Sue Wronsky QFR Responses 07/18/23 Hearing

The Honorable Greg Pence

Ms. Wronsky,

In Indiana, there are 110 thousand people aged 65 and older suffering from Alzheimer's, and 2,238 Hoosiers have tragically lost their lives to this terrible disease in 2021, according to the CDC. It is important CMS incentivize research and development by being transparent with the methodology and process used to determine coverage of drugs. I recently joined my colleagues in the Indiana delegation on a letter to the Biden Administration urging them to provide access to FDA-approved Alzheimer's therapeutics. While Medicare has traditionally covered all FDA approved drugs, CMS has now set up a registry portal that could create logistical challenges for patients and caregivers as well as providers in rural areas.

1) Can you explain why opening a National Coverage Determination reconsideration is important to patients, particularly those in rural communities?

On July 6, 2023, the Centers for Medicare and Medicaid Services announced it will extend the coverage of Alzheimer's treatment drugs that have been granted traditional approval by the Food and Drug Administration to physicians enrolled in a registry. I appreciate that CMS did its due diligence to make the registry enrollment process as streamlined and straightforward as possible for physicians. However, tying any conditions to accessing these life-changing drugs shows CMS is not fully committed to reconsidering the National Coverage Determination and granting unconditional coverage. This should not still be the case, considering the strong evidence supporting this class of drugs released since the January 2023 accelerated approval and subsequent July 2023 traditional approval of Leqembi. Individuals living with Alzheimer's and their caregivers, particularly in rural and underserved communities with limited access to care, need full confidence that they will be able to access these drugs by all clinicians - not just those enrolled in registries. I have firsthand experience that the millions of families facing this devastating disease already spend extensive time worrying about the future: the last thing they need is to live in uncertainty of whether they or their loved ones will be able to continue receiving treatment.

The Honorable Dan Crenshaw

1) To your knowledge, *before* restricting Medicare coverage of FDA-approved therapies and devices to participants in clinical trials and studies does, does CMS do any analysis of the potential impacts on access to rural or other underserved populations? If so, is that information publicly available?

Not to my knowledge.

2) How will CMS's decision to require beneficiaries to enroll in a clinical study in order to have

Medicare coverage affect people's access to FDA-approved therapies shown to delay Alzheimer's progression? What barriers to people with Alzheimer's disease and their families face in terms of getting to the point of even qualifying for treatment, including challenges with identifying a health issue, seeking diagnosis, finding a provider, and the like?

Alzheimer's can begin 20 years or more before memory loss and other symptoms develop. In turn, receiving a formal diagnosis early in the disease progression enables the best medical care and health outcomes for the 6.7 million Americans living with the disease. In fact, according to the Centers for Disease Control and Prevention, of those who have been diagnosed with Alzheimer's or another dementia, only 35 percent of them or their caregivers are aware of the diagnosis. In contrast, more than 90 percent of seniors with cancer or cardiovascular disease have been told their diagnosis. In my family's case, my mother was diagnosed with early-onset Alzheimer's at age 63 and lived with the disease for 11 years until her untimely death in 2002. With an early diagnosis, her care team - which primarily consisted of our family - could better manage co-occurring conditions, reduce the risk of injuries, and create advanced directives for her care and finances. This significantly enhanced her quality of life living with the disease, as well as our own as her caregivers.

When my mom was first diagnosed over 30 years ago, there were no options for people living with Alzheimer's. With two FDA-approved treatments and potentially a third later this year, early detection and diagnosis, such as using cognitive assessment tools or discussing memory issues in annual wellness visits, can ensure individuals and their caregivers will be able to receive treatment soon as possible, and while they are still eligible. Meanwhile, these drugs are only covered under Medicare if a physician is enrolled in a registry. I appreciate that CMS did its due diligence to make the registry enrollment process as streamlined and straightforward as possible for physicians. However, tying any conditions to accessing these life-changing drugs shows CMS is not fully committed to reconsidering the April 2022 National Coverage Determination and granting unconditional coverage. This should not still be the case, considering the strong evidence supporting this class of drugs released since the January 2023 accelerated approval and subsequent July 2023 traditional approval of Leqembi. The full benefits of these treatments will only be realized if patients, like many friends and loved ones of mine, have unconditional access.