



## **The Future Cost of Innovation: An Analysis of the Impact of Breakthrough Therapies on Government Spending**

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Avalere maintained full editorial control.*

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avalere.com

# Analysis Overview

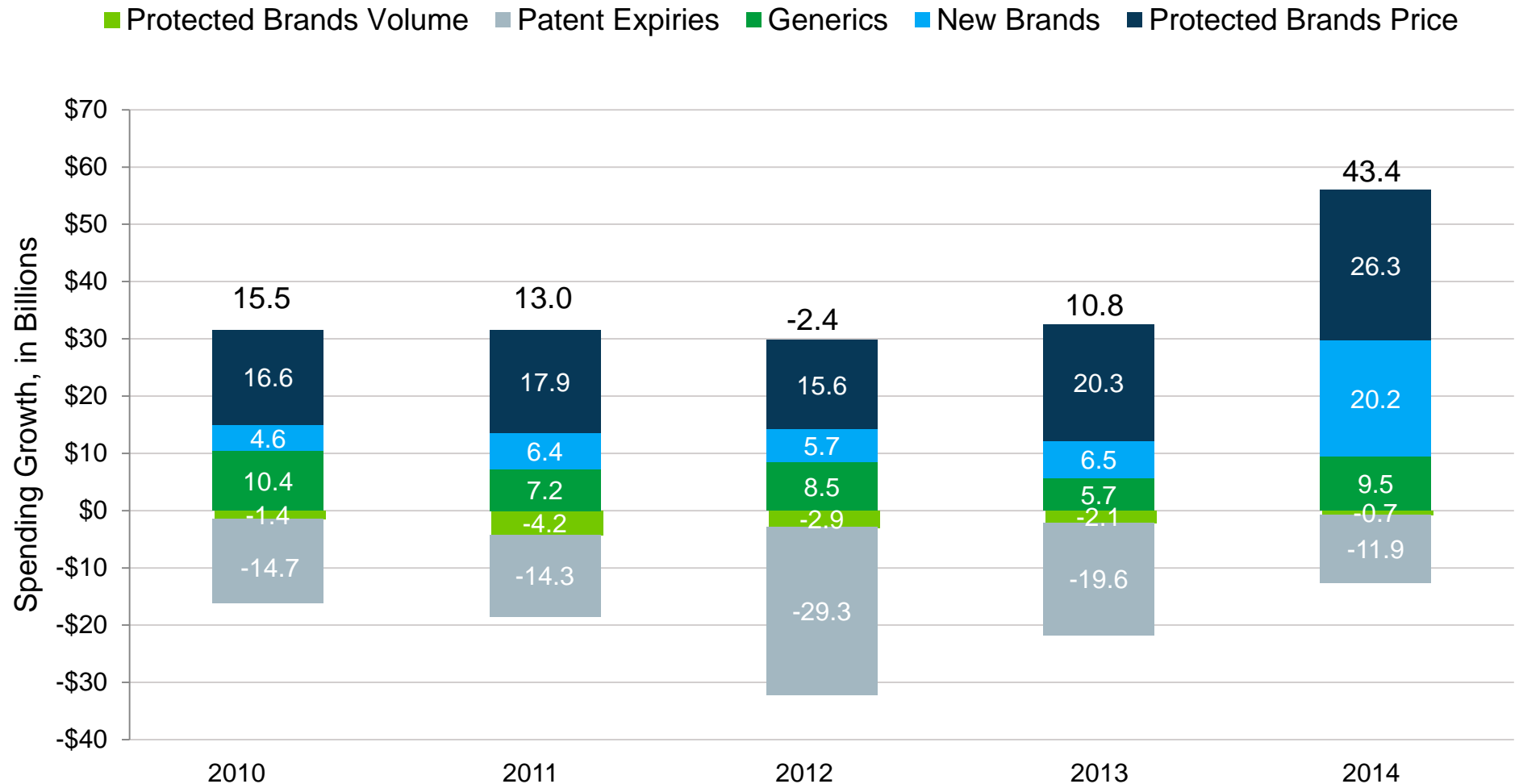
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- To evaluate new medications in the drug development pipeline, Avalere projected the fiscal impact of 10 FDA breakthrough therapies to Medicare, Medicaid, and the health insurance exchanges created by the Affordable Care Act (ACA).
- These therapies have the potential to offer substantial improvement over existing therapies used to treat serious or life-threatening diseases or conditions and receive priority and / or expedited review by the FDA. Breakthrough therapies represent only a small subset of the estimated 5,400 medications in the clinical development pipeline.<sup>1</sup>
- The 10 selected medications are likely to result in medication costs to the government of \$49.3 billion over a 10-year period, including: \$31.3 billion in Medicare spend; \$15.8 billion in state and federal Medicaid spend; and \$2.1 billion as a result of subsidies provided through exchange plans.
- Over 10 years, total U.S. spending may exceed these estimates because the analysis does not: 1) include the impact on government programs other than those identified above; 2) evaluate the potential impact on commercial payers or patient out-of-pocket costs (OOP); or 3) consider costs potentially attributable to off-label use of medications, which can be significant.
- Estimates reflect the gross cost of new medication use. This analysis does not: 1) consider savings or additional costs associated with other potential medical or pharmaceutical spending as a result of new medication utilization, or 2) explicitly evaluate the impact of payer coverage policies and OOP costs on patient access.

