J Prev Alz Dis 2023;3(10):346-348
Published online June 13, 2023, http://dx.doi.org/10.14283/jpad.2023.75

Viewpoint

Defining FDA Approved Treatments as Reasonable and Necessary: Perspectives of Individuals Living with Alzheimer's Disease and Care Partners

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In its decision to deny coverage of FDA-approved treatments for people living with Alzheimer's, CMS stated that «to provide coverage nationally, CMS is required to examine whether a medication is reasonable and necessary.» CMS policy defines reasonable and necessary as treatments and services that are: (1) safe and effective, (2) not experimental or investigational, and (3) appropriate for Medicare patients, including duration and frequency that is considered appropriate for the item or service.

The Alzheimer's Association's National Early-Stage Advisory Group (ESAG) is composed of individuals from across the country who are living with early-stage Alzheimer's or other dementias, or mild cognitive impairment (MCI) (hereafter, "Advisors"). The mission of the ESAG is to:

- Reduce stigma by offering their unique perspectives and experiences related to living with the disease,
- Help raise concern and awareness of Alzheimer's disease,
- Advocate for more funding for research, and
- Provide invaluable input on the development of programs and support services designed for people living with the disease.

The Association held one hour virtual calls with Advisors and their care partners. The purpose of the calls was to gain their perspective on whether the current class of treatments -- monoclonal antibodies directed against beta amyloid -- are reasonable and necessary for individuals living with mild Alzheimer's disease or MCI due to Alzheimer's disease, and the importance of access to treatment. This document summarizes these conversations, representing the perspectives of individuals living with dementia and their care partners.

"These treatments aren't only reasonable and necessary, they are life-affirming and every Alzheimer's patient's right as Americans."

Doug H., Care Partner

Defining what is reasonable and necessary

CMS' policy defining whether a medication is reasonable or necessary was shared with the Advisors and their care partners. They were then asked if they thought the current class of FDA-approved treatments met CMS's definition of reasonable and necessary for individuals with early stage Alzheimer's.

Respondents overwhelmingly agreed that the FDA-approved treatments for Alzheimer's disease met CMS' definition of reasonable and necessary. They referenced results from the clinical trials as well as the FDA's rigorous review and approval process as evidence that this class of treatment met all three of the CMS requirements.

They were also asked for their personal perspective on whether the current FDA-approved treatments are reasonable and necessary for individuals living with early Alzheimer's. One care partner stated, "As I sit by and watch the progression along the path that leads nowhere good, I think about the reality of our situation: the diagnosis with a terminal illness that will strip away my spouse's ability to be my spouse. I'm expected to accept bureaucratic denial, which ultimately could mean access to medications that can prolong a good quality of life with my husband, and then I need to justify what is reasonable and necessary in order to preserve a quality of life for us both."

An Advisor asked "Is it reasonable to extend our lives, continue to function independently, and spend quality time with family? Absolutely! Is it necessary? Absolutely! Consider that Alzheimer's destroys a person's ability to contribute to society. We should be able to live and enjoy life like any other person living with a chronic disease."

A few of the Advisors and care partners considered how reasonable and necessary these FDA-approved treatments would be for those now living in the early stage of the disease. One Advisor stated, "thousands of people, not statistics, will move from mild cognitive impairment to moderate cognitive impairment each year. Meaning every year these individuals will be doomed to die from Alzheimer's when an approved drug could have slowed its progression."

Received May 9, 2023
Accepted for publication May 12, 2023

"I find CMS's decision to be random and arbitrary, when they cover drugs that provide less to others who are in far worse situations that will never change the inevitable."

Tim W., Care Partner

Reflection on CMS' coverage decision

Advisors and care partners were asked about CMS' decision to deny access to FDA-approved treatments for people living with early Alzheimer's disease. All Advisors and care partners said they felt discriminated against by CMS' decision. All felt discriminated against because CMS has never denied coverage for any other FDA-approved treatments including those approved for heart disease, cancer and arthritis. One Advisor felt this discrimination against Alzheimer's patients would severely impact diverse and underserved people, including those living in rural communities and commented "It is unjust and discriminatory. Why is CMS doing this to Alzheimer's patients and not others?"

