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MEDICARE'S FINANCES AND THE ADUHELM SAGA

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Introduction

The Centers for Medicare & Medicaid Services (CMS) created headlines last fall when it increased the Medicare Part B premium for 2022 by 14.5 percent. A significant portion of the increase was aimed at creating "contingency reserves" in the event that Medicare ended up covering Aduhelm – the controversial and expensive new drug for early-stage Alzheimer's disease. In January, the decision was made to limit the coverage of Aduhelm to those in clinical trials. While the CMS decision will hold Medicare costs in check for the short run, it highlights the program's financial vulnerability to high-priced, potentially valuable drugs when CMS has no ability to negotiate prices.

The discussion proceeds as follows. The first section provides a brief overview of Medicare financing. The second section describes the *2021 Trustees Report* projections that use current-law assumptions and projections based on alternative assumptions that involve higher payments for hospital and medical services. The third section turns to payments for drugs, an expenditure component not considered in the alternative assumptions, and explores the implications of Aduhelm for Medicare and its beneficiaries. The final section concludes that the Aduhelm saga has highlighted the risk to the system's finances if a very valuable and very expensive drug should become available and Medicare remains unable to negotiate prices. Hopefully, the lessons from Aduhelm will rekindle Congressional interest in giving Medicare some authority to do so.

An Overview of Medicare

Medicare is the largest public health program in the United States. It covers virtually all persons ages 65 and older and most citizens with disabilities.

Traditional Medicare is composed of two programs (see Table 1 on the next page). The first – Part A, Hospital Insurance (HI) – covers inpatient hospital services, skilled nursing facilities, home health care, and hospice care. The second – Supplementary Medical Insurance (SMI) – consists of two separate accounts: Part B, which covers physician and outpatient hospital services; and Part D, which was enacted in 2003 and covers prescription drugs. The arrangements are slightly more complicated because Medicare also includes Part C (the Medicare Advantage plan option), which makes payments to private plans that provide both Part A and Part B services.

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Table 1. Medicare Spending in Billions of Dollars, 2020

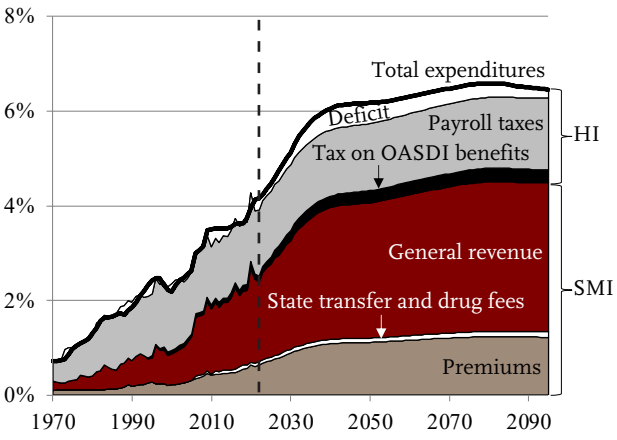
Program	HI	SMI		Total
	Part A	Part B	Part D	
Traditional Medicare				
HI (Part A)	$266			$266
SMI				
Part B		$238		238
Part D			$105	105
Part C	136	181		317
Total	$402	$419	$105	$926

Source: Medicare Trustees Report (2021).

Each Medicare program has its own trust fund and its own source of revenues. Part A (HI) is paid for primarily by a 2.9-percent payroll tax, shared equally by employers and employees. In addition, high-income workers pay a 0.9-percent tax on their earnings above a threshold of $200,000 for singles and $250,000 for married couples. The HI trust fund also receives a portion of federal income taxes that Social Security recipients pay on their benefits. SMI is financed by a combination of general revenues – about 75 percent – and participant premiums – about 25 percent.

Figure 1 shows total Medicare spending and its sources of income. SMI is adequately financed for the indefinite future because the law provides for general revenues and participant premiums to meet the next year's expected costs. Of course, an increasing claim on general revenues puts pressure on the federal budget and rising premiums place a growing burden on beneficiaries. For HI, the small trust fund is projected to be exhausted in 2026, and revenues are not sufficient to cover costs, yielding a long-term deficit shown at the top of the figure.

Figure 1. Medicare Spending and Sources of Non-Interest Income, Percentage of GDP, 1970-2095



Source: Medicare Trustees Report (2021).

