Quantifying Impact of Accelerated Approval Drugs on Medicaid Spending:

An Update through 2020 and State-Level Analysis

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ABSTRACT:

State policymakers are seeking the Centers for Medicare & Medicaid Services (CMS) approval to limit coverage of drugs approved through the Food and Drug Administration's (FDA) accelerated approval pathway. The pathway is designed to speed availability of medications for serious or life-threatening conditions with limited to no treatment options. Because of concerns over these drugs' perceived level of impact on Medicaid spending, several states and the federal advisor Medicaid and CHIP Payment and Access Commission (MACPAC) are targeting these therapies for coverage exclusions, increases in mandatory rebates, or both. The analysis described in this paper estimated the impact accelerated approved drugs had on Medicaid spending growth both nationally and on a state-by-state basis (2007 to 2020). The analyses demonstrates that on both a national and state level, accelerated approval drugs accounted for approximately one percent or less of annual Medicaid spending consistently, year over year. In 2020, across all states, accelerated approval drugs consumed well less than one dollar for every one hundred dollars of total Medicaid spending, and similarly contributed a minimal amount to Medicaid spending growth. These data support that accelerated approval drugs are not driving Medicaid spending and current policy proposals are misguided. Additionally, to meet President Biden Administration's goal of reducing health disparities and achieving health equity, CMS and state Medicaid programs should ensure access to accelerated approval drugs for seriously ill Medicaid beneficiaries.

INTRODUCTION

Created in 1992, the accelerated approval pathway expedites FDA's rigorous review of safety and efficacy to facilitate access for patients whose lives depend on timely access to therapies. In the 30 years since the pathway's inception, the FDA has approved more than 270 drugs or biologics via accelerated approval, providing new, innovative treatment options, and hope for patients and their families. Millions of patients have benefitted significantly from therapies approved through accelerated approval–initially people diagnosed with HIV/AIDS, then people with various cancers, and today people with several rare diseases.

These medicines are reviewed and approved using the FDA's same rigorous scientific standards as with traditional approval. These standards are applied to different clinical endpoints to expedite access for seriously ill patients. Despite that, both private and public payers, including several state Medicaid programs, have been moving to avoid or severely restrict coverage of accelerated approval medicines, directly undermining the purpose of the pathway and federal patient protections required of Medicaid.

Since expressed reluctance to cover these medicines includes statements of financial concerns about the costs of accelerated approval drugs without citing supporting data, this analysis included calculating the total costs of accelerated approval medicines to Medicaid from 2007 through 2020 nationally and examining state-specific Medicaid spending. The analysis confirms that these medicines comprised less than one percent of total Medicaid annual spending nationally with no significant increase over this timeframe. Among the states and examining drug spend in greater detail, in 2020 for all states and the District of Columbia spending on accelerated approval drugs accounted for less than one percent of their overall Medicaid spending. States making assertions about costs in seeking permission to avoid federal coverage requirements should reconsider as this analysis shows accelerated approval drugs have a de minimus impact on state Medicaid spending.

FDA's Accelerated Drug Approval Program

The Food and Drug Administration has developed five distinct expedited programs for hastening access to safe and efficacious drugs for serious or life-threatening conditions: fast track designation, breakthrough therapy designation, Regenerative Medicine Advanced Therapy (RMAT) designation, priority review designation, and the accelerated approval pathway.[1] Importantly, none of these programs compromises FDA's long-standing standards for safety and efficacy. Of the five, only accelerated approval provides an alternative pathway to approval. Given recent and ongoing proposals from states—Massachusetts,[2] Tennessee,[3] and Oregon[4]—as well as MACPAC[5] that focus on accelerated approval drugs as a cost driver, this analysis focuses

exclusively on drugs approved using the accelerated approval pathway compared to other components of Medicaid spending.

The accelerated approval pathway allows drugs for serious conditions that fill an unmet medical need to be approved based on a surrogate or intermediate clinical endpoint that is reasonably likely to predict a clinical benefit.[6] Studies demonstrating a drug's effect on a surrogate or intermediate clinical endpoint must meet standards demonstrating the study is "adequate and well controlled."[7] The FDA created the accelerated approval pathway 30 years ago in response to the HIV/AIDS epidemic where the surrogate endpoint of immune cell response was used to predict survival. Using a surrogate endpoint reasonably likely to predict long-term clinical benefits, which could otherwise take years to measure, saves valuable time for patients whose critical illness does not afford time to wait. Congress first codified the accelerated approval pathway in 1992[8] and then modernized and enhanced it in 2012[9] to expand the pathway's use beyond treatments for HIV/AIDS or oncology to include rare diseases.

In weighing accelerated approval applications, the FDA must also consider the severity, rarity, or prevalence of the condition treated and the availability or lack of existing treatments.[7] Under accelerated approval, the FDA's continued approval is contingent on the sponsor's completion of post-marketing study to assess clinical benefit, referred to as a confirmatory study. A streamlined withdrawal process exists for drugs where benefit is not confirmed, drugs are found to be unsafe, or the sponsor fails to conduct confirmatory trials.[7]

Those who argue that the post-market confirmatory study requirement of the process is broken ignore the fact that nearly 80 percent of accelerated approval drugs approved prior to 2020 have been converted to traditional approval, and of the remaining, confirmatory studies are underway.[10] The fact that all do not convert reflects the risk/benefit analysis FDA makes based on the severity of the condition and the availability of other treatment options. According to Janet Woodcock, Director of FDA's Center for Drug Evaluation and Research:

> [W]e're really talking about what is the cost of failing to approve an effective therapy versus the cost of making a mistake and approving a therapy that is not effective. There may be thousands of lives to be lost if you delay for another three years or whatever it takes to get more definitive evidence. . . People say they want placebo-controlled trials, but I always ask them would you be willing to die to give a p-value?[11]

Several payers have singled out accelerated approval drugs for coverage limits and exclusions, arguing that accelerated approval drugs have insufficient evidence and are "experimental", despite these drugs meeting FDA's safety and efficacy standards. For example, Medicaid agencies in Tennessee,[3] Massachusetts,[2] and Oregon[4] have petitioned CMS for the ability to restrict coverage of accelerated approval drugs, citing cost concerns and questioning FDA's approval. The Oregon Health Authority's request is pending with CMS.[4]

Specifically, TennCare's Medicaid proposal states "much of the current volatility in prescription drug prices is driven by new drugs coming to market through the FDA's accelerated approval pathway . . . [though] many of them have not yet demonstrated actual clinical benefit."[3] In its application, the Oregon Health Authority conflated spending on accelerated approval drugs with specialty medicines in defense of its request: "New drugs approved under the FDA's accelerated approval pathway tend to be specialty medications that represent a significant portion of pharmacy expenditures."[4] However, neither state supported its costs claims with data. More states may seek similar waivers. As a Kaiser Family Foundation study[12] indicates, a majority of states are developing strategies related to new high-cost therapies, referencing those approved on an accelerated pathway.

Given the serious implications these waiver requests have on patient access, FDA authority, and the accelerated approval pathway, understanding the actual extent to which spending on accelerated approval drugs contributes to total Medicaid spending and to overall Medicaid spending growth as a matter of national and state policy is important. The analysis below examines these issues on both national and state levels.

METHODS AND DATA

Accelerated Approval Drugs

Accelerated approval drugs, date of approval, and date of conversions to traditional approval where applicable were identified from the FDA Center for Drug Evaluation and Research (CDER) drug and biologic accelerated approvals document.[13] These data informed calculations of the Medicaid amount reimbursed for each year. Total Medicaid drug reimbursements for the year were also tabulated using CMS State Drug Utilization Data.[14]

Because most accelerated approval drugs convert to traditional approval, the analysis takes into account conversion status and categorizes the spending contribution from an accelerated approval drug to prescription drugs generally once a drug completed confirmatory trials and FDA changed its approval status to regular approval. Importantly, since drug rebate information for specific drugs is unavailable, the analysis for accelerated approval drugs were developed using pre-rebate drug spending. Total Medicaid spending and overall increases in Medicaid spending are net of drug rebates. Accordingly, percentages of spending and spending increases associated with accelerated approval drugs are higher than they would be if rebate information on these medicines were available.

For national drug spending, the data source reports drugs dispensed at the outpatient level and includes deductions for rebates. All the data on accelerated approval drug spending relies upon a more specific data set that includes accelerated approval drug, pre-rebate spending reported by states that includes both outpatient level and physician-administered medications.

National Spending Estimates

The national analysis examines both total Medicaid spending from 2007-2020 and growth in Medicaid spending over the same period. For those data, the national analysis estimates the correlation of Medicaid spending to each source of care (hospital services, physician and clinic services, nursing home, home health, outpatient prescription drugs overall, and covered accelerated approval drugs specifically). Data on Medicaid spending for 2007 were collected from the Medicaid Budget and Expenditure System/State Children's Health Insurance Program Budget and Expenditure System (MBES/CBES) expenditure reports and data for years 2010-2020 were collected from Medicaid and CHIP Payment and Access Commission (MACPAC) Medicaid expenditure reports. These data also include Medicaid-specific spending on hospital care, physician and clinic services, nursing homes, home health, and outpatient prescription drugs among other covered services.[15] The national estimates for total drug spending account for prescription drug rebates, which in 2017 represented 55 percent of state Medicaid drug spending.[16] Drug rebates are reported by states in the aggregate to CMS, so delineating drug rebates for accelerated approval drugs specifically is not possible. Accordingly, drug spending on accelerated approval drugs does not deduct drug rebates from that spending and is larger than the amount actually spent. National spending data includes Medicaid managed care as well as fee-for-service spending for each of source of care (hospital services, physician and clinic services, nursing home, home health, and outpatient prescription drugs).

State Spending Estimates

Given the significant differences in state Medicaid programs in terms of populations covered, managed care penetration, policies relating to prescription drug carve-outs, the size of a state's Medicaid budget, and other factors, examining state-level experiences with accelerated approval drug spending is important to consider. National averages may conceal large variations among the states.

Though state data as reported by CMS includes both gross drug spending and drug spending net of total rebates, rebates on specific medicines or for accelerated approval medicines as a group is not available. Accordingly, this analysis considers accelerated approval drug spending without consideration of rebates.

Most drugs approved using the accelerated approval pathway convert to traditional FDA approval over time.[10] The analysis of state-level spending provides spending totals that account for the conversion of drugs to traditional FDA approval during the 2007-2020 timeframe. State-level data includes reporting of fee-for-service and managed care spending that includes spending on hospital care, physician visits, and prescription drugs.

