Weekly Checkup

Aduhelm, the FDA Approval Controversy, and Medicare Coverage

CHRISTOPHER HOLT | JUNE 11, 2021

This week the Food and Drug Administration (FDA) approved Biogen's new Alzheimer's treatment aducanumab, which will be branded Aduhelm. The decision was controversial for several reasons including the nature of the clinical trials, the FDA's approval process, the treatment's price, questions about its efficacy, and what it all means for the future of drug approvals. **These various points of controversy, and the reality that FDA approval does not guarantee Medicare coverage, raise the question of whether—or, more likely, how—Medicare will cover this drug.**

While Alzheimer's advocacy groups have been quick to celebrate the FDA's decision, many researchers have objected. Biogen suspended the phase three clinical trials for aducanumab, after initially determining there was no difference between patients receiving aducanumab and those getting a placebo. Upon later review of additional data, however, Biogen argued that there was evidence that aducanumab led to some slowdown in cognitive decline in patients who received especially high doses, and so it asked the FDA to approve the therapy. The FDA's own advisory panel recommended against approving the medication on the grounds that the clinical trials did not conclusively demonstrate that aducanumab does in fact slow cognitive decline.

Ultimately, however, the FDA set aside these concerns and approved the drug using the Accelerated Approval Program, which allows the for approval of therapies "that treat serious conditions, and that fill an unmet medical need." Because of this accelerated approval, Biogen will be required to conduct a phase four clinical trial to confirm that aducanumab does slow cognitive decline and is safe. One danger, however, is that getting patients to enroll in a clinical trial after a drug has been approved is especially difficult because enrollees are not guaranteed they won't be placed in the placebo group. Additionally, failure of the confirmation trial allows the FDA to revoke approval, but the agency is not required to.

There has also been a fair amount controversy over the price of Aduhelm, which Biogen has set at $56,000 per year, per patient. Additionally, the FDA label is especially broad, allowing the drug to be used for anyone suffering from Alzheimer's, while the clinical trials were limited to a much narrower population that was believed to be more likely to benefit. **Given the large population of Alzheimer's patients and the paucity of effective treatments, demand could be especially high. Some have argued that the price is excessive given the efficacy questions**, and the Institute for Clinical and Economic Review has argued a more appropriate price would be in the range of $2,560 to $8,290 annually (though your author is suspicious of the wisdom of turning over drug pricing decisions to self-selected academics).

The majority of U.S. Alzheimer's patients are enrolled in Medicare, and estimates indicate that the impact of Aduhelm on Medicare spending could easily surpass $100 billion annually and could approach as much as $400 billion. For context, total Medicare spending in 2019 was $799.4 billion while Part B spending was $37 billion. **FDA approval does not guarantee that Medicare will cover a drug, and while Medicare is expected to ultimately cover the therapy, some are calling for the Centers for Medicare and Medicaid Services (CMS) to approve this drug in a nonconventional way**

. CMS makes coverage decisions based on three criteria: The treatment must be safe and effective, not experimental, and appropriate to Medicare patients. **While CMS cannot adjust the price of drugs, it can put in place limitations on who is eligible for a treatment, require prior tests or treatments, or even require further study of the therapy's efficacy.** Further, Medicare Advantage plans are now authorized to use formulary management tools for Part B drugs, which could limit the number of Medicare beneficiaries who could access Aduhelm, although Alzheimer's patients are disproportionately enrolled in traditional fee-for-service Medicare.

Stepping back a bit, there is some concern that the FDA risks losing credibility by being too quick to approve treatments with so many question marks. **The agency is always in a difficult position, trying to balance patient demand for even glimmers of hope with maintaining rigorous scientific and safety standards. At least in this case, the FDA seems to be leaning into hope, and surely there are patients and families who are grateful for that. Whether CMS follows suit remains to be seen.**

VIDEO: HEALTH CARE PRICE TRANSPARENCY

Christopher Holt explains why bipartisan support for health care transparency doesn't necessarily mean it's effective.

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TRACKING COVID-19 CASES AND VACCINATIONS

Jake Griffin, Health Care Policy Intern

To track the progress in vaccinations, the Weekly Checkup will compile the most relevant statistics for the week, with the seven-day period ending on the Wednesday of each week.

Week Ending:	New COVID-19 Cases: 7-day average	Newly Fully Vaccinated: 7-Day Average	Daily Deaths: 7-Day Average
9-Jun-21	13,996	474,448	347
2-Jun-21	14,890	475,533	340
26-May-21	22,310	732,424	428
19-May-21	28,000	998,344	513
12-May-21	34,832	1,195,366	564
5-May-21	45,386	1,396,548	594
28-Apr-21	52,120	1,438,059	622

21-Apr-21	60,923	1,472,237	637
14-Apr-21	68,399	1,722,112	644
7-Apr-21	63,963	1,560,017	625
31-Mar-21	63,941	1,360,750	739
24-Mar-21	65,882	959,019	750
17-Mar-21	53,421	1,018,850	891
10-Mar-21	54,191	949,549	1,169
3-Mar-21	61,172	907,997	1,430
24-Feb-21	64,420	838,318	1,793
17-Feb-21	73,942	739,099	1,943
10-Feb-21	100,059	694,729	2,396
3-Feb-21	129,204	479,719	2,742
27-Jan-21	159,113	333,317	3,177

Sources: Centers for Disease Control and Prevention Trends in COVID-19 Cases and Deaths in the US, and Trends in COVID-19 Vaccinations in the US

Note: The U.S. population is 332,406,878.

WORTH A LOOK

New York Times: Outcry Forces UnitedHealthcare to Delay Plan to Deny Coverage for Some E.R. Visits

The Hill: CDC to hold ’emergency meeting’ on heart inflammation after COVID-19 vaccines