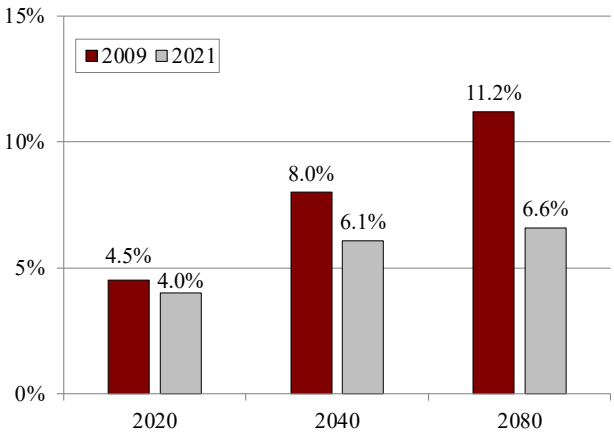
A Closer Look at Medicare Finances

The Medicare Trustees issue an annual report projecting the program's finances under current law. In addition, the actuaries prepare an alternative scenario that limits the extent to which Medicare payments to hospitals and physicians fall below those made by private insurers. The concern is that prices can only be reduced so far before they become unreasonably low and jeopardize Medicare beneficiaries' access to mainstream medical care.

Current Law Projections

For a number of years, the Medicare current-law projections have assumed a substantial reduction in the growth rate of per capita health expenditures relative to historical experience. While such projections for government programs sometimes prove optimistic, Medicare has actually experienced slower spending growth in recent years. As shown in Figure 2, be-

Figure 2. Projected Medicare Spending as Share of GDP for Selected Years from 2009 and 2021 Trustees Reports

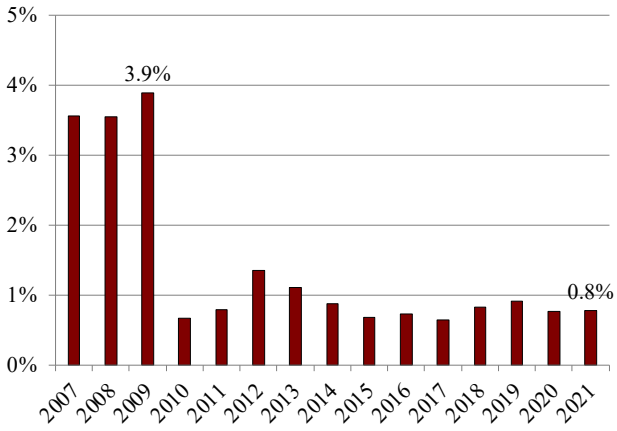


Sources: Medicare Trustees Reports (2009 and 2021).

tween the 2009 and 2021 Trustees Reports, projected long-term costs for Medicare – HI and SMI combined – declined dramatically.

In terms of the HI program – the component of Medicare financed by the payroll tax – the lower projected costs have led to substantially smaller 75-year deficits. The 2021 Medicare HI deficit of 0.8 percent of taxable payroll is consistent with the overall post-2009 range (see Figure 3).

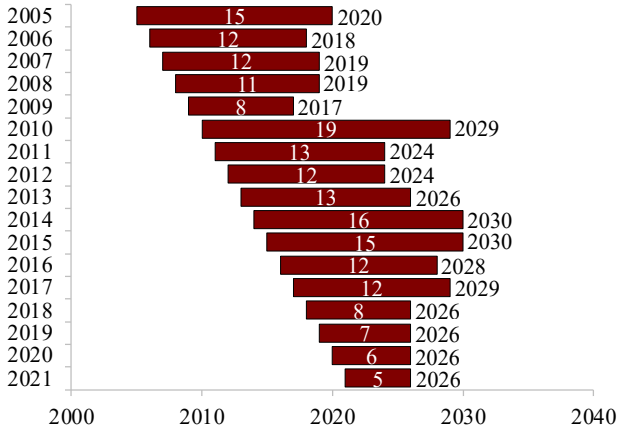
Figure 3. HI 75-year Deficit as a Percentage of Taxable Payroll, 2007-2021



Sources: Medicare Trustees Reports (2007-2021).

The HI trust fund is projected to deplete its reserves in 2026 (see Figure 4). But the depletion date tells observers little about the finances of the overall Medicare program because the trust fund is very small compared to HI expenditures, and HI is less than half of the Medicare system.