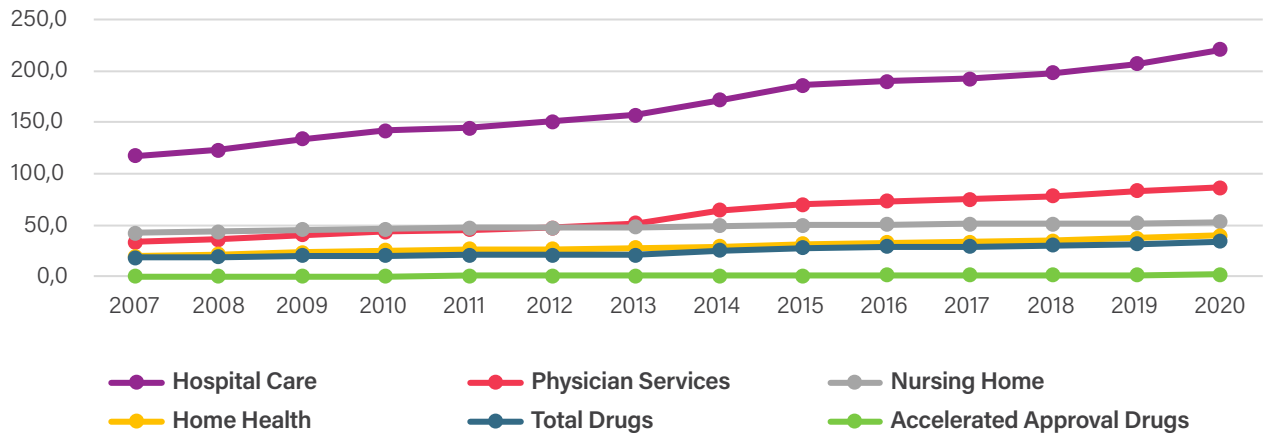
We also provide examples from Massachusetts, Tennessee, and Oregon to illustrate state-specific experiences with spending on accelerated approval drugs.

RESULTS

National Spending Trends

Exhibit 1 presents data on the distribution of national Medicaid spending by source of treatment from 2007 to 2020 from the CMS National Health Expenditure Data. Hospital spending accounts for the largest share of Medicaid spending, though hospital spending as a percentage of total declined from 36 percent in 2007 to under a third in 2020. Physician and clinic services accounted for a growing share of Medicaid spending, increasing from 10 percent in 2007 to 13 percent by 2020. Total outpatient drug spending accounted for 5.6 percent of Medicaid spending in 2007 declining slightly to 5.1 percent in 2020, net of drug rebates. Accelerated approval drugs remained low throughout the period covered, represent pre-rebate spending, and include both outpatient dispensed and provider-administered medications.

Exhibit 1: Distribution of Medicaid Spending by Source and By Accelerated Drug Approval Status, 2007-2020



Source: See Data and Methods

More specifically, in 2007, spending on accelerated approval drugs, before deducting for rebates, accounted for 0.1 to 0.3 percent of total Medicaid spending rising to 0.1 to 0.5 percent by 2010 and remaining relatively constant through 2020.

Exhibit 2 examines each source of care and its contribution to the overall growth in Medicaid spending 2007-2020. Over the entire period, hospital spending accounted for almost 30 percent of the overall growth in Medicaid. Over the same period, increased spending on outpatient prescriptions drugs net of rebates accounted for 5 percent of the growth in Medicaid spending. This estimate does not include provider-administered therapies, so the overall contribution of all prescription drugs to spending increases will be higher.

Exhibit 2: Contribution to Overall Growth in Medicaid Spending by Source of Care and Accelerated Drug Approval Status, 2007-2020

Year	Hospital Care	Physician and Clinic Services	Prescription Drugs (Outpatient, Post-rebate)	Nursing Home	Home Health	Pre-Rebate Accelerated Approval Drugs
2007-2020	30.0%	15.4%	5.0%	3.2%	6.0%	0.5%

Notes: A variety of smaller contributors not illustrated account for the remaining percentage of spending increases. Rebate information on accelerated approval drugs is not available and are not included. Spending on outpatient prescription drugs generally does include rebates.

Spending on accelerated approval drugs accounts for a small fraction of the overall growth in Medicaid spending. Between 2007 and 2020, increased pre-rebate spending on these medications amounted to 0.5 percent of the growth in overall Medicaid spending. Since rebates account for roughly half of gross Medicaid drug spending, the actual contribution of accelerated approval drugs as a percent of the growth in total Medicaid spending is lower.

State Spending Trends

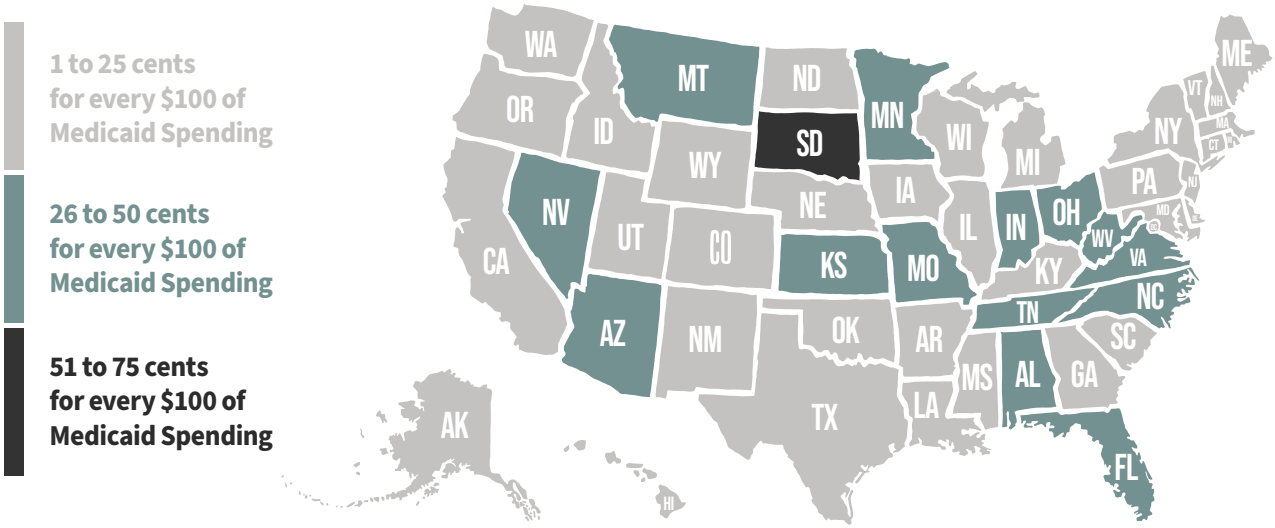
Examining state experiences over the same timeline revealed consistent results compared with national averages. Importantly, state-level data provides more detail, not only because the data describe individual state experiences, but also because they have more detail on total drug spending.