<sup>1</sup> Analysis Group, "Innovation in the Biopharmaceutical Pipeline: A Multidimensional View," January 2013.

# Nearly Half of Drug Spending Growth in 2014 Was Driven by Products Entering the Market in the Past Two Years

2014 U.S. DRUG SPENDING GROWTH DRIVERS, IN BILLIONS



New Brands includes products launched in the last two years.  
 IMS Health, National Sales Perspective, December 2014.

# The Analysis Includes 10 Therapies with Breakthrough Designation from the FDA

Drug	Disease	Indication	Projected Launch Date*	Current Development Status
Viekira Pak™	Hepatitis C	Hepatitis C (Genotype 1)	On market	Approved December 19, 2014
Ibrance®	Breast Cancer	Post-menopausal women with locally advanced or metastatic breast cancer ER+, HER2-	On market	Approved February 3, 2015
Eylea®	Diabetic Retinopathy	Diabetic retinopathy in patients with diabetic macular edema	On market	Approved March 25, 2015
Orkambi™	Cystic Fibrosis	Cystic Fibrosis in patients aged 12 and older, homozygous for the F508delta mutation in CFTR	2016	NDA submitted
Keytruda®	Lung Cancer	EGFR-negative & ALK rearrangement-negative NSCLC	2017**	Phase III
MK-5172	Hepatitis C	Hepatitis C (Genotype 1)	2017***	Phase III
Entinostat	Breast Cancer	Locally recurrent or metastatic ER+ breast cancer when added to exemestane in postmenopausal women whose disease has progressed following non-steroidal aromatase inhibitor therapy	2018	Phase III
Rociletinib	Lung Cancer	Second-line treatment of EGFR mutant NSCLC with T790M mutation	2018	Phase III
Daclatasvir	Hepatitis C	Hepatitis C (Genotype 1b)	2018	Phase III
CTL019	Acute Lymphoblastic Leukemia (ALL)	Pediatric and adult patients with elapsed/refractory ALL	2020	Phase II

ALK: Anaplastic Lymphoma Kinase CFTR: Cystic Fibrosis Transmembrane Conductance Regulator EGFR: Epidermal Growth Factor Receptor ER+: Estrogen Receptor  
 Positive HER2: Human Epidermal Growth Factor Receptor 2  
 NSCLC: Non-Small Cell Lung Cancer

\* Based on FDA time for acceptance and priority review once the application is submitted as well as general R&D timelines available here: "Drug Discovery and Development: Understanding the R&D Process." Washington, DC: PhRMA, 2014.