Figure 4. Projected Depletion of Reserves in HI Trust Fund, by Year of Trustees Report, 2005-2021



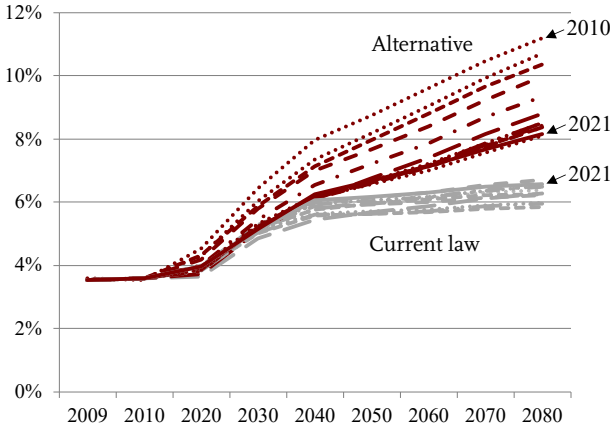
Sources: Medicare Trustees Reports (2005-2021).

Alternative Assumptions

The Trustees' main projections are based on current law and, therefore, include the impact of cost-control provisions in the ACA and subsequent legislation. To the extent that these provisions end up producing inadequate reimbursement rates for Medicare providers, Congress may find it necessary to curtail the payment reductions.[1] To account for the uncertain future of the cost control measures, the Medicare actuaries also produce alternative projections.[2]

The most recent estimates under the alternative assumptions show expenditures in 2095 equal to 8.5 percent of GDP compared to only 6.5 percent under current law. To provide perspective on how the projections have changed over the past decade, Figure 5 shows total Medicare spending projections from each *Trustees Report* over the 2010-2021 period under the current-law assumptions and the alternative scenario. The current-law projections have remained within a relatively narrow band, while the alternative projections declined noticeably until 2015, at which point they appear to have stabilized. As a result, the gap between the two sets of projections for 2095 has stabilized at 2-percentage points of GDP.

Figure 5. Projected Medicare Spending as Share of GDP under Trustees and Alternative Assumptions from 2010-2021 for 75-Year Projection Period



Source: Shatto and Clemens (2010-2021).

While the alternative projections take account of the uncertainty surrounding Medicare's ability to control payments for hospital and physician services, they do not address the potential impact of much higher drug prices. The recent events surrounding Aduhelm, the controversial and expensive drug for early-stage Alzheimer's disease, highlight the vulnerability of Medicare's finances to potentially valuable but extremely high-priced drugs.

The Aduhelm Saga

Aduhelm, a drug developed recently by Biogen, has raised enormously important issues for Medicare. Biogen's initial proposed price for Aduhelm was $56,000 per patient per year. Because Aduhelm is administered intravenously by physicians, it would be covered under Medicare Part B. (Medicare Part D covers retail prescription drugs.) While to date Medicare has covered virtually all drugs approved by the Food and Drug Administration (FDA), CMS officials issued a draft decision in January 2022 to limit coverage of Aduhelm to those in clinical trials.[3] The basis for their decision was concerns about whether the benefits of the drug outweighed the safety risks. The final decision is expected by April.[4]

Two aspects of the Aduhelm issue are fascinating. On the one hand, the efficacy of Aduhelm is unproven, patients face serious risks, and the FDA approval was extremely controversial, so Medicare officials faced a real dilemma. On the other hand, what if clinical trials had clearly demonstrated that the drug could slow cognitive decline and Biogen had kept the price at $56,000 per year?

The Current Situation

The story started with the FDA approval of Aduhelm in June 2021. The drug is the first new treatment for Alzheimer's in almost 20 years, the first aimed at treating the source of the disease rather than targeting the symptoms, and the need for a cure is compelling. On the other hand, three years ago, Biogen halted two late-stage clinical trials after experts concluded that the drug would not slow cognitive decline and functional impairment (see Box). Subsequently, the company released additional data from one of the trials, asserting the drug at a high dose could be effective in slowing cognitive decline.