State experiences closely paralleled the national averages without significant variation. As shown in **Exhibit 3**, state spending on accelerated approval drugs was well under one percent of total spending for 2020 without accounting for any savings from rebates. In 2020, Rhode Island experienced the smallest contribution of pre-rebate spending on accelerated approval drugs toward total Medicaid spending at 0.03 percent. South Dakota experienced the highest percentage at 0.72 percent. Accounting for drug rebates would reduce those contributions even further.

Exhibit 3: Pre-Rebate Spending on Accelerated Approval Drugs as Percentage of Total Medicaid Spending 2020

ACCELERATED APPROVAL DRUGS ACCOUNT FOR WELL UNDER $1 FOR EVERY $100 SPENT IN MEDICAID IN ALL STATES.

2020 Pre-Rebate Spending on Accelerated Approval Drugs



Source: See Data and Methods. State-specific details are available in the Appendix, Exhibit B. Note that total Medicaid spending is net of rebates, but spending on accelerated approval drugs does not account for rebates since that information is not available.

We also estimated the contribution accelerated approval drugs have made to overall Medicaid spending increases 2007-2020, as shown in **Table 1**. This analysis compares how much Medicaid spending increased over the period and how much spending on accelerated approval drugs have contributed to that increase. We found that spending on accelerated approval drugs accounted for less than 1 percent of the overall increase in Medicaid spending for the majority of states. For only two states, Alabama, and South Dakota, did spending on accelerated approval drugs contribute to the overall Medicaid spending increases by more than 1 percent.

Since this analysis of spending on accelerated approval drugs does not include rebates, these estimates actually overstate these drugs' overall contribution to Medicaid spending and to Medicaid spending increases over time.

Table 1: Accelerated Approval Drugs Percentage Contribution to Overall Increases in Medicaid Spending 2007 – 2020

State	2007-2020	State	2007-2020
Kentucky	0.08%	Delaware	0.36%
Rhode Island	0.08%	New Jersey	0.36%
District of Columbia	0.11%	Mississippi	0.37%
North Dakota	0.12%	Nevada	0.37%
Wyoming	0.12%	Hawaii	0.40%
Colorado	0.14%	Illinois	0.41%
Alaska	0.15%	Maine	0.41%
Oregon	0.15%	New Hampshire	0.41%
Arkansas	0.17%	Texas	0.41%
New Mexico	0.19%	Montana	0.43%
Maryland	0.20%	Georgia	0.46%
South Carolina	0.20%	Nebraska	0.46%
Vermont	0.20%	West Virginia	0.52%
Iowa	0.21%	Arizona	0.59%
Utah	0.21%	Minnesota	0.59%
Wisconsin	0.22%	North Carolina	0.65%
California	0.26%	Ohio	0.69%
Louisiana	0.26%	Missouri	0.71%
Washington	0.26%	Indiana	0.73%
Massachusetts	0.27%	Tennessee	0.77%
Idaho	0.28%	Virginia	0.78%
Pennsylvania	0.29%	Florida	0.81%
Connecticut	0.31%	Kansas	0.83%
New York	0.32%	Alabama	1.30%
Oklahoma	0.32%	South Dakota	2.09%
Michigan	0.33%		

Source: See Data and Methods

States Seeking to Waive Medicaid Coverage Requirements

Taking a closer look at Medicaid spending in Massachusetts, Tennessee, and Oregon, which have sought CMS waivers to exclude coverage for accelerated approval drugs, citing budget impact concerns, yields similar results. As **Table 2** demonstrates, over time, the percentage of total spending on accelerated approval drugs in each state has remained consistently low. In both Oregon and Massachusetts, spending on accelerated approval drugs, not including drug rebates, remained steady at 0.1 percent of total spending, 2010, 2015, and 2020. Tennessee

experienced slight increases over these time periods, from 0.1 percent of spending in 2010 to 0.3 percent of spending in 2020. According to MACPAC, in 2020 across all drugs, rebates reduced gross drug spending by 55 percent nationally, 78 percent in Massachusetts, 45 percent in Oregon, and 69 percent in Tennessee.[18]

Table 2: Pre-Rebate Spending on Accelerated Approval Drugs as a Percentage of Overall Medicaid Spending for Massachusetts, Oregon, and Tennessee, 2010, 2015, 2020

	2010	2015	2020
State	AA Drugs % of Total Medicaid Spending	AA Drugs % of Total Medicaid Spending	AA Drugs % of Total Medicaid Spending
Massachusetts	0.1%	0.1%	0.1%
Oregon	0.1%	0.1%	0.1%
Tennessee	0.1%	0.2%	0.3%

