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**View Public Comments for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease (CAG-00460N)**

Commenter:

Klein, Keavney

Title:

Senior Counsel, Government Relations

Organization:

Kaiser Permanente

Date:

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Comment:

Kaiser Permanente[1] appreciates the opportunity to provide comments in response to the National Coverage Determination (NCD) analysis for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s disease. Given the controversy surrounding the approval of the first-in-class Aduhelm™ (aducanumab), Kaiser Permanente strongly supports CMS’ opening of an NCD process to determine if Aduhelm™ and future drugs directed against amyloid should be covered for the Medicare population.

As the largest private integrated health care delivery system in the United States, Kaiser Permanente delivers health care to more than 12.5 million members in eight states and the District of Columbia. Kaiser Foundation Health Plan, Inc., one of the nation’s largest not-for-profit health plans, and all our health plan subsidiaries are Medicare Advantage Organizations (MAOs), serving a total of more than 1.7 million Medicare beneficiaries. Within our footprint, we maintain a primarily internalized pharmacy system, including over 550 outpatient, hospital, infusion, specialty and mail order pharmacy sites staffed by over 14,000 pharmacy personnel. Kaiser Permanente spends approximately $10 billion annually on pharmaceuticals. Our Permanente Medical Group (PMG) physicians and other authorized practitioners prescribe, and our pharmacies dispense, over 90 million prescriptions annually. Kaiser Permanente’s mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve.

Given our large Medicare Advantage population and our primarily internalized drug purchasing and pharmacy operations, Kaiser Permanente and our members will be directly affected by the outcome of the NCD for Aduhelm™ and this new class of therapies. We endorse the comments being submitted by America’s Health Insurance Plans (AHIP) and wish to emphasize certain concerns in these comments.

Kaiser Permanente has significant concerns regarding the accelerated approval by the Food and Drug Administration (FDA) of Aduhelm™ over the strong opposition of the advisory committee. The drug was not shown in clinical trials to improve memory or function, and while the drug was shown to reduce beta-amyloid in the brain, the link between reduction of beta-amyloid and a clinical benefit has yet to be established even though it has been widely studied. Equally importantly, Aduhelm™ has been shown to have significant safety risks: 30 to 40 percent of patients developed brain swelling and bleeding after only 12 to 18 months of treatment.

Kaiser Permanente clinicians know and witness daily that Alzheimer’s disease and related dementia syndromes take a devastating toll on patients and their families and caregivers. We are committed to working to improve the diagnosis, treatment and support of patients and families suffering from these conditions. The impact on the Medicare population is outsized, with over 11 percent of Medicare beneficiaries diagnosed with Alzheimer’s disease or a related dementia. Kaiser Permanente therefore acknowledges and supports the need for effective treatments. However, we have serious concerns regarding Aduhelm™ given the lack of clinical effectiveness and the significant safety concerns. Our clinical specialists believe that the risks to our patients exceed the benefit of reducing amyloid burden, without significant clinical improvement. Therefore, our specialists believe the drug should only be administered in the context of a randomized clinical trial. The data do not support its routine use for the treatment of Alzheimer’s disease.

Below we have provided responses to CMS’ specific questions, representing input from across our integrated system including Pharmacy, Neurology, Psychiatry, Geriatrics and Adult Medicine.

1. Which health outcomes are important, and what degree of improvement in them is meaningful for patients receiving treatment?  
Aduhelm™ was designed specifically to slow progression of Alzheimer’s disease. Meaningful improvement would be a noticeable and significant slowing of progression, which would enable continued independence and maintaining level of function. Unfortunately, even in the one study that purported to show slowing of progression (the EMERGE study), the change of 0.39 on the Clinical Dementia Rating scale (CDR-SB) is not considered meaningful. We note that the identical ENGAGE study did not show any improvement. The clearing of amyloid is not a substitute for meaningful clinical improvement. Safety is also critical, so the drug’s benefits should outweigh its safety risks.

2. What characteristics of patients with Alzheimer’s disease are important to optimizing the likelihood of positive health outcomes from treatment?  
Based on the research, early diagnosis and treatment will be most effective. Keeping an individual with mild cognitive impairment from advancing to dementia, or mild dementia from progressing to moderate dementia, is likely more impactful than treating patients with more advanced disease.

3. What issues of equity and inclusion must be accounted for in the diagnosis and treatment of Alzheimer’s disease?  
A safe and effective drug for treating Alzheimer’s (which at this time would not include Aduhelm™) could potentially benefit many patients, if accessible in terms of provider access and affordability. The high launch prices of new therapies (which for many new drugs can be in the tens or hundreds of thousands of dollars annually) would almost certainly exacerbate existing disparities in access to both diagnosis and treatment of Alzheimer’s disease. There are equity concerns to consider regardless of CMS’ coverage decision: while Medicare non-coverage would lead to the drug only being available to those with the financial means to pay for the drug out-of-pocket, broader coverage of a drug therapy with significant safety concerns would mean that patients without access to intensive clinical oversight would be particularly at risk.

4. What health care providers should be included as part of the patient’s treatment team? Should medical specialists be included in the care team of patients receiving treatment? If so, which specialists should be included in the care?  
Adult and family medicine physicians, neurologists, geriatricians, psychiatrists, social workers and pharmacists are all part of the health care team that cares for patients with Alzheimer’s disease. Our clinical specialists are recommending that patients being prescribed innovative therapies be guided to neurologists and geriatricians within our system. These specialists should be involved in overseeing administration of any drug that is clinically indicated and safe and effective.

5. In what setting(s) should treatment and care be given?  
An Alzheimer’s drug, if shown through clinical trials to be safe and effective, should be provided on an outpatient basis.

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Kaiser Permanente appreciates CMS’ consideration of these comments and would be pleased to provide additional information as the agency develops the NCD.

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[1] Kaiser Permanente comprises Kaiser Foundation Health Plan, Inc. and its health plan subsidiaries outside California and Hawaii; the not-for-profit Kaiser Foundation Hospitals, which operates 39 hospitals and over 700 other clinical facilities; and the Permanente Medical Groups, self-governed physician group practices that exclusively contract with Kaiser Foundation Health Plan and its health plan subsidiaries to meet the health needs of Kaiser Permanente’s members.