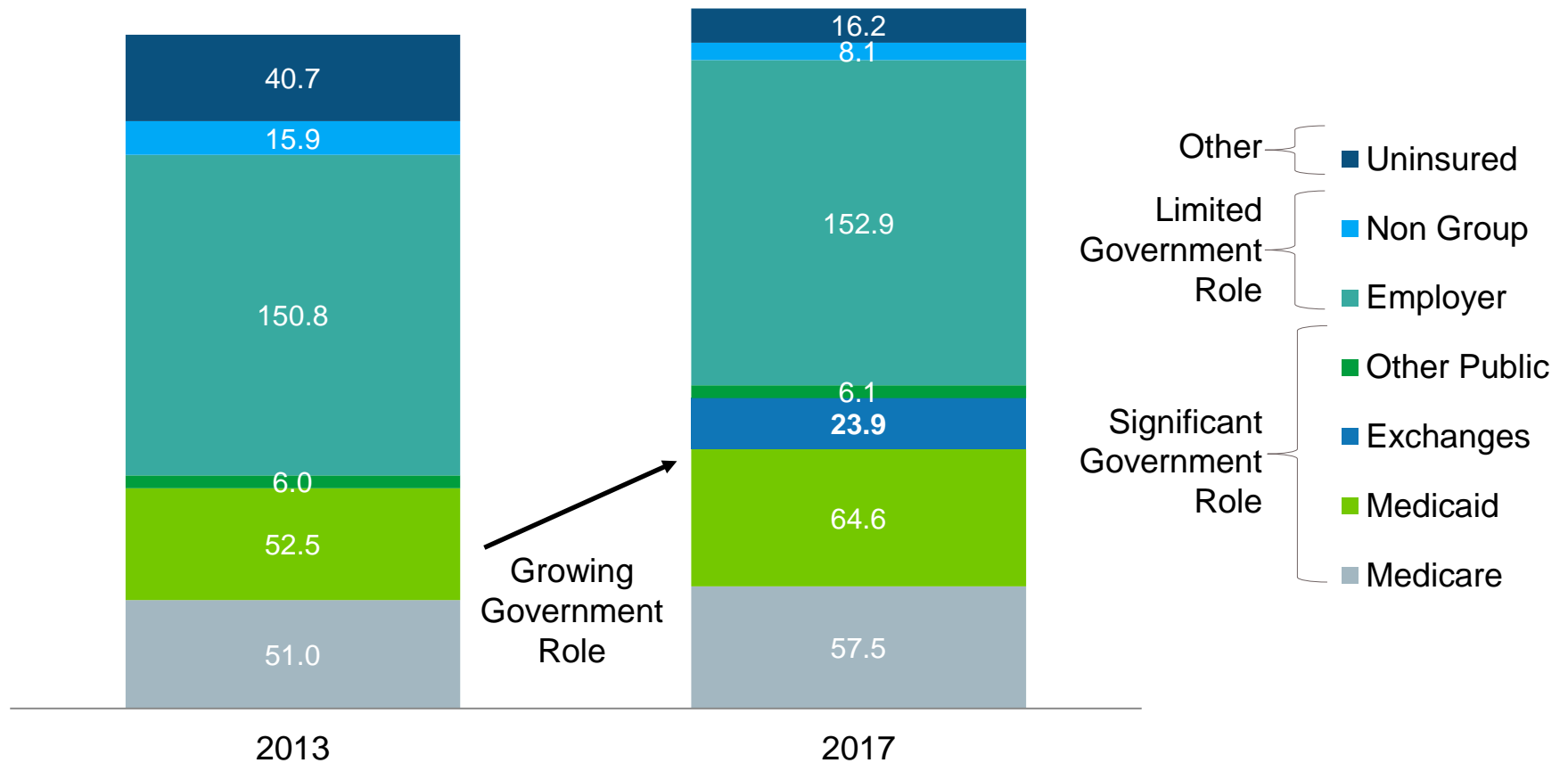
\*\*Keytruda was initially assumed to have a 2018 launch given Phase III clinical trial status, but the manufacturer has said it intends to file for approval in 2015. Given a competitor, Opdivo®, has recently been approved for this indication, it is assumed that the approval timeline will be 12+ months from the file date without priority status.