Source: See Methods and Data

DISCUSSION

Unlike the federal government, governors and state legislatures are responsible for spending within balanced budgets. Similar to commercial payers, states are concerned about rising health care costs. The perennial focus on lowering health care spending, the current political debate about prescription drug costs, and the slow pace of federal drug pricing legislation has spurred states into action. The negative impact COVID-19 is having on state economies and budgets has added urgency to cut spending. Several states have pursued a variety of policies to manage Medicaid drug spending, including efforts to void federal statutory protections and exclude coverage of accelerated approval drugs. Massachusetts (MassHealth), Tennessee (TennCare), and Oregon Medicaid programs have sought specific federal permission to either exclude or restrict access to accelerated approval drugs.

In support of its request to CMS, TennCare sought flexibility to exclude accelerated approval medicines to "avoid exorbitant spending on high-cost drugs that are not medically necessary, which do not provide additional clinical benefit, and/or which actually pose health risks for members when prescribed without sufficient medical evidence…".[3] MassHealth sought to exclude from its closed formulary drugs with "limited or inadequate clinical efficacy," defined to include drugs where "only surrogate endpoints have been reported."[2] CMS ultimately denied Massachusetts's request while Tennessee's request awaits a final verdict under the Biden Administration. CMS has expressed willingness to consider a request from Massachusetts to exclude coverage if they would be willing to forego the mandatory rebates for all drugs and negotiate with individual drug companies. Though TennCare's request to include coverage restrictions for accelerated approval medicines was approved by the Trump Administration in

January 2021,[17] the Biden Administration reopened the comment period and next steps remain uncertain. Oregon's request to CMS is pending.[4]

Denying Medicaid coverage undercuts the purpose of the accelerated approval pathway and the Medicaid Drug Rebate Program (MDRP), through which Congress sought to provide patients with rapid access to drugs treating serious, often fatal, medical conditions and to provide Medicaid beneficiaries coverage to drugs for which companies provide a mandatory minimum 23.1 percent discount. The MDRP actually generates rebates that reduce Medicaid drug costs by more than half.[19] By comparison, rebates in the Medicare Part D program, which allows payors significant discretion in establishing formularies, are less than 25 percent.[20] Allowing exceptions to the MDRP could open it up to further changes that weaken Medicaid's ability to provide affordable access to therapeutics for serious unmet medical needs that FDA's accelerated approval pathway was designed to address.

Moreover, regardless of the state in consideration, pre-rebate spending on accelerated approval drugs 2007-2020 was less than one percent of total Medicaid spending. Accounting for rebates would reduce those contributions further. These medicines are neither a primary driver of state Medicaid spending or spending growth, nor an effective target for reform.

Nevertheless, the pressures on state and federal budgets resulting from the COVID-19 pandemic and uncertain prospects for federal drug pricing legislation will increase states' demand for drug pricing reform, including MDRP flexibility for Medicaid formularies. CMS's recent National Coverage Determination establishing different coverage criteria for Alzheimer's treatments based on accelerated approval and traditional FDA approval status sets a dangerous precedent as Medicare is the largest payer of care and is a bell weather for state Medicaid programs and private payers.[21] Stakeholders are watching to see if CMS will take similar action with Oregon Medicaid's 1115 waiver request to restrict patient access to accelerated approval drugs or if CMS will uphold FDA's authority as the sole determiner of a drug's safety and efficacy and maintain the requirements of the Medicaid drug rebate program.

To preserve and strengthen the accelerated approval pathway to ensure patients have access to medicines for serious or life-threatening medical conditions, the FDA should use its authority to enforce the conditions of accelerated approval and work with manufacturers to increase the rigor of interactions and monitoring from study design through completion of post-approval confirmatory studies. Collection and consideration of real-world evidence in supporting post-approval commitments would boost understanding of drug effectiveness within real-world settings while potentially addressing some uncertainties held by payors. By exercising its existing post-approval authority. Adopting these policies will bolster confidence in the accelerated approval program and prevent payers and other critics from undermining FDA authority by raising doubts as to its clinical standards required to demonstrate safety and efficacy.

Limitations

The lack of detailed information on Medicaid rebates obscures information about rebates specific to accelerated approval drugs and other on-patent medicines. That limits the analysis and ability to quantify how rebates relating to both accelerated approval and other on-patent medicines affect net drug spending. During the study period, Medicaid also underwent significant changes largely driven by Medicaid expansion as a part of the Affordable Care Act. Nationally after 2010, Medicaid enrollment increased by an average of 3.9 percent per year. Though spending on all categories of care increased during Medicaid expansion, the percentage of total Medicaid spending attributable to accelerated approval drugs remained stable, 2010-2020.

State variations based on decisions to expand Medicaid and other eligibility criteria, overall Medicaid budgets, state demographics and health status, and a variety of other factors make comparing state Medicaid programs challenging. Smaller Medicaid programs may experience greater variations in spending, for example, than larger programs.

CMS's recent National Coverage Determination differentiating Medicare coverage for a therapeutic class of Alzheimer's disease treatments based on accelerated approval status, though not directly applicable to Medicaid, may have significant implications for Medicaid, other payors, and for accelerated approval drugs in general. The nature of those implications is unclear and not included in the analysis described above.