The FDA approved the drug using the "accelerated approval" pathway, which is intended to provide earlier access to potentially valuable therapies when

A Few Details on the Clinical Trials

Aduhelm was evaluated in two identical, mostly contemporaneous, randomized clinical trials – ENGAGE and EMERGE. The trials involved 3,285 patients ages 50-85 with early-stage Alzheimer's. One third of participants were given a low dose of Aduhelm, one third were given a high dose of Aduhelm, and one third a placebo. All patients were to receive IV infusions of the drug or placebo every week for 78 weeks.

Both trials were scheduled for a futility analysis by an independent data monitoring committee beginning in December 2018. At that time, 50 percent of participants had completed the 78-week protocol. Based on an examination of the results for those individuals, the committee determined that, while the drug was effective at reducing plaque, it had no effect on cognition scores. Both trials were terminated in March 2019. At the time of termination, however, the results from ENGAGE and EMERGE were trending in different directions, and investigators sought to understand why the identical trials were yielding different outcomes. Accordingly, they examined an expanded dataset that included three additional months of data collected between December 2018 and the termination date of March 2019. At that point, 60 percent of EMERGE participants and 66 percent of ENGAGE participants had completed the full 78 weeks of the trial.

At week 78, ENGAGE showed no effect on cognition from either the low or high dose of the drug, but EMERGE showed a small but statistically significant improvement in cognition scores for those receiving the high dose. Experts disagree, however, on how to explain the differences in outcomes from the two trials, since the relationship between removing plaque and slowing cognitive decline has not yet been conclusively demonstrated, with negative results from more than 20 other trials on anti-plaque drugs. Experts also disagree on whether the degree of improvement in the EMERGE trial is clinically important.[5]

uncertainties exist about their ultimate benefit. In the case of Aduhelm, the drug had a clear impact on a "surrogate endpoint" – the removal of plaque – which the FDA concluded was reasonably likely to produce a "clinical benefit" – the slowing of cognitive decline.

The backlash was immediate. Three of the agency's outside advisors quit over the decision; a watchdog agency is investigating the approval process; and many prominent providers – Cleveland Clinic, Mt. Sinai, Mass General Brigham, and the Department of Veterans Affairs – have declined to adopt Aduhelm. Internationally, the European Union's drug regulator recommended against approving the drug, and leading Canadian Alzheimer's research organizations said adoption "cannot be justified."

In some ways, the debate over Aduhelm reflects the medical debate among doctors and researchers over what causes Alzheimer's. Aduhelm reduces a protein (amyloid) that clumps in the brain of people with Alzheimer's, but many specialists say that extensive research has shown that reducing the protein does not slow cognitive decline. Moreover, the drug can cause serious side effects such as headaches, dizziness, falls, and brain bleeds.[6]

Aduhelm is also expensive. Biogen originally priced the drug at $56,000 per year, as noted, but cut the price to $28,200 in December after weak sales. Patients receive the drug in monthly infusions and also require regular MRI scans to monitor for dangerous side effects such as brain swelling and bleeding. About half of Medicare's premium increase for 2022 was attributable to the anticipated costs of covering Aduhelm.

In the wake of the controversy, Medicare opened a National Coverage Determination (NDC) process.[7] The process involved a review of the clinical evidence to determine whether the drug is "reasonable and necessary for the diagnosis and treatment of an illness." That is, is the evidence adequate to ensure that the drug will improve outcomes? Cost is not included as a factor in the assessment. The determination was that the risks exceeded the benefits and that the coverage of Aduhelm would be limited to randomized clinical trials, with some patients getting placebos. The trials must be approved by CMS or supported by the National Institutes of Health, conducted in a hospital-based outpatient setting, and cover a diverse population. This decision will limit treatment to a few thousand individuals over the next 3-5 years.

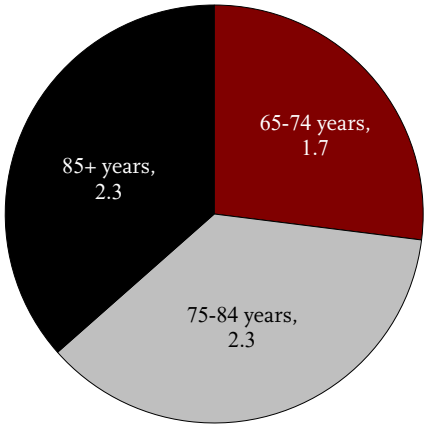
The Bigger Issue

While Medicare's decision to limit the coverage of Aduhelm to clinical trials will hold costs in check for a while, the bigger issue is the financial implications of an *effective* drug for early Alzheimer's in an environment where Medicare has no ability to negotiate prices. The total cost will consist of two components: the price and the number of beneficiaries.