Many felt strongly that Alzheimer's disease should be recognized and treated as a chronic disease. As with other chronic diseases such as heart disease or incurable conditions like certain forms of cancer, doctors should be allowed to treat Alzheimer's with FDA-approved treatments.

Some Advisors felt CMS' decision had given them a death sentence. One Advisor described it as "a long and horrible death" and asked "Who are they to play God this way?" One care partner commented, "CMS' decision not to cover an FDA-approved drug is unprecedented as this class of treatments are the only FDA-approved drugs that CMS does not cover. It is not rational to withhold treatment from Alzheimer's patients." Others felt CMS was overstepping its intended role. As one care partner described, "It's FDA's role to ensure treatments are safe and effective. There have now been two drugs that have been approved by the FDA based on rigorous clinical trials. CMS is the payment piece: administer insurance, don't play doctor."

"We have finally found something after decades of failure, and to single out Alzheimer's as the only disease where (CMS) has done this. This was supposed to be the easy part. We should be celebrating, and instead we are fighting for our lives."

Phil G., Living with Alzheimer's disease

Importance of access to FDA approved treatments

Advisors and care partners were asked about the importance of access to FDA-approved treatments by people living with the disease. All vehemently agreed that access to FDA- approved treatments was not only necessary, but a matter of life and death. An Advisor stated, "Every single day that these drugs go without coverage, thousands of people living with early Alzheimer's transition to a more advanced stage of the disease where the new treatments will not help them – they will have missed their window of treatment opportunity. Through no fault of their own, but through the fault of CMS, these individuals face a life of cognitive decline, and eventual death."

All felt that it was imperative that people living with Alzheimer's disease be given affordable access to medications that are scientifically proven to slow disease progression and clinical decline and provide the opportunity to give patients more time to live a high-quality life. All agreed that the decision to receive treatment should be left to the patient and their doctor. One Advisor stated, "Let it be my decision, (CMS) stay out of my treatment room." Another Advisor commented, "How many people are beginning to talk to their doctor about symptoms that should be getting access to treatment before it gets worse? We need to get treatments before it gets worse!"

Many also noted that there appears to be no consideration given to the emotional, physical and financial burden a denial of coverage places on the patient, caregiver and society as a whole. Many felt access to treatments that can slow cognitive decline can help to delay or reduce this burden. As one care partner commented, "Even in its mildest form of the disease, caregiving can get burdensome. However, there is no thought or consideration given to this."

Closing

In closing, Advisors and their care partners felt that monoclonal antibodies against beta amyloid met CMS's definition of reasonable and necessary for people with early Alzheimer's disease. They felt the results of the clinical studies and the FDA's rigorous review and approval of the treatments met CMS' definition of reasonable and necessary. When asked their personal perspective on whether this class of treatments were reasonable and necessary, their definition included the impact disease progression has on a person's ability to maintain their independence, and continue to engage meaningfully in relationships and life.

Advisors and care partners felt discriminated against by CMS' decision to deny coverage of FDA-approved treatments given this is the only class of FDA-approved treatment for which CMS has denied coverage. There were feelings that this discrimination would have an even greater impact on diverse, underserved and rural communities. Additionally, they want Alzheimer's disease to be recognized and treated similarly to other chronic diseases that are provided access to FDA-approved treatments. They also felt that CMS was overstepping its role and was re-making a determination of safety and efficacy, which is the FDA's role.

Lastly, Advisors and care partners vehemently agree that access to FDA-approved treatments is not only necessary, but a matter of life and death, and they should not be denied access.

How to cite this article: M.C. Carrillo, M. Moreno. Defining FDA Approved Treatments as Reasonable and Necessary: Perspectives of Individuals Living with Alzheimer's Disease and Care Partners. J Prev Alz Dis 2023;3(10):346-348; http://dx.doi.org/10.14283/jpad.2023.75