

# MEDICINES IN MEDICARE: PART B



Medicare is the government program that insures many of the nation’s retirees and Americans with disabilities. This chapter contains information on prescription drug coverage under Part B, which generally covers medications administered by a physician, like injected or infused vaccines and medicines. The medicines covered by Part B represent significant medical advances, including breakthroughs in cancer, rheumatoid arthritis, and autoimmune conditions.

For Part B medicines, Medicare pays the Average Sales Price (ASP)—a market-based price that reflects manufacturer sales and includes rebates that are negotiated (with certain exceptions). This methodology lets the government benefit from discounts negotiated on physician-administered drugs in the commercial market.

Spending on Part B medicines represents a small and stable share of overall Part B spending, and research shows the volume-weighted ASP for Part B drugs has remained steady, suggesting that prices for prescription medicines and biologicals are not drivers of costs. This is, in part, because Medicare Part B benefits from brand and generic competition, as well as negotiation by commercial payers.

# Part B Covers Complex Medicines for a Range of Serious Conditions



CANCER



RHEUMATOID  
ARTHRITIS



HEMOPHILIA



AUTOIMMUNE  
DISEASE



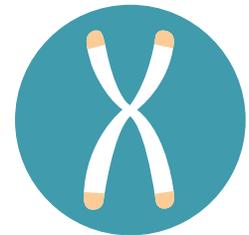
MACULAR  
DEGENERATION



OSTEOPOROSIS



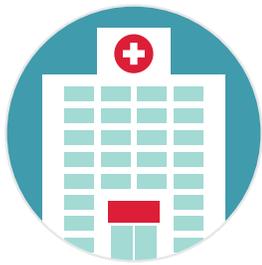
MENTAL  
ILLNESS



RARE  
DISEASE

# Part B Generally Covers Injected and Infused Medicines Across Several Settings

Medicines used in several types of settings are covered by Part B. Some types of drugs listed are available in other settings.



## HOSPITAL OUTPATIENT DEPARTMENTS

- Physician-administered (infused/injected) drugs
- Durable medical equipment (DME) drugs
- Some oral drugs



## PHYSICIAN OFFICES

- Physician-administered (injected/infused) drugs
- Some oral drugs
- Some vaccines



## PATIENT'S RESIDENCE

- Drugs requiring nebulizer or infusion pump (ie, DME drugs)
- Parenteral nutrition



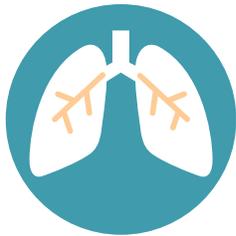
## DIALYSIS CENTERS

- Dialysis-related (eg, erythropoietin for treatment of anemia) drugs

Source: Medicare.gov<sup>4</sup>

# Recent Advances in Part B Medicines

Recent advances in physician-administered medicines are improving outcomes for hemophilia, cancer, migraines, autoimmune diseases, and other serious conditions.



Two-year relative survival for **NON-SMALL CELL LUNG CANCER** has increased from 34% for patients diagnosed from 2009 to 2010 to 42% for those diagnosed from 2015 to 2016.<sup>2</sup>



New monoclonal antibody treatment for **HEMOPHILIA A** dramatically reduces treatment burden and the potential for bleeding events.<sup>3</sup>



Long-acting medications for **SCHIZOPHRENIA** can be dosed up to 3 months apart and have the potential to help individuals who have difficulty adhering to a daily treatment regimen.<sup>3</sup>

Sources: Siegel RL et al<sup>2</sup>; PhRMA analysis of data from AdisInsight<sup>3</sup>

# New Advances Are on the Horizon

Novel therapies for cancer and other diseases are in the pipeline.

## Neurological Disorders<sup>4</sup>

- Physician-administered treatments in the pipeline for neurological disorders, like **Alzheimer's**, **ALS**, and **Parkinson's**, could provide hope for patients who currently have few or no options. Such therapies could also save money elsewhere in the health care system.
- A new Alzheimer's treatment approved by 2025 that delays onset by 5 years could reduce costs by \$367 billion a year by 2050.