Neither the FDA nor Medicare takes price into account when making its decisions. Hence, if the drug itself were not so controversial, Biogen's price of $56,000 per year would have held. This price is high, given that the Institute for Clinical and Economic Review – a drug-cost watchdog – estimated that, based on the most positive assessment of the clinical evidence, Aduhelm should cost at most $8,360 per year.[8] And clearly, Biogen has considerable flexibility in its price setting since it cut the ask by half – to $28,200 – in the face of weak sales.

In 2021, a total of 6.2 million Americans ages 65 and older had Alzheimer's (see Figure 6), and that number is projected to increase to 7.2 million by 2025, and 13.8 million by 2060.[9] Aduhelm, however, is designed only for those in the early stages. Biogen's promotional material for investors states that between 1 and 2 million have been clinically diagnosed with mild dementia due to Alzheimer's. Even if the drug worked

Figure 6. Number of Older Americans with Alzheimer's by Age, in Millions, 2021



Source: Alzheimer's Association (2021).

perfectly, it would not reverse or cure Alzheimer's; the goal is to slow the rate of cognitive decline. As a result, each year many of last year's recipients would continue to be eligible, and some newly diagnosed with the disease would come on board. Hence, it is not difficult to imagine total recipients going to 3 million and more.

With an annual price of $28,200 and 1 million recipients, Medicare's bill for Aduhelm would be $23 billion (Medicare pays 80 percent, and beneficiaries pay 20 percent in copayments). Aduhelm expenditures would have amounted to about two-thirds of what Medicare Part B currently spends on all drugs and eight times what it spends on the current most expensive drug – Eylea (see Table 2).

Table 2. Part B Drug Spending by Drug, Billions of Dollars, 2019

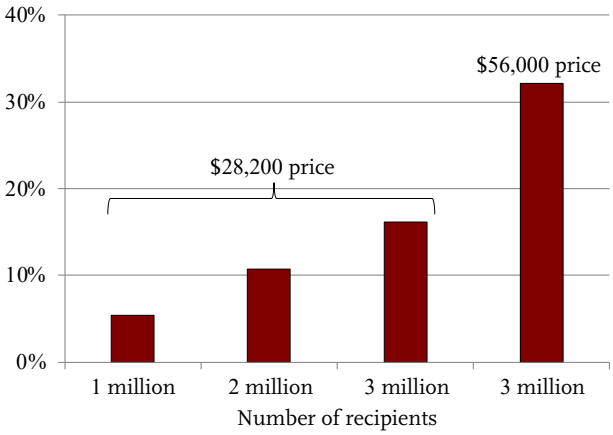
Brand name	Condition treated	Total spending
Eylea	Macular degeneration	$2.9
Keytruda	Cancer	2.7
Opdivo	Cancer	1.8
Rituxan	Cancer	1.7
Prolia	Osteoporosis	1.6
Lucentis	Macular degeneration	1.3
Neulasta	Bone marrow stimulant	1.2
Avastin	Cancer	1.0
All other		23.1
Total		$37.3

Source: Cubanski and Neuman (2021).

Since total Medicare Part B expenditures in 2020 were $419 billion, a $23-billion increase would require a 5.4-percent increase in Part B premiums. Those costs would rise over time as more and more individuals stricken with Alzheimer's become eligible. And they could double if a competitor offers a clearly effective product at Biogen's original price of $56,000. The growing volume of eligible patients and Biogen's original price could require an eventual 32-percent increase in Part B premiums (see Figure 7).

Alzheimer's patients would also pay high out-of-pocket costs both for the drug and for related medical services (such as regular MRI scans), since beneficiaries usually pay 20-percent coinsurance. So, even at the "reduced price" of $28,200, beneficiaries would pay $5,640 for one year's supply of Aduhelm. At the original $56,000 price, the coinsurance would have been $11,200. Traditional beneficiaries without a Medigap policy would face the cost directly; those with a Medigap policy would see their premiums rise; and those in Medicare Advantage plans would also be responsible for cost-sharing until they reached their annual out-of-pocket maximum. All these increased expenditures would be devastating to the typical Medicare beneficiary with an average income of about $30,000. And, as noted, Aduhelm is not a cure, so patients would likely incur these costs for multiple years.