CONCLUSION

Medicaid programs looking for ways to lower drug costs will not find success in severely restricting coverage or eliminating coverage altogether for accelerated approval drugs. This analysis of Medicaid claims data from 2007 to 2020 shows that such efforts and the rationale used are misguided. Regardless of the state under consideration, in 2020 pre-rebate Medicaid spending on accelerated approval drugs accounted for less than one percent of overall Medicaid spending, while representing the only treatment options available for many beneficiaries with serious or life-threatening conditions. During the COVID-19 pandemic, people living with serious conditions face increased vulnerability. This situation places paramount importance on facilitating access to treatments for serious or life-threatening conditions.

To enhance the pathway, greater enforcement of FDA authority on confirmatory studies could reinforce confidence in the rigor of accelerated approval. Limiting Medicaid coverage for accelerated approval drugs, however, would appear to have a *de minimus* impact on spending and a devastating impact on patients benefiting from these treatments.

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APPENDIX

Exhibit A: Total Medicaid Spending, 2007 – 2020 (millions of dollars)

	2007		2010		2015		2020	
State	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs
Alabama	4415	0	4994	8.2	5496	17.5	6311	24.7
Alaska	1031	0.6	1303	1.3	1535	0.8	2189	2.3
Arizona	6795	n/a	9530	5.4	10895	13.7	14672	46.5
Arkansas	3201	2	4071	5.3	5853	3.5	7080	8.5
California	38592	33	45535	72.2	90614	152.6	103887	202.3
Colorado	3057	2.3	4194	3.8	7686	18.4	10118	12.2
Connecticut	4397	0.8	5674	6.7	7597	15.7	8828	14.6
Delaware	1052	0.2	1344	1.1	2024	2.6	2458	5.2
District of Columbia	1457	0.1	1900	0.2	2521	0.8	3370	2.2
Florida	14059	11.7	17877	37.1	22023	69.4	25934	108.5
Georgia	7236	6.5	8072	16.6	10245	25.3	11824	27.6
Hawaii	1163	0.2	1428	0.9	2077	0.8	2432	5.3
Idaho	1151	0.4	1430	0.9	1820	2.3	2615	4.5
Illinois	13097	6.3	15891	29.6	17962	42.2	23323	48.3
Indiana	5327	3.4	6233	15.5	9722	28.4	14782	72.1
Iowa	2576	1.3	3153	3.6	4672	6.8	5963	8.3
Kansas	2288	1.1	2538	4.6	3194	2.9	4057	15.7
Kentucky	4691	4.5	5670	7.4	9666	7.1	12191	10.5
Louisiana	5376	2.5	6918	10.1	8152	9.5	12906	22.2
Maine	2082	0.5	2405	1.6	2620	1.6	3355	5.7
Maryland	5667	0.6	7265	5.8	9882	9.3	12426	14.3
Massachusetts	10636	2.6	12224	8.2	16164	17	18928	24.9
Michigan	9619	2.4	12035	8.7	16561	33.2	19780	35.9
Minnesota	6674	0.5	7855	4.7	11295	15	14365	45.8
Mississippi	3383	1	4217	5.6	5314	5.3	5769	9.9
Missouri	6786	0.6	8312	12	9869	19.3	11335	32.7
Montana	769	0.2	984	1.8	1207	2.4	2094	5.9
Nebraska	1609	0.3	1710	0.7	1974	0.9	2459	4.1
Nevada	1298	0.6	1588	2.6	3266	6.1	4315	11.8
New Hampshire	1224	0.2	1391	2.7	1841	1.2	2371	4.8

Exhibit A: Total Medicaid Spending, 2007 – 2020 (millions of dollars)

	2007		2010		2015		2020	
State	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs	Total	Pre-Rebate Accel. Appr. Drugs
New Jersey	9287	5.1	10677	10.4	14830	25.8	17476	34.6
New Mexico	2700	0	3581	2.2	5083	3.4	6584	7.2
New York	44821	27	51791	59.4	59681	74	72816	117.7
North Carolina	9898	5.3	10892	19.4	13878	30.9	15608	42.5
North Dakota	534	0.2	719	0.4	549	0.3	1374	1.2
Ohio	13279	2.2	15585	12.6	22284	33.7	26187	90.9
Oklahoma	3450	2.6	4089	7	4948	12.2	5174	8
Oregon	3119	0.3	4269	2.4	8569	7.6	11196	12.5
Pennsylvania	16656	2.1	19500	12.1	24100	45.9	36002	58.6
Rhode Island	1778	0	1995	0.3	2729	0.2	2961	1
South Carolina	4171	6.3	5143	8.8	6028	10	7032	12
South Dakota	648	0.1	840	0.5	861	0.5	982	7.1
Tennessee	7483	3.9	8795	12.7	9507	16.6	12258	40.8
Texas	21058	15.3	27431	32.8	36148	44.8	43298	105.4
Utah	1486	0.2	1805	2.7	2300	1.3	3262	4
Vermont	1065	0	1254	1.7	1666	1.3	1795	1.5
Virginia	5151	1	6661	4.1	8511	16.6	13993	69.9
Washington	6312	1.8	7488	6.8	11075	11.7	14578	23.5
West Virginia	2250	0.5	2650	6.1	3836	6.7	4295	11.1
Wisconsin	5057	1.7	6720	8	8212	14.3	9846	12.1
Wyoming	461	0	570	0.3	621	0.3	692	0.3

Exhibit B: Percentage of Total Medicaid Spending Accounted for by Pre-Rebate Spending on Accelerated Approval Drugs by State and Year Noted

