Alzheimer's Association charges CMS with discrimination for not paying for Alzheimer drug

By Paula Hartman-Stein, Ph.D.

In January, the Center for Medicare and Medicaid Services (CMS) announced its draft decision to reimburse consumers for an Alzheimer's disease drug, marketed as Aduhelm (aducanumab), but only to patients enrolled in research studies, setting off a firestorm of complaints, allegations and applause.

Alzheimer's Association Chief Executive Officer Harry Johns said in a press release following the decision that "Today's draft decision is shocking discrimination against everyone with Alzheimer's disease, especially those who are already disproportionately impacted by this fatal disease, including women, Blacks and Hispanics."

In clinical trials, the drug did not significantly reduce Alzheimer's symptoms and 40 percent of participants experienced brain swelling and bleeding. Other side effects included disorientation and falls.

After weak sales and widespread criticism of its pricing, the drug's manufacturer, Biogen, lowered its cost from $56,000 annually to $28,200.

Daniel George, Ph.D., associate professor of humanities and public health sciences at Penn State College of Medicine, wrote in a recent Psychology Today blog that the Alzheimer's Association (AA) used emotionally manipulative tactics by alleging the CMS is creating health inequities in order to put pressure on CMS to overturn its decision.

According to George, "…the AA snapped into 'psychopolitical' mode, attacking the decision using the social justice tropes of contemporary identity politics (i.e., oppression, privilege, inequity). A sensible decision by CMS not to fully pay for an expensive drug with no proven benefits but clear risks was instead spun as damning evidence that the institution has been compromised by the most reviled moral specters of our time like racism, misogyny and white supremacy."

Patients receiving the drug over 78 weeks had about a 30 percent reduction in beta-amyloid, the protein that forms plaques in the brain. Amyloid plaque is a surrogate marker of Alzheimer's and not an accepted clinically meaningful outcome measure.

George wrote that many in the Alzheimer's field bristled at the strong-arm tactics the Alzheimer's Association is using on behalf of Biogen. The company has given the

organization $1.4 million since 2018. The AA and other advocacy groups have flooded CMS and various social media with testimonials as to the effectiveness of the drug.

Judith Garber, a health policy and communications fellow at the Lown Institute in Needham, Mass. wrote in her blog, "…we don't know if Aduhelm actually works to reduce Alzheimer's symptoms or progression…Restricting access to an unproven and potentially harmful drug is not discrimination, it's good policy."The U.S. Veteran's Administration, as well as major insurers and health systems such as the Cleveland Clinic, Mass General Brigham and Blue Cross Blue Shield, have also declined to pay, for the treatment.

In June, the Federal Drug Administration (FDA) approved the drug despite objections from its advisors. Following the approval, three advisors resigned. Referring to the decision, Michael Carome, M.D., director of health research for the watchdog group, Public Citizen, called the approval reckless and said the agency's credibility has been damaged. In December, the Right Care Alliance, a group of international experts in dementia research and treatment, petitioned for accelerated withdrawal of Aduhelm by the FDA.

The petition reads in part, "We are deeply concerned about the broader issues raised by the approval of this drug. The FDA's acceptance of amyloid plaque PET scans instead of actual patient improvement for approving drugs for Alzheimer's disease is not scientifically well-founded. In the absence of clear evidence of meaningful clinical benefit, the continued availability of Aduhelm is likely to lead to widespread overtreatment that will not improve the quality of life of patients. It will expose them to unnecessary harms, and will consume extensive resources better spent on supportive services and public health measures to help people with this potentially devastating disease."

CMS closed public comment on access to aducanumab on February 11 and will make its final decision on reimbursement in April.

In a recent interview, Peter Whitehouse, M.D., geriatric neurologist and chair of the aducanumab advisory committee of the Right Care Alliance, said, "Let's not be deceived by outlandish rhetoric that those who advocate for aducanumab are representing the poor and the downtrodden; they are defending their own false promises and bottom lines. True hope lies in community and public health, not in outmoded reductionistic models of conditions like Alzheimer's that clearly are not caused by a single factor."

Paula Hartman-Stein, Ph.D., had served on MEDCAC, the advisory committee to CMS regarding Medicare reimbursement of clinical services. Currently, she has a psychology consulting practice and offers webinars on dementia prevention and the psychological benefits of nature and narrative. She has recently co-authored a chapter, "Preventing What's Preventable in Dementia," in the Handbook of Evidence-Based Prevention of Behavioral Disorders in Integrated Care*. She may be reached by email at: paula@centerforhealthyaging.com*