Figure 7. Potential Increase in Part B Premium

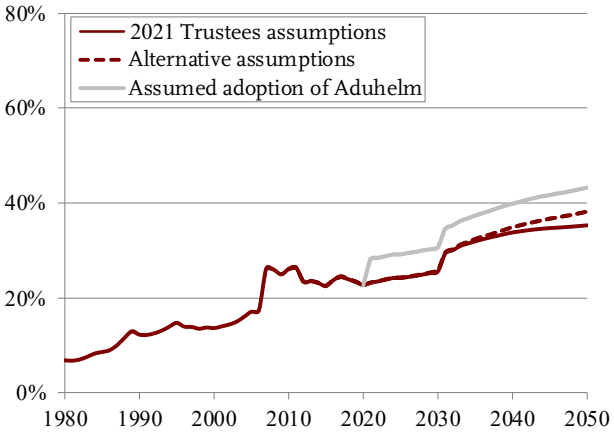


Note: The estimated increase in premiums is based on an increase in Part B drug spending of 80 percent of the total Aduhelm costs, since participants pay 20 percent of costs.
Source: Authors' calculations.

The increase in Part B premiums and coinsurance from Aduhelm would have increased average out-of-pocket costs significantly as a share of the average Social Security benefit. These costs, which now amount to about 25 percent of the average benefit, are scheduled to rise to 35 percent by 2050 under the 2021 Trustees assumptions, and to 38 percent under the alternative assumptions (see Figure 8 on the next page). If Medicare had approved Aduhelm at the original price of $56,000 and 3 million beneficiaries qualified for the drug, the projected out-of-pocket costs would equal 43 percent of the average Social Security benefit by 2050.[10] Of course, at some point patents expire and generics emerge, placing some control over the drug creator's price.

Clearly, the goal of society is to alleviate the ravages of a dreadful disease, but the Aduhelm saga has highlighted the risk to the system's finances if a valuable drug should become available and Medicare remains

Figure 8. Total SMI Out-Of-Pocket Expenses as Share of Average Social Security Benefit, 1980-2050



Note: Aduhelm contribution to out-of-pocket costs calculated using its original list price of $56,000 and a beneficiary annual co-payment of $11,200.
Sources: Authors' calculations from *Medicare Trustees Reports* (2009 and 2021); and Shatto and Clemens (2010-2021).

unable to negotiate prices. Hopefully, the Aduhelm saga will rekindle Congressional interest in giving Medicare some authority to negotiate drug prices.

Medicare and Price Negotiation

Medicare is limited in its ability to negotiate drug prices by the "noninterference clause" in the Social Security Act, which restricts the Secretary of Health and Human Services (HHS) from interfering in negotiations between drug manufacturers and drug plan sponsors. This provision means that Medicare is a price taker for drugs purchased under both Parts B and D.[11]

Medicare would actually pay more than the list price, at least in the short term. For most Part B drugs, the program reimburses providers for 106 percent of the Average Sales Price (ASP), which is the average price (inclusive of rebates) to U.S. purchasers outside the federal government. For new drugs, such as Aduhelm, where no ASP is available, Medicare pays 103 percent of the wholesale acquisition cost – that is, the list price – until ASP data are available.[12]

Several recent pieces of legislation have been introduced to allow the program to negotiate prices, at least in specific circumstances. H.R. 3, introduced in April 2021, would require the Secretary of HHS to negotiate prices on at least 50 name-brand drugs that do not have generic competitors and are among the highest in national spending or Medicare program spending. The negotiated prices would be available to both Medicare and private customers. In determining a maximum fair price, the Secretary would be required to consider research and development expenses, production and distribution costs, and existing alternatives, including their comparative effectiveness.[13] Importantly, though, a new drug with no customers like Aduhelm would not be covered under this bill.

Looking to the future, being able to negotiate the prices for a hypothetically effective version of Aduhelm could benefit program enrollees by getting them the care they need while also preserving the program's finances. As new and exciting drugs continue to be developed and released, the Medicare program should not be forced to choose between refusing treatment to needy beneficiaries or rapidly depleting both program and beneficiaries' finances.