	2007	2010	2015	2020
State	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs
Alabama	0.00%	0.16%	0.32%	0.39%
Alaska	0.06%	0.10%	0.05%	0.10%
Arizona	0.00%	0.06%	0.13%	0.32%
Arkansas	0.06%	0.13%	0.06%	0.12%
California	0.09%	0.16%	0.17%	0.19%
Colorado	0.07%	0.09%	0.24%	0.12%
Connecticut	0.02%	0.12%	0.21%	0.17%
Delaware	0.02%	0.08%	0.13%	0.21%
District of Columbia	0.00%	0.01%	0.03%	0.07%
Florida	0.08%	0.21%	0.32%	0.42%
Georgia	0.09%	0.21%	0.25%	0.23%
Hawaii	0.01%	0.07%	0.04%	0.22%
Idaho	0.03%	0.06%	0.13%	0.17%
Illinois	0.05%	0.19%	0.24%	0.21%
Indiana	0.06%	0.25%	0.29%	0.49%
Iowa	0.05%	0.11%	0.15%	0.14%
Kansas	0.05%	0.18%	0.09%	0.39%
Kentucky	0.10%	0.13%	0.07%	0.09%
Louisiana	0.05%	0.15%	0.12%	0.17%
Maine	0.02%	0.07%	0.06%	0.17%
Maryland	0.01%	0.08%	0.09%	0.11%
Massachusetts	0.02%	0.07%	0.11%	0.13%
Michigan	0.03%	0.07%	0.20%	0.18%
Minnesota	0.01%	0.06%	0.13%	0.32%
Mississippi	0.03%	0.13%	0.10%	0.17%
Missouri	0.01%	0.14%	0.20%	0.29%
Montana	0.02%	0.18%	0.20%	0.28%
Nebraska	0.02%	0.04%	0.05%	0.17%
Nevada	0.04%	0.16%	0.19%	0.27%
New Hampshire	0.01%	0.19%	0.06%	0.20%
New Jersey	0.05%	0.10%	0.17%	0.20%
New Mexico	0.00%	0.06%	0.07%	0.11%
New York	0.06%	0.11%	0.12%	0.16%

Exhibit B: Percentage of Total Medicaid Spending Accounted for by Pre-Rebate Spending on Accelerated Approval Drugs by State and Year Noted

	2007	2010	2015	2020
State	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs	Pre-Rebate Accel. Appr. Drugs
North Carolina	0.05%	0.18%	0.22%	0.27%
North Dakota	0.03%	0.05%	0.06%	0.09%
Ohio	0.02%	0.08%	0.15%	0.35%
Oklahoma	0.07%	0.17%	0.25%	0.16%
Oregon	0.01%	0.06%	0.09%	0.11%
Pennsylvania	0.01%	0.06%	0.19%	0.16%
Rhode Island	0.00%	0.01%	0.01%	0.03%
South Carolina	0.15%	0.17%	0.17%	0.17%
South Dakota	0.01%	0.06%	0.06%	0.72%
Tennessee	0.05%	0.14%	0.17%	0.33%
Texas	0.07%	0.12%	0.12%	0.24%
Utah	0.01%	0.15%	0.05%	0.12%
Vermont	0.00%	0.13%	0.08%	0.08%
Virginia	0.02%	0.06%	0.19%	0.50%
Washington	0.03%	0.09%	0.11%	0.16%
West Virginia	0.02%	0.23%	0.18%	0.26%
Wisconsin	0.03%	0.12%	0.17%	0.12%
Wyoming	0.00%	0.04%	0.04%	0.04%

Exhibit C: Percent of Increase in Medicaid Spending Accounted for by Pre-Rebate Spending on Accelerated Approval Drugs, 2007 – 2020

State	2007-2010	2010-2015	2015-2020	2007-2020
Alabama	1.4%	1.9%	0.9%	1.3%
Alaska	0.2%	-0.2%	0.2%	0.1%
Arizona	n/a	0.6%	0.9%	n/a
Arkansas	0.4%	-0.1%	0.4%	0.2%
California	0.6%	0.2%	0.4%	0.3%
Colorado	0.1%	0.4%	-0.3%	0.1%
Connecticut	0.5%	0.5%	-0.1%	0.3%
Delaware	0.3%	0.2%	0.6%	0.4%
District of Columbia	0.0%	0.1%	0.2%	0.1%
Florida	0.7%	0.8%	1.0%	0.8%
Georgia	1.2%	0.4%	0.1%	0.5%

Exhibit C: Percent of Increase in Medicaid Spending Accounted for by Pre-Rebate Spending on Accelerated Approval Drugs, 2007 – 2020

