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February 7th, 2022

Chiquita Brooks-LaSure, Administrator
Center for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Comments on National Coverage Determination for monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease

Dear Administrator Brooks-LaSure:

Thank you for the opportunity to submit comments on the National Coverage Determination (NCD) for monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease. The Global Healthy Living Foundation (GHLF) writes to express our concern with the Coverage of Evidence Development (CED) included in the NCD. We have concerns with some of the specifics in the NCD and the precedent that the CED would set for other classes of medications.

By way of background, GHLF is a 501(c)(3) non-profit patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events, and our online support and education. GHLF works to improve the quality of life for patients living with chronic disease by making sure their voices are heard and advocating for improved access to care at the community level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, and migraine. These patients incur significant financial burdens due to the high cost of the necessary treatments to manage their condition.

Given the potential beneficial impact of the new class of medications being approved for Alzheimer's, GHLF was initially very encouraged to see an NCD issued to ensure their coverage as they come to market. These medications offer Alzheimer's patients a new hope of possibly delaying or preventing the worst parts of their disease. However, GHLF is concerned with the CED that accompanied the NCD, which sought the clinical benefit of removing Amyloid from the brain. While we do not have an issue with the question itself, we have concerns about the processes manufacturers must go through, or in the case of treatments already in Phase 3 trials, restart to answer the CED. Many of the medications in this new class have been approved by the FDA through the accelerated approval pathway. As such, large-scale, fully enrolled, fully funded Phase 3 trials have already begun so that manufacturers can continue to study the impact of these medications over a longer period. These trials are expected to lead to initial confirmatory data in 2023 and 2024, which should answer the question posed by the CED. Unfortunately, the CED

was unclear whether these trials would be accepted under the current conditions. If they are not, manufacturers will need to fully restart their trials under the new requirements, further delaying market entry of these medications and ultimately harming patients by delaying their access to these new medications.

Additionally, outside of the exact language of the CED, GHLF is worried about the precedent that this would set for medications that have been approved through the accelerated approval pathway. This issue impacts patients in multiple different patient communities that rely on medications that frequently take years to evaluate fully. If these medications are now subjected to further rigorous studies beyond those already underway and heavily scrutinized, it defeats the purpose of approving these medications in such a manner. By approving medications through accelerated approval, FDA is acknowledging that they are safe and effective, and there is a benefit to patients having access to them immediately. By adding these overly complicated and time-consuming processes to the NCD, CMS effectively negates the impact of approving the medication through an accelerated pathway.

In the final version of the NCD, GHLF hopes to see a few changes made. Our primary ask is to remove the CED from the NCD. However, if the CED must remain, we would like to see it clarified to ensure that results from currently enrolled Phase 3 trials will be accepted should they show sufficient confirmatory data that answers the clinical question in the CED. The goal of accelerated approval is to get these medications onto the market faster, and the NCD should not be a barrier to that. We hope the NCD clarifies that patients can receive these medications outside of a hospital setting. Many patients in rural areas do not live near a hospital. Allowing them to receive their care from a local provider or infusion center will increase their likelihood of treatment adherence.

Thank you for your consideration and please contact us if further information is needed.

Sincerely,



Steven Newmark
Director of Policy
Global Healthy Living Foundation

