be forced to travel to a treatment center or pay out of pocket to receive these services in the home. Vulnerable beneficiaries who cannot access a treatment center and cannot afford to pay out of pocket for home administration will not have access to these drugs.

To address this access issue, NHIA recommends that Medicare beneficiaries have coverage of home infusion services and supplies regardless of whether the drug they need requires an external infusion pump to administer. We propose that home infusion therapy services providers would be allowed to bill a bundled payment to Medicare Part B for services, supplies and

[1] https://www.cms.gov/medicare-coverage-database/view/ncacal-decision-memo.aspx?proposed=Y&NCAId=305

equipment and bill separately to Medicare Part D for drugs used in the home setting. This model is consistent with reimbursement in Medicare Advantage programs and has been overwhelmingly effective at lowering overall costs of care for patients and health plans. A similar approach was recently used to successfully establish coverage for home infusion for COVID-19 monoclonal antibody treatments. As a result, most eligible home infusion providers enrolled with Medicare supported the pandemic response by offering these important treatments to patients at home. NHIA believes a similar model could be implemented to cover treatments for Alzheimer's Disease and other conditions as a demonstration project through the Center for Medicare and Medicaid Innovation (CMMI).

NHIA appreciates the opportunity to provide these comments. If you have questions or need additional information, please contact me at connie.sullivan@nhia.org.

Sincerely,

Connie Sullivan, B.S. Pharm
President and Chief Executive Officer
National Home Infusion Association