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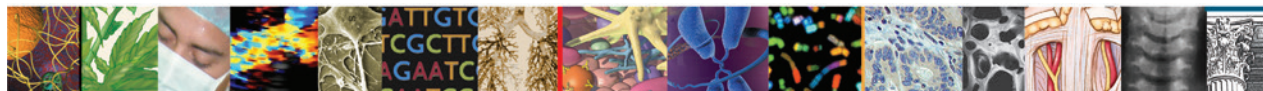
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Why Is Aducanumab Priced at \$56,000 per Patient? Lessons for Drug-Pricing Reform

James C. Robinson, Ph.D., M.P.H.

The approval of aducanumab by the Food and Drug Administration (FDA) for patients with Alzheimer's disease has proven to be one of the most controversial regulatory decisions in recent

memory. Attention has focused on the FDA's unusual use of the accelerated approval pathway and its postapproval changes in the product label. But now that the decision has been made, attention should shift to the price charged for each patient and, because of the large affected patient population, to the budgetary impact on public and private insurers.

Biogen, the manufacturer of aducanumab, has announced a list price of \$56,000 — 10 times the evidence-based benchmark recommended by the independent Institute for Clinical and Economic Review.¹ Given the size of the potential patient population, this price could translate into enormous spending. According

to one estimate, if even 10% of U.S. patients with Alzheimer's disease were prescribed aducanumab, drug spending for Medicare Part B would increase from \$37 billion to \$69 billion per year.²

It is safe to assume that the manufacturer made its pricing decision only after careful assessment of the regulatory and market environment into which the product would be launched. The aducanumab experience therefore offers important insights into the structural factors responsible for high drug prices, as well as key lessons for the policy debate over drug-pricing reform.

The price posted for aducanumab is a response to three important features of the market

environment for physician-administered drugs: the formula used by Medicare to calculate its reimbursement rate, the way in which physicians are paid for office-infused drugs, and the cost-sharing requirements faced by patients.

First, the price charged to private insurers for aducanumab determines the amount that will be paid by Medicare, which covers most U.S. patients with Alzheimer's. Under Part B, Medicare pays an average sales price (ASP), calculated as the average of private insurer prices minus any discounts and rebates. Pharmaceutical firms thus have an incentive to charge high prices to private insurers and to refuse to offer discounts and rebates, since these adjustments would translate directly into reductions in Medicare's ASP. It doesn't matter to manufacturers if private insurers impose onerous utilization management in response to a high

price, thereby limiting the number of prescriptions, as long as the price remains high and most patients are covered by Medicare.

Second, infused drugs are distributed to hospital clinics and physician practices by a “buy-and-bill” mechanism. Providers acquire the drugs from the manufacturer at one price and file for reimbursement from insurers at a higher price, retaining the difference as revenue. Medicare pays physicians a reimbursement price 4 to 6% over the acquisition price, which translates into a larger dollar sum for expensive than for cheap drugs. Private insurers cannot dictate, but must negotiate, payments with care providers, and pay even larger drug markups. Independent physician practices and hospitals obtain markups averaging 10% and 100%, respectively, above acquisition prices.³ In the context of buy-and-bill distribution, price moderation by the manufacturer would reduce providers’ revenues and dampen, rather than boost, their enthusiasm for prescribing the drug.

Third, now that the FDA has adopted an accommodating stance toward aducanumab despite inconclusive evidence of its clinical efficacy, competing products with similar mechanisms of action will soon follow. Therapeutic competition will not lead to price competition, however, unless physicians and patients perceive an advantage in using cheaper options. Under Medicare Part B, beneficiaries are responsible for 20% of the price of the drug they use, which creates an incentive to prefer products with low prices. But 80% of any price difference between competing drugs is paid by Medicare, which creates a countervailing incentive for manufac-

turers not to compete on price. It could be said that Medicare imposes too much cost sharing on low-priced options and too little on high-priced options. There is little reason to expect the manufacturer to reduce its \$56,000 price once therapeutically similar products are launched.

The case of aducanumab comes at a time when policymakers are debating potentially important changes in drug pricing, distribution, and consumer cost sharing. It can thus provide valuable insights into how the pharmaceutical system should be restructured if public and private insurers don’t wish to face similar financial shocks whenever a new drug is launched for a disease affecting large numbers of people.