\*\*\* MK-5172 was initially assumed to have a 2018 launch given Phase III clinical trial status, but the manufacturer has said it intends to file for approval in 2015. Given other competitors in the market, it is assumed that the approval timeline will be 12+ months from the file date without priority status.



# ACA and Population Trends Will Lead to a Larger Role for the Government in Health Insurance over Time

PROJECTED ENROLLMENT BY PAYER TYPE (MILLIONS), 2013 & 2017



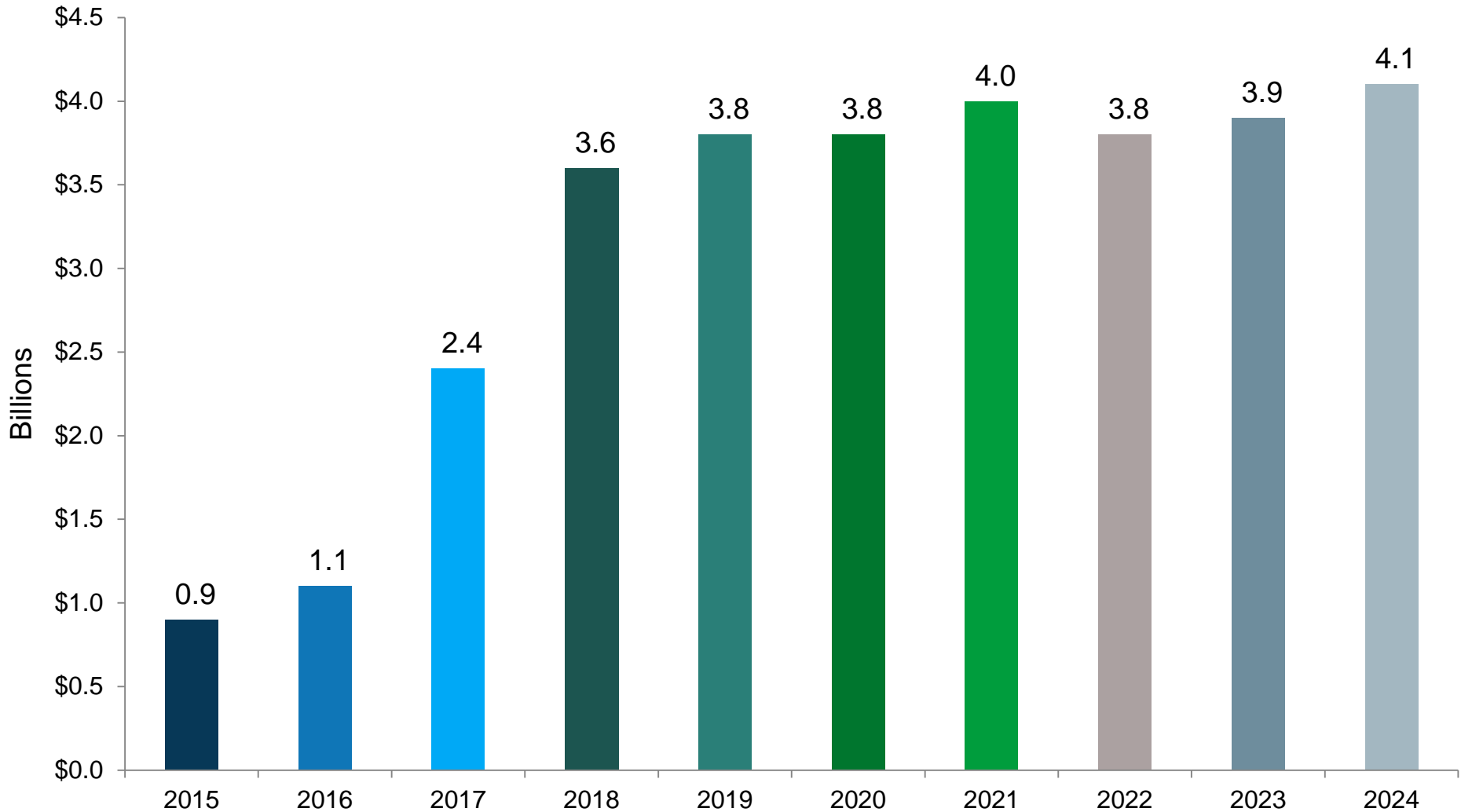
# Medicare Has the Largest Exposure to the Therapies Included in the Analysis

Drug	Major Government Payers			Total	Other
	Medicare	Medicaid	Exchanges*		
Viekira Pak	55.8%	7.7%	2.0%	65.5%	34.5%
Ibrance	38.5%	8.0%	1.8%	48.2%	51.8%
Eylea	59.5%	7.8%	1.4%	68.7%	31.3%
Orkambi	4.0%	40.0%	2.8%	46.8%	53.2%
Keytruda	69.6%	6.9%	0.5%	77.0%	23.0%
MK5172	55.8%	7.7%	2.0%	65.5%	34.5%
Entinostat	38.5%	8.0%	1.8%	48.2%	51.8%
Rociletinib	55.9%	6.9%	0.5%	63.3%	36.7%
Daclatasvir	55.8%	7.7%	2.0%	65.5%	34.5%
CTL019	8.9%	42.9%	2.8%	54.5%	45.5%

\*Government costs incurred through tax credit subsidies and cost-sharing reductions.  
Avalere analysis, 2015.

# Between 2015 and 2024, the 10 Therapies Selected for the Analysis Will Cost the Medicare Program \$31.3 Billion

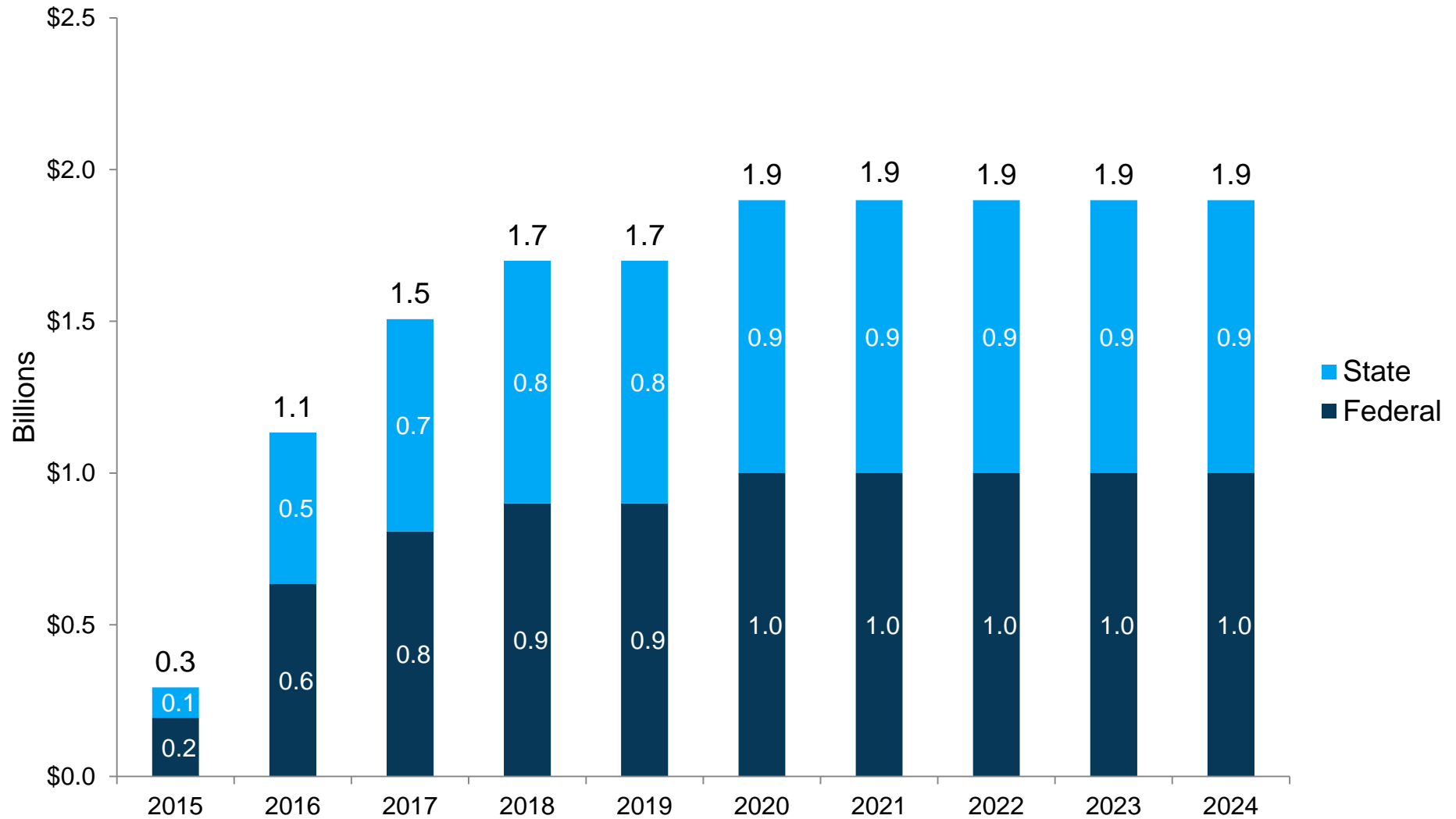
MEDICARE COSTS, 2015-2024, IN BILLIONS



Note: Figures may not add due to rounding.  
Avalere analysis, June 2015.

# Between 2015 and 2024, the 10 Therapies Selected for the Analysis Will Cost the Medicaid Program \$15.8 Billion

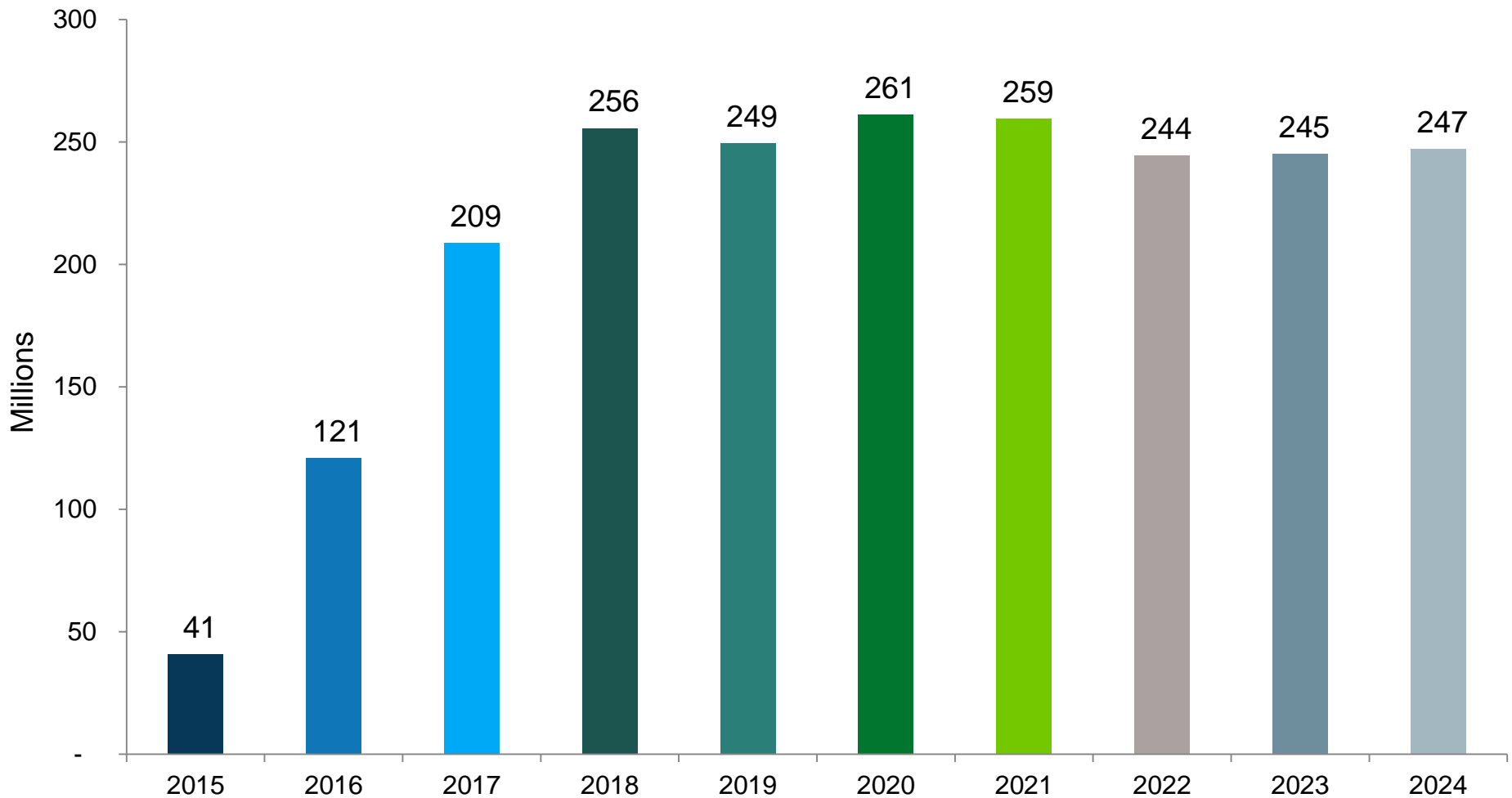
MEDICAID COSTS, 2015-2024, IN BILLIONS





# Between 2015 and 2024, the 10 Therapies Selected for the Analysis Will Increase Exchange Subsidy Costs by \$2.1 Billion

FEDERAL EXCHANGE COSTS, 2015-2024, IN MILLIONS



Note: government costs incurred through tax credit subsidies and cost-sharing reductions.  
Avalere analysis, June 2015.

# The 10 Selected Therapies Will Cost Medicare, Medicaid, and Public Exchanges \$49.3 Billion Over 10 Years

	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2015-2019	2015-2024	2015-2024
<b>Federal Government Costs</b>													
Medicare	0.9	1.1	2.4	3.6	3.8	3.8	4.0	3.8	3.9	4.1	11.8	19.6	31.3
Medicaid	0.2	0.6	0.8	0.9	0.9	1.0	1.0	1.0	1.0	1.0	3.3	5.1	8.4
Exchanges	0.0	0.1	0.2	0.3	0.2	0.3	0.3	0.2	0.2	0.2	0.9	1.3	2.1
<b>Total Federal Government Costs</b>	<b>1.1</b>	<b>1.9</b>	<b>3.4</b>	<b>4.7</b>	<b>4.9</b>	<b>5.1</b>	<b>5.3</b>	<b>5.0</b>	<b>5.2</b>	<b>5.4</b>	<b>16.0</b>	<b>26.0</b>	<b>41.9</b>
<b>State Government Costs</b>													
Medicaid	0.1	0.5	0.7	0.8	0.8	0.9	0.9	0.9	0.9	0.9	2.9	4.5	7.4
<b>Total State Government Costs</b>	<b>0.1</b>	<b>0.5</b>	<b>0.7</b>	<b>0.8</b>	<b>0.8</b>	<b>0.9</b>	<b>0.9</b>	<b>0.9</b>	<b>0.9</b>	<b>0.9</b>	<b>2.9</b>	<b>4.5</b>	<b>7.4</b>
<b>Total Costs</b>													
<b>Total (Federal and State)</b>	<b>1.2</b>	<b>2.4</b>	<b>4.0</b>	<b>5.5</b>	<b>5.7</b>	<b>6.0</b>	<b>6.2</b>	<b>5.9</b>	<b>6.1</b>	<b>6.3</b>	<b>18.9</b>	<b>30.5</b>	<b>49.3</b>

Note: Figures may not add due to rounding.  
Avalere analysis, June 2015.