



VOICES FROM THE FIELD: PROBLEMS PERSIST FOR ALZHEIMER'S PATIENTS

CMS's National Coverage Determination with **Coverage with Evidence Development (CED)** requirement for new, FDA-approved Alzheimer's treatments puts us steps back in the fight against this disease and sets a concerning precedent for access to new treatments for other costly chronic conditions. With its CED requiring patients to participate in a registry for further data collection to obtain coverage, CMS is severely limiting access to treatments... with no clear end in sight. For a progressive and irreversible disease like Alzheimer's this not only undercuts the benefits of new treatments for patients, providers, and caregivers, but also significantly diminishes the value of innovations that could meet broad unmet need.

Coverage for and access to FDA-approved treatments for Alzheimer's disease should not be conditioned on participating in a clinical study or registry. Patients, caregivers, providers, advocates, and others continue to voice concerns about the access delays and resulting impact on people with Alzheimer's and their families:

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... the CMS registry is an unfunded mandate...It requires time and effort by someone, a provider or other clinical staff member, to enter the data into the registry, but there is no payment for that effort. ALZ-NET, on the other hand, will provide some funding for the people who will enter the data.¹

DUKE-UNC ALZHEIMER'S DISEASE RESEARCH CENTER CO-DIRECTOR DR. GWENN GARDEN

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Never before has CMS applied CED to an on-label use of FDA-approved medications. There are strong signals that this won't be the last time... a report on CED... found that Medicare beneficiaries of color and those living in rural areas are more likely to be denied access under CEDs because the rigid conditions of coverage primarily direct care to urban medical centers in wealthier areas.²

**ALLIANCE FOR AGING
RESEARCH PRESIDENT AND
CEO SUE PESCHIN**

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While these CED requirements remain in place, patients and providers face increased burden to obtain coverage, potentially limiting patients' access to life-saving treatments... This undue burden placed on patients disproportionately affects rural, lower-income, and lower-resourced communities, leading to widening gaps in healthcare disparity and delayed initiation to appropriate treatment for many patients.³

CENCORA WHITE PAPER

VICTORIA LOO, AUTHOR OF CENCORA PAPER, “really examine the CED policy and what its intent is – they must provide more guidance on what it actually takes for these products and services to graduate from that program, how long will data collection be needed, and at what point is enough data sufficient.”⁴



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One of the biggest challenges is that practitioners don't necessarily want to engage in the lengthy process...because reimbursement for that time has not been good compared to other diseases.⁵

MEDSTAR HEALTH NEUROLOGIST DR. SAURABH SHARMA

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Disparities are locked in place as long as access to breakthrough treatments is limited to those in approved clinical trials or those who are willing and able to pay out-of-pocket... If policymakers at CMS are to live up to their rhetoric about eliminating health disparities and achieving health equity, they must ensure access to approved treatments.⁶

CAREGIVER ACTION NETWORK CEO MARVELL ADAMS JR.

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If we had the capacity, I could easily have 200 patients on treatment now. One of the greatest hurdles has been finding infusion centers...We are sending patients to Milwaukee, northern Wisconsin, Michigan, and Illinois. This is a lot to manage, and the registry is just one more thing.⁷

UNIVERSITY OF WISCONSIN SCHOOL OF MEDICINE AND PUBLIC HEALTH PROFESSOR OF MEDICINE AND PSYCHIATRY, AND DIRECTOR OF GERIATRICS MEMORY CLINICS DR. ROBERT PRZYBELSKI

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While this registry may not be cumbersome in and of itself, if somebody is in a standalone neurology practice this might be quite a burden for them on top of all of the other pieces required. To get someone from the point of a probable Alzheimer's diagnosis to sitting in the infusion chair to receive this treatment, it is many steps. Even though we at Dent have everything all under one roof it's a process that took up two pages when I wrote it out step by step.⁸

DENT NEUROLOGICAL INSTITUTE'S INTEGRATIVE CENTER FOR MEMORY PROGRAM DIRECTOR SARAH HARLOCK

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The biggest problem with a registry is the ability to access timely care. By the time a patient has enrolled in a registry, the disease has often progressed from mild to moderate and is out of the range of treatability...

Registries compromise treatment.”⁹

PENNSYLVANIA PRIMARY CARE PHYSICIAN DR. DARLENE DUNAY

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It should go without saying that the data needs to be usable, and if you have a lot of separate silos with data that is collected slightly differently or is duplicating information, the data that you're going to have is going to be poor quality, and it seems like it defeats the purpose of why there should be a registry in the first place.¹⁰

MESULAM CENTER FOR COGNITIVE NEUROLOGY AND ALZHEIMER'S DISEASE DIRECTOR OF CLINICAL TRIALS OPERATIONS DR. IAN MICHAEL GRANT

We urge CMS to do what it promised: open reconsideration and remove CED in light of the current, compelling body of evidence and ensure that more patients who stand to benefit from FDA-approved treatments can access them in time to realize their value.

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^{1,7,10} https://journals.lww.com/neurotodayonline/fulltext/2024/01180/alzheimer_monoclonal_antibody_registries_how_will.1.aspx

² https://www.realclearhealth.com/blog/2024/01/09/should_federal_funding_for_medical_research_be_used_to_ration_access_to_alzheimers_drugs_1003657.html

³ <https://www.amerisourcebergen.com/insights/manufacturers/Cost-and-Resource-Burden-of-Coverage-With-Evidence-Development>

^{4,5,8} <https://www.fightchronicdisease.org/blog/pfcd-and-caregiver-action-network-host-critical-discussion-current-state-alzheimer%E2%80%99s-care>

⁶ <https://dcjournal.com/alzheimers-discrimination-continues-in-more-ways-than-one>

⁹ <https://healthpolicytoday.org/2024/01/31/when-medicare-registries-block-patient-access>