Medicare’s method of calculating ASPs for physician-administered drugs such as aducanumab creates a strong disincentive for manufacturers to moderate prices or offer discounts. Medicare needs new statutory authority to negotiate prices, based on evidence of patient benefit and its leverage as a major purchaser, rather than passively adopting the prices negotiated by fragmented and sometimes unsophisticated private insurers. The price charged for a new drug should be evaluated in light of the evidence of its performance relative to that of other available treatments — evidence that should be gathered by means of formal health technology assessments. Other countries rely on public or semipublic agencies to conduct such assessments and to generate benchmarks to align prices with assessed benefits.

The ASP formula for drug reimbursement exempts Medicare from the scientifically complex

and politically volatile process of technology assessment and price negotiations. But having Medicare base the prices it pays on those negotiated by private insurers turns the purchasing side of the market on its head, given the large share of prescriptions written for elderly patients. Medicare needs to lead, not follow, private insurers. Private insurers assess new drugs on the basis of often-incomplete and variable evidence and do not disclose the methods used.⁴ They lack the bargaining leverage that Medicare would enjoy as the insurer for 80% of the patients likely to be prescribed aducanumab. Physicians and patients deserve access to the evidence used in evaluating innovative technologies, as well as a price aligned with clinical benefit.

In addition, the buy-and-bill method of drug distribution is inherently inflationary. Physicians and hospitals should be reimbursed by insurers at the drug’s acquisition price and not use reimbursement margins as a major revenue source. Past policy efforts to reform the distribution system for infused drugs have faltered in the face of opposition from physicians and hospitals. Many practices in oncology and other specialties that use infused drugs depend on drug markups to cover the costs of care planning and shared decision making, patient evaluation and education, and treatment monitoring and modification. It has been easier for insurers to permit providers to earn drug margins than to assess the true cost of professional services and pay professional fees that are adequate to cover them. Reforming pricing for infused drugs will necessitate

reform of payment for related professional services.

Finally, Medicare's cost-sharing policies do not create clear incentives for patients to prefer low-priced options. Under the prevalent coinsurance design, even the cheapest option requires substantial cost sharing, and there is not a large cost-sharing difference between high- and low-priced options. In contrast, some other countries have designed their insurance benefits to encourage adoption of low-priced

 **An audio interview with Dr. Robinson is available at NEJM.org**

options and thereby reward manufacturers that reduce prices. In Germany, for

example, patients face little or no cost sharing when selecting biosimilars and other affordable options, but pay the full price difference when selecting high-

priced options. This approach ensures that patients can easily access at least one option, but gives them a strong incentive to be sensitive to price differences among therapeutically similar products.⁵

The \$56,000 price for aducanumab is a rational manufacturer response to an irrational insurance system. If the United States does not wish to face similarly high prices for each new pharmaceutical product, it must address the inflationary incentives inherent in Medicare's reimbursement formula, the method of drug distribution for infused drugs, and the structure of consumer cost sharing.

Disclosure forms provided by the author are available at NEJM.org.

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Medicare Coverage of Aducanumab — Implications for State Budgets

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Aducanumab (Aduhelm), the controversial \$56,000-per-year Alzheimer's disease drug approved by the Food and Drug Administration (FDA) in June 2021, has the potential to cost the federal government many billions of dollars — more, by one estimate, than it spends on agencies such as the Environmental Protection Agency or the National Aeronautics and Space Administration. The drug's extraordinary price tag helps explain why, soon after its approval, the Centers for Medicare and Medicaid Services (CMS) opened a national coverage determination to decide whether

and under what circumstances Medicare would pay for it.¹

A restrictive coverage determination could save the federal government a lot of money — but, as a recent letter from the National Association of Medicaid Directors (NAMD) noted, it would also shift substantial costs to the states.² The emerging debate over who will pay for aducanumab has important implications for Medicare spending, state fiscal health, and existing laws requiring Medicare and Medicaid to cover nearly all approved drugs, no matter their prices and no matter how poorly they work.

Usually, Medicare coverage of FDA-approved drugs is a foregone conclusion: the clinical evidence to support FDA approval is deemed sufficient to show that a product is “reasonable and necessary” for the treatment of an illness or injury, as the Medicare statute requires. But aducanumab is a special case. In granting accelerated approval to aducanumab, the FDA concluded that the drug's ability to reduce amyloid plaques was reasonably likely to translate into clinical benefits. But this claim is hotly contested and was not presented to the FDA's advisory committee, which voted against