June 5, 2023

The Honorable Chiquita Brooks-LaSure,
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Administrator Brooks-LaSure,

Thank you for your testimony before the Energy and Commerce Health Subcommittee on April 26, 2023. During the hearing, multiple bipartisan Members of Congress urged you to provide Medicare coverage to Alzheimer’s treatments approved by the Food and Drug Administration (FDA).

On or before July 6, 2023, it is anticipated that the FDA will approve lecanemab through the traditional approval pathway based on confirmation of clinical benefit. During your testimony before the Health Subcommittee, you stated “when FDA approves the drug [lecanemab], whichever populations they say it is appropriate for, that will be the basis of which people will get the drug.” You also agreed to a statement from Rep. Nanette Barragán (D-CA) that “all patients indicated for the drug lecanemab and any future therapies in the class will have coverage upon full approval.”

On June 1, 2023, Medicare announced that it will cover drugs with traditional FDA approval when a physician and clinical team participates in the collection of evidence about how these drugs work in the real world, also known as a registry. Clinicians will be able to submit this evidence through a nationwide, CMS-facilitated portal that will be available when any product gains traditional approval and will collect information via an easy-to-use format.

Despite these affirmative statements, the ability for beneficiaries to access the drug as soon as July 6, 2023 is still very unclear. In the June 1st press release, CMS published no details about the required registry and failed to answer basic questions such as:

- When will the national registry be live and accessible to doctors and patients?
- What data must be collected through the registry?
- How do doctors participate in the registry to provide the data required?
- How do patients find the doctors who are participating in the registry so that they are able to access the drug?
- How is CMS working to reduce the amount of burden or cost on doctors who participate in the registry?
- Will doctors be able to participate in the registry via their existing electronic health record systems?
- Will CMS be able to use already-provided claims data to fulfill the registry requirement?
- How will the data collected by the registry differ from the FDA’s existing postmarket safety assessment tools?
- How is CMS ensuring that patients in rural or underserved areas can access providers who participate in the registry?
- How is CMS ensuring that the registry does not increase disparities in access to treatment for Black, Hispanic, or Native American populations?
- What is CMS doing to ensure patients indicated for the drug based on the label will have coverage for and access to lecanemab on July 6th assuming it receives FDA traditional approval?
In order to fulfill your promise of broad coverage once the FDA approves an Alzheimer’s treatment through the traditional pathway, we encourage you to either reconsider the coverage with evidence requirements for the Alzheimer’s treatments or to immediately begin preparing for a registry that is clearly defined and minimizes provider and patient burden. At minimum, Congress, doctors, and patients deserve to have the answers to the above questions immediately.

There needs to be clarity and transparency about the standards for coverage for FDA-approved treatments for deadly diseases with unmet medical needs. Please do not allow CMS’s demand for additional evidence generation be a barrier to patient care.

Sincerely,

Anna G. Eshoo
Member of Congress

Nanette Diaz Barragan
Member of Congress