Conclusion

The outlook for Medicare finances is considerably more favorable than it was a decade ago, and that picture persists even under the alternative projections that assume Congress phases out some of the cost controls in recent legislation. That said, Medicare does face significant financing challenges: it operates in a country with extraordinarily high health care costs; its out-of-pocket expenses take a large and growing share of Social Security benefits; and it has some serious gaps in protection.

Further, the drama around Aduhelm has clarified several issues the program faces. Since it cannot negotiate prices for the drugs it covers, Medicare faces an uncertain financial future given the possibility of drastic increases in program spending in response to new drugs. Aduhelm has shown how expensive new drugs could potentially consume huge and unexpected portions of the program's spending with little warning. Even if this particular drug never gains traction or widespread use, comparable and effective drugs for Alzheimer's or other debilitating diseases hopefully will emerge in the future. Congress needs to change the rules of the road, so that these much-needed products do not bankrupt the Medicare program or individual beneficiaries.

Endnotes

1 For example, under the Trustees assumptions, the actuaries estimate that Medicare payment rates for inpatient hospital services would fall from about 60 percent of private insurance today to just 40 percent by 2095, and Medicare physician payments would fall from about 75 percent to 25 percent of private health insurance payment rates over the same period (Shatto and Clemens, 2021).

2 The actuaries note that the use of an alternative scenario for analysis should not be construed as an endorsement by the Trustees, CMS, or the actuaries themselves.

These illustrative projections are based on the assumption that Congress modifies two provisions by: 1) phasing down the productivity adjustments prescribed for payments for hospital (and other non-physician) services; and 2) increasing physician payment rates. The alternative assumptions pertain only to HI and Part B of the SMI program; Part D, which covers prescription drugs, is unaffected.

3 Chambers, May, and Neumann (2013) examined the period 1999-2011 and found that Medicare covered all FDA drugs and biologics approved during that time and most medical devices.

4 Centers for Medicare and Medicaid Services (2022).

5 Regarding the FDA approval process, see Cavazzoni (2021), FDA (2020), and Institute for Clinical and Economic Review (2021). For more information on the Biogen trials, timeline, and decision process, see Biogen (2020), Biogen Investor Relations (2019), and Kuller and Lopez (2021).

6 Belluck (2022).

7 During the NDC process, decisions were left in the hands of the 12 Medicare Administrative Contractors. Medicaid urged CMS to cover the drug, because it must pay for almost any drug approved by the FDA. Exceptions include the ability to require generic substitutions if they exist. In the case of Aduhelm, no competitors currently exist, and Medicaid reportedly does have to cover the drug.

8 Institute for Clinical and Economic Review (2021).

9 Alzheimer's Association (2021).

10 A stipulation in the law, known as the hold-harmless provision, prevents the actual dollar amount of the Medicare premium increase from exceeding the dollar increase in the cost-of-living adjustment to Social Security benefits. Practically, this provision means that higher earners will bear a greater share of the cost of premium increases, as the dollar value of their benefit adjustment allows for higher increases in premium payments. This chart assumes that the full cost of Aduhelm spending is absorbed across the program on average, although premium out-of-pocket costs may in reality be lower due to this limit on maximum premiums for lower earners.

11 While private insurance plans do not face the same legal constraints as Medicare, they would not necessarily have much leverage to influence the price of an expensive and effective drug for a widespread health condition. In such a case, then, their customers would also likely see large premium increases.

12 Cubanski, Neuman, and Freed (2021). In some cases, Medicare pays less than these amounts for drugs. For example, the federal government's 340B program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs to health care providers at a discount, which also reduces Medicare payments for these drugs as well.

13 An earlier version of this bill passed the House of Representatives in 2020, but stalled in the Senate. In addition to H.R. 3, a similar bill is pending in both houses that would simply require the Medicare program to negotiate the prices it pays for covered drugs. Estimates of the savings of such legislation from the Congressional Budget Office have been in the range of $448 billion to $530 billion over 10 years (Cubanski, Neuman, and Freed, 2021). These cost savings would significantly reduce Medicare beneficiary premiums and cost-sharing. At the same time, the legislation would lower revenues for drug manufacturers and could lead to higher prices in other countries and a lag in the introduction in new drugs.

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