State	2007-2010	2010-2015	2015-2020	2007-2020
Hawaii	0.3%	0.0%	1.3%	0.4%
Idaho	0.2%	0.4%	0.3%	0.3%
Illinois	0.8%	0.6%	0.1%	0.4%
Indiana	1.3%	0.4%	0.9%	0.7%
Iowa	0.4%	0.2%	0.1%	0.2%
Kansas	1.4%	-0.2%	1.5%	0.8%
Kentucky	0.3%	0.0%	0.1%	0.1%
Louisiana	0.5%	0.0%	0.3%	0.3%
Maine	0.4%	0.0%	0.6%	0.4%
Maryland	0.3%	0.1%	0.2%	0.2%
Massachusetts	0.3%	0.2%	0.3%	0.3%
Michigan	0.3%	0.5%	0.1%	0.3%
Minnesota	0.4%	0.3%	1.0%	0.6%
Mississippi	0.6%	0.0%	1.0%	0.4%
Missouri	0.7%	0.5%	0.9%	0.7%
Montana	0.8%	0.3%	0.4%	0.4%
Nebraska	0.4%	0.1%	0.7%	0.5%
Nevada	0.7%	0.2%	0.5%	0.4%
New Hampshire	1.5%	-0.3%	0.7%	0.4%
New Jersey	0.4%	0.4%	0.3%	0.4%
New Mexico	0.3%	0.1%	0.3%	0.2%
New York	0.5%	0.2%	0.3%	0.3%
North Carolina	1.4%	0.4%	0.7%	0.7%
North Dakota	0.1%	0.0%	0.1%	0.1%
Ohio	0.5%	0.3%	1.5%	0.7%
Oklahoma	0.7%	0.6%	-1.9%	0.3%
Oregon	0.2%	0.1%	0.2%	0.2%
Pennsylvania	0.4%	0.7%	0.1%	0.3%
Rhode Island	0.1%	0.0%	0.3%	0.1%
South Carolina	0.3%	0.1%	0.2%	0.2%
South Dakota	0.2%	0.0%	5.4%	2.1%
Tennessee	0.7%	0.5%	0.9%	0.8%
Texas	0.3%	0.1%	0.8%	0.4%
Utah	0.8%	-0.3%	0.3%	0.2%
Vermont	0.9%	-0.1%	0.2%	0.2%
Virginia	0.2%	0.7%	1.0%	0.8%
Washington	0.4%	0.1%	0.3%	0.3%

Exhibit C: Percent of Increase in Medicaid Spending Accounted for by Pre-Rebate Spending on Accelerated Approval Drugs, 2007 – 2020

State	2007-2010	2010-2015	2015-2020	2007-2020
West Virginia	1.4%	0.1%	0.9%	0.5%
Wisconsin	0.4%	0.4%	-0.1%	0.2%
Wyoming	0.2%	0.0%	0.0%	0.1%

Exhibit D: Pre-Rebate Accelerated Approval Drug Spending as Percentage of Pre-Rebate, Overall Drug Spending by State by Noted Year

State	2007	2010	2015	2020
Alabama	0.00%	1.70%	2.80%	3.10%
Alaska	1.00%	1.00%	1.10%	1.60%
Arizona	n/a	1.10%	1.40%	3.10%
Arkansas	0.90%	1.70%	0.90%	2.20%
California	1.20%	1.90%	2.10%	2.60%
Colorado	1.10%	1.50%	2.30%	1.10%
Connecticut	0.60%	1.30%	1.40%	1.10%
Delaware	0.70%	0.90%	1.20%	2.30%
District of Columbia	0.50%	0.30%	0.60%	0.90%
Florida	1.30%	2.50%	2.60%	3.60%
Georgia	1.80%	2.60%	2.30%	2.30%
Hawaii	0.50%	0.40%	0.10%	2.80%
Idaho	0.40%	0.80%	1.30%	1.40%
Illinois	1.20%	2.10%	3.10%	2.20%
Indiana	1.10%	2.10%	2.50%	3.80%
Iowa	0.70%	1.50%	1.50%	1.80%
Kansas	1.10%	2.60%	1.10%	5.10%
Kentucky	1.00%	1.10%	1.00%	0.70%
Louisiana	0.50%	1.20%	1.20%	1.30%
Maine	0.30%	0.90%	0.70%	1.70%
Maryland	0.30%	1.20%	0.90%	1.10%
Massachusetts	1.10%	1.20%	1.40%	1.50%
Michigan	0.60%	1.10%	2.00%	1.60%
Minnesota	0.30%	1.20%	1.60%	4.10%
Mississippi	0.50%	1.70%	1.00%	2.20%
Missouri	1.20%	1.30%	1.60%	2.70%
Montana	0.30%	2.90%	2.40%	2.10%
Nebraska	0.60%	0.50%	0.60%	2.00%
Nevada	1.00%	2.20%	1.60%	2.20%

Exhibit D: Pre-Rebate Accelerated Approval Drug Spending as Percentage of Pre-Rebate, Overall Drug Spending by State by Noted Year

State	2007	2010	2015	2020
New Hampshire	0.30%	2.70%	1.10%	2.50%
New Jersey	1.60%	1.50%	1.90%	2.40%
New Mexico	0.40%	3.00%	1.20%	2.00%
New York	0.90%	1.30%	1.40%	1.90%
North Carolina	1.00%	1.70%	1.80%	2.20%
North Dakota	1.10%	1.20%	0.50%	1.70%
Ohio	0.50%	0.90%	1.30%	2.60%
Oklahoma	0.90%	1.80%	2.60%	1.50%
Oregon	0.40%	1.20%	1.20%	1.70%
Pennsylvania	0.70%	1.30%	2.00%	1.80%
Rhode Island	0.10%	3.40%	2.10%	0.40%
South Carolina	1.70%	2.30%	2.30%	2.00%
South Dakota	0.90%	1.10%	0.50%	6.30%
Tennessee	0.80%	1.70%	1.70%	3.40%
Texas	0.90%	1.40%	1.70%	3.30%
Utah	0.70%	1.80%	0.70%	1.20%
Vermont	0.30%	1.50%	0.80%	0.90%
Virginia	0.50%	1.40%	1.60%	1.80%
Washington	0.90%	1.80%	1.40%	1.80%
West Virginia	0.20%	1.70%	1.30%	1.60%
Wisconsin	1.40%	1.20%	1.40%	0.80%
Wyoming	0.00%	0.80%	0.70%	0.90%