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January 25, 2022

David Dolan, MBA
Lead Analyst
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed National Coverage Determination for Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer's Disease (CAG-00460N)

Dear Mr. Dolan,

The Centers for Medicare and Medicaid Services (CMS) made the correct decision to sharply limit Medicare coverage for the Alzheimer's drug Aduhelm to qualified clinical trials. I would strongly urge that this proposal be finalized as soon as possible and that CMS reject calls by the pharmaceutical industry to greatly expand coverage for this vastly overpriced and controversial drug.

While I applaud Secretary Becerra's decision to instruct CMS to reconsider the outrageous increase in Medicare premiums attributable to the original $56,000 price tag for Aduhelm, much more must be done.

In my view, the administration should immediately lower Medicare premiums by at least $11.50 a month and provide a refund to some 57 million senior citizens for the premium increases that have already gone into effect this month.

Alzheimer's is a horrible disease and we must do everything possible to find a cure for the millions of seniors who suffer from it, but we cannot allow pharmaceutical companies to rip-off seniors.

Biogen's outrageous original $56,000 price for Aduhelm is the poster child for how dysfunctional our drug pricing system has become, and it is the perfect example of why Medicare should be negotiating drug prices with the pharmaceutical industry.

If the administration takes no action, Medicare recipients will continue to see their biggest premium increase in history. We cannot allow that to happen.

While Biogen recently reduced the price of this drug to $28,200, let's be clear. The Institute for Clinical and Economic Review, an independent nonprofit organization, has estimated that, even if it were proven to be effective, the maximum price of Aduhelm should be no higher than between $3,000 and $8,400.

If the Administration accepts Biogen's price for this drug, seniors who receive it would be forced to come up with a 20 percent co-pay of $5,600 out of their own pockets – which would be simply unacceptable.

In my view, the Administration must reinstate and expand the reasonable pricing clause that was established in 1989 by the National Institutes of Health requiring drug makers to charge "reasonable" prices for prescription drugs and treatments that receive federal funding – a policy that was revoked in 1995.

Beyond the incredibly high price of this drug, serious concerns have been raised by the scientific community that Aduhelm could do more harm than good. In November of last year, the Journal of the American Medical Association published an article finding that 41 percent of people who received the approved dose of Aduhelm experienced amyloid-related imaging abnormalities including brain swelling and bleeding.

This is a drug that has been rejected by the VA. In August 2021, the Department of Veterans Affairs announced that it will not cover Aduhelm due to safety concerns and the "lack of evidence of a robust and meaningful clinical benefit."

This is a drug that has been rejected by major private health insurance companies. In July of last year, six major health insurance companies affiliated with Blue Cross and Blue Shield in North Carolina, Pennsylvania, Michigan, New York and Kansas announced that it will not cover Aduhelm. According to Independence Blue Cross of Pennsylvania: "We have evaluated the published peer-reviewed literature on the evidence of Aduhelm's safety and effectiveness in treating Alzheimer's disease. We have concluded that it does not sufficiently show that the drug's clinical benefits outweigh its harms or that it reduces progression of the disease."

Empire Blue Cross Blue Shield announced last year that "[Aduhelm] is considered experimental/investigational and therefore non-covered as there is a lack of conclusive evidence confirming clinical efficacy."

None of the 25 major insurers surveyed by Bloomberg News last November found that Aduhelm was "medically necessary" and most believed that the drug is too experimental to cover.

This is a drug that was rejected by 10 out of the 11 experts on the FDA's scientific advisory panel. Ten out of 11 members of the Food and Drug Administration's (FDA) Drug Advisory Committee recommended against approving Aduhelm with the last member voting "uncertain."

Three members of the committee resigned over the FDA's decision to approve the drug against their recommendations. One of the members, Dr. Aaron Kesselheim of Harvard, stated, "…the [Aduhelm] decision by FDA administrators was probably the worst drug approval decision in recent U.S. history." He further stated that decisions like this "undermine the care of these patients, public trust in the FDA, the pursuit of useful therapeutic innovation, and the affordability of the health care system."

Dr. David Knopman, another member of this panel, stated that the FDA's decision to approve Aduhelm "made a mockery" of the advisory committee's role. A third member of this panel, Dr. Joel Perlmutter of Washington University in St. Louis said: "Approval of a drug that is not effective has serious potential to impair future research into new treatments that may be effective."

This is a drug that has been rejected by the European Medicines Agency (EMA). On December 16, 2021 the European Medicines Agency rejected the marketing authorization for Aduhelm stating: "…although Aduhelm reduces amyloid beta in the brain, the link between this effect and clinical improvement had not been established. Results from the main studies were conflicting and did not show overall that Aduhelm was effective at treating adults with early stage Alzheimer's disease. In addition, the studies did not show that the medicine was sufficiently safe as images from brain scans of some patients showed abnormalities suggestive of swelling or bleeding, which could potentially cause harm. Furthermore, it is not clear that the abnormalities can be properly monitored and managed in clinical practice. Therefore, the Agency's opinion was that the benefits of Aduhelm did not outweigh its risks…"

This is a drug that has been rejected by major hospitals. Mount Sinai announced Aduhlem would not be administered at their health care system stating: "The FDA's approval of Aduhelm has raised serious concerns and questions by clinicians, patients and caregivers, and a cautious approach is required. Mount Sinai Health System will not administer Aduhelm until the outcome of the FDA Inspector General's investigation of Biogen is complete. Depending on this outcome, if appropriate, our experts will follow formulary addition protocols and consider best practices for Aduhelm to inform clinical practice."

Moreover, the Cleveland Clinic also announced that Aduhelm would not be provided in their system stating, "Based on the current data regarding its safety and efficacy, we have decided not to carry [Aduhelm] at this time."

Simply put, at a time when 10 out of 11 experts on the FDA's advisory committee voted against approving Aduhelm, when the VA announced that it would not be covering Aduhelm due to safety concerns and when the European Union and at least a half a dozen private health insurance companies have also decided not to cover Aduhelm, neither should Medicare.

Let us have the courage to take on the greed of the pharmaceutical industry, lower the outrageous prices of prescription drugs, and prevent seniors from paying unnecessarily inflated Medicare premiums and co-payments.

Sincerely,

BERNARD SANDERS
UNITED STATES SENATOR

Cc: The Honorable Xavier Becerra
Secretary, Department of Health and Human Services

The Honorable Chiquita Brooks-LaSure
Administrator, Centers for Medicare and Medicaid Services

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