Voices of Alzheimer's

VoA Oral Comments - MEDCAC panel on CMS coverage under CED

My name is Jim Taylor, and I am the President and CEO of Voices of Alzheimer's. The mission of VoA is to empower people living with or at risk of Alzheimer's and other cognitive illnesses to drive equitable access to innovative treatment and care.

This is my wife Geri who was diagnosed with Alzheimer's over 10 years ago. Geri participated in the aducanumab clinical trial for seven years.

According to CMS, we are here today to focus on proposed revisions to Medicare's coverage with evidence development study criteria. This meeting was advised not to review CMS' track record with CED or to examine its severe limits on specific treatments for beneficiaries. My question is—why not?

In my professional life, I worked for more than 30 years in IBM finance. We continually scrutinized what was and was not working for our client. We set specific development and financial goals and evaluated results against those goals.

Of course, a big difference between Medicare and IBM is that IBM is a private corporation with shareholders, where profit margins drive innovation. Medicare is a public insurance program for older adults and people with disabilities. We, the American people, are its shareholders, participating in a social contract, paying into the program our entire working lives with the assurance that it will be available to us when we need it.

So, like at IBM, I look at the track record of CED as a key component of today's very important conversation. That record is abysmal. Instead of a timely process that provides supplementary data to help inform care decisions, half of today's CEDs have dragged on for more than a decade. In many cases. fewer than a hundred patients have gotten access to treatment. In others, the number of participants is in the thousands, but the vast majority of those eligible for treatment have been denied access. In cases where the gathered evidence is evaluated to determine whether the CED should be terminated, the goalposts have frequently been moved. Please provide me evidence for all of this. Individual situations are okay, but what are the statistics?

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To place my comments about the proposed CED revision in the context of our lived Alzheimer's experience, I want to briefly address two CEDs in place today that are completely blocking access to two FDA-approved treatments for Alzheimer's

The first CED restricts Medicare beneficiary access to amyloid PET scans, essential for validating, or ruling out, an Alzheimer's diagnosis. Timely and equitable access to these scans will become even more critical for Medicare beneficiaries with the recent FDA approval of the disease modifying therapy Leqembi. But, for nearly a decade, CMS has used CED to limit PET scan access and reduce costs for Medicare. Medicare claims that there is coverage for PET scans because they cover one PET scan for participants in the one CMS-approved clinical trial currently recruiting participant. The agency is fully aware that its strict conditions of coverage have disproportionately restricted PET scan access to people of color. Despite this, they outrageously exploited the study's "lack of diversity" as one of the bogus reasons to require a second study.

The second egregious CED is for FDA-approved monoclonal antibody medications for early Alzheimer's, now being used to deny access to the recently approved Alzheimer's disease modifying treatment Leqembi. We in the Alzheimer's community have waited decades for this drug and now CMS will deny coverage to the vast majority of patients for whom the drug was approved. Additionally, this decision was the first time CMS used CED for an FDA-approved drug for its on-label use. That opens the door to apply CED to future Part B drugs for cancer, infectious disease, and new gene therapies for rare diseases. Every one of us should be concerned about this alarming precedent.

So, let's shoot straight with each other today. Making CED study criteria "more rigorous" is also a way of making the studies last longer and be even more inaccessible for the vast majority of patients whom the FDA has deemed eligible for treatment. The ambiguous language used in several of the proposed CED study criteria will give CMS more power permanently prevent access. For instance:

- The CED clinician studies will have to "reflect the demographic and clinical diversity among the Medicare beneficiaries" who are the intended users of the intervention, which will include "attention to the intended users' racial and ethnic backgrounds, gender, and socio-economic status." First, we completely support policies to improve diversity in clinical research. However, this level of information on subpopulations is required for no other drugs or devices that are covered by the Medicare program. So, tell me again that CMS

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is not discriminating against people with Alzheimer's. Second: Let's acknowledge that CED renders the medication completely inaccessible to the great majority of individuals for whom the FDA approved it. It is particularly inaccessible to underserved communities. Once again, this allows CMS to leverage equity concerns as a reason to deny care. This is especially egregious for Alzheimer's, given that Black Americans are approximately two times more likely, and Hispanic Americans are 1.5 times more likely to develop the disease than non-Hispanic white people.

Our nation's Medicare program shouldn't succumb to the pessimistic view that healthcare is a zero-sum game. As advisors to Medicare, you are too smart, creative, and resourceful to fall back on CMS' lazy reasoning that CED clinical studies are anything more than utilization management tools. improve our understanding have to do with collecting evidence. for years on end. The only solution that will support more equitable, broader access to innovative new medical care for individuals with Alzheimer's, is to do away with the CED process altogether.

Thank you.