## Blood Cancers

- New immunotherapies for the treatment of blood cancers, such as **CAR-NK therapy**, would give a patient's cells the skills to recognize and destroy cancer cells that have made themselves invisible.

Source: Alzheimer's Association<sup>4</sup>

# Explaining the Current Medicare Part B Reimbursement Methodology

## AVERAGE SALES PRICE:

- Enacted in Section 303(c) of Medicare Modernization Act (MMA)<sup>5</sup>
- Reflects the weighted average of manufacturer sales prices net of rebates and discounts (subject to certain exceptions)
- Savings lead to reductions in beneficiary premiums, deductibles, and coinsurance

## 6% ADD-ON PAYMENT COULD HELP COVER:

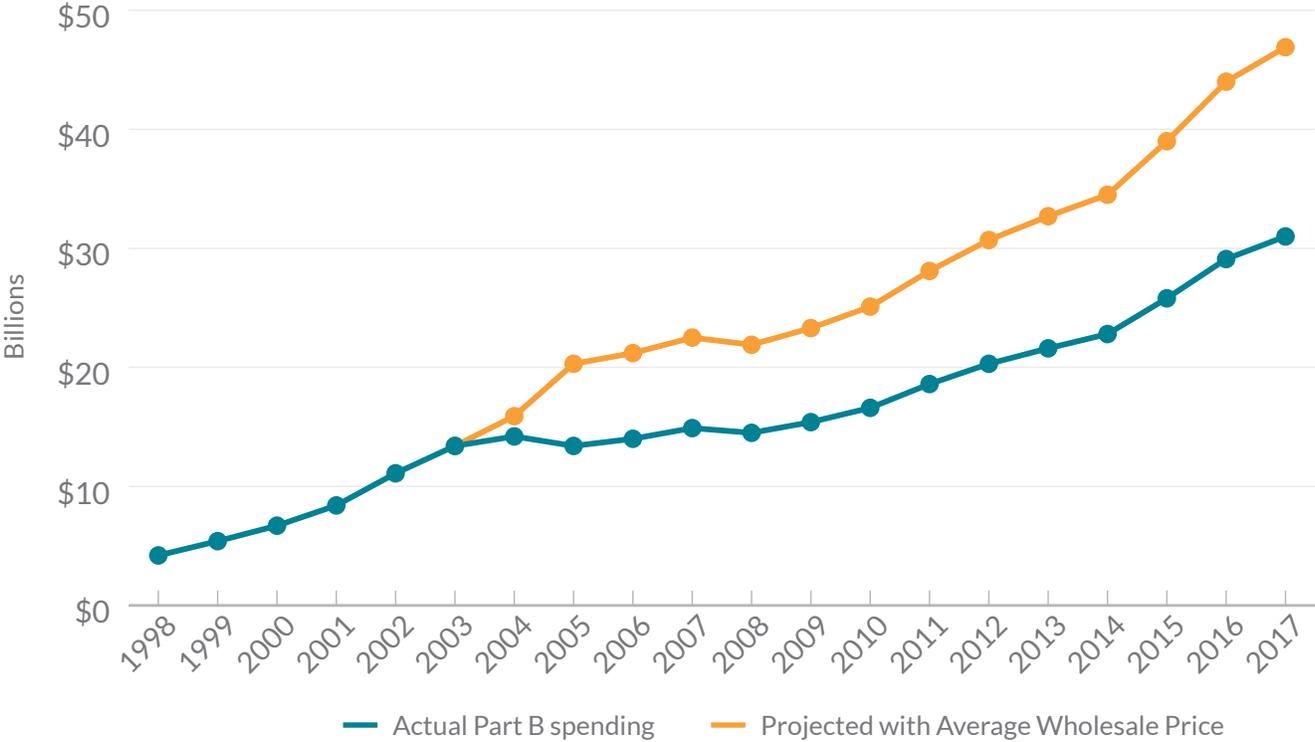
- Geographic and provider purchasing variability
- Shipping fees
- Ongoing patient monitoring and education
- Overhead for complex storing and handling requirements



Sources: MMA<sup>5</sup>; Holtz-Eakin D et al<sup>6</sup>

# Shift to Average Sales Price-Based Payment Has Yielded Significant Savings for Medicare

Reduction in Drug Spending Attributable to Switch to ASP-Based Reimbursement for Drugs Under Medicare Part B



Source: The Moran Company<sup>7</sup>

# In Part B, Beneficiaries Save Through Price Negotiations Between Manufacturers and Providers

Discounts and rebates negotiated by doctors, hospitals, health systems, and other purchasers are factored into the Medicare Part B payment rate (called Average Sales Price or ASP) and can lead to lower costs to the Medicare program and for beneficiaries.

Doctors, hospitals, health systems, and other purchasers negotiate discounts and rebates.



Savings lead to reductions in:

**PART B**

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Premiums

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Deductibles

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Coinsurance



# Average Sales Price Is an Effective Pricing Mechanism for Part B

The Centers for Medicare & Medicaid Services' (CMS) analysis of the ASP pricing mechanism found that ASP for the most commonly used drugs changed less than 2%, and almost a third declined.



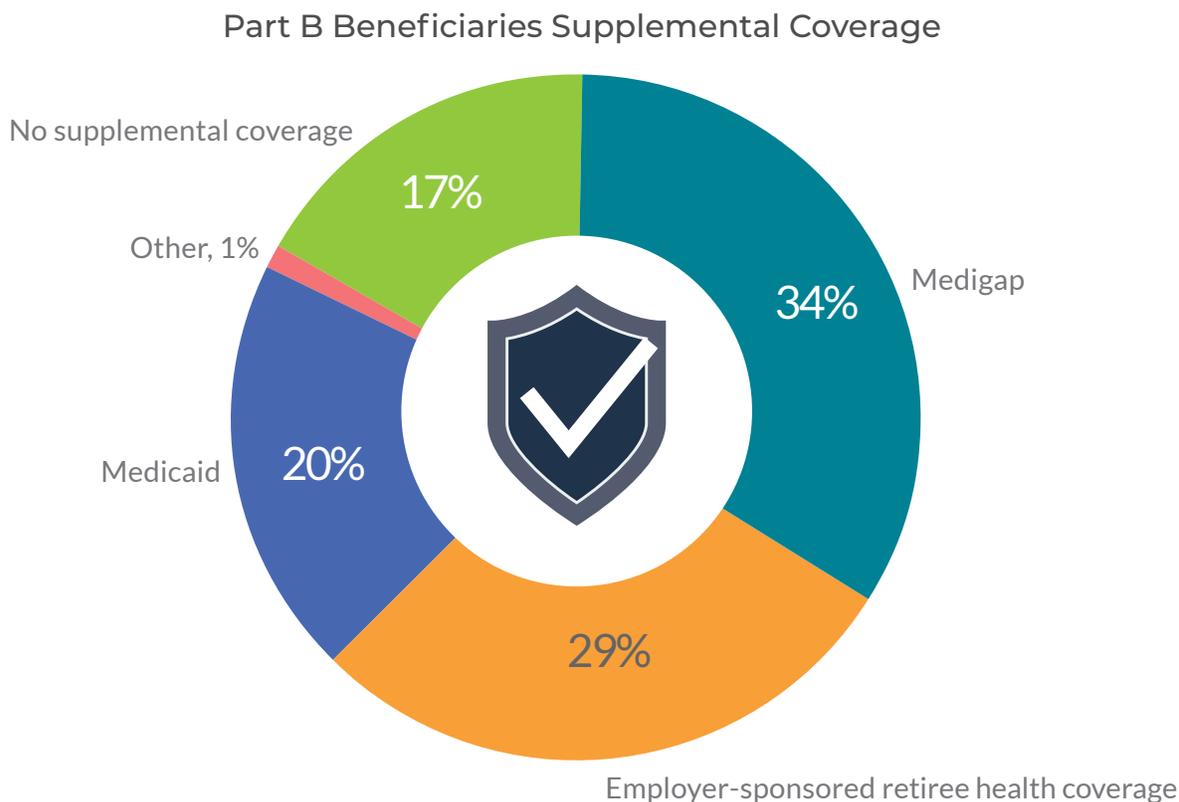
[T]here are a number of competitive market factors at work—multiple manufacturers, alternative therapies, new products, recent generic entrants, or market shifts to lower priced products.”

**CMS**



# The Majority of Part B Fee-for-Service Beneficiaries Have Supplemental Coverage

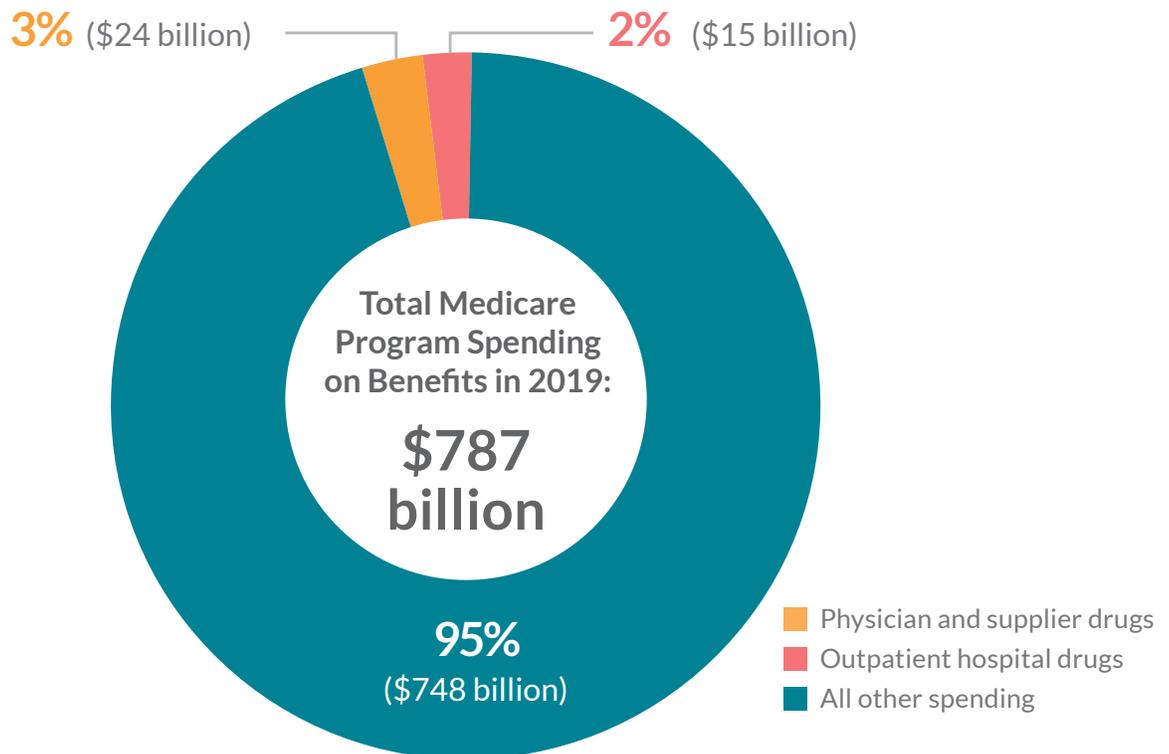
Some 83% of Part B beneficiaries have supplemental coverage, which significantly reduces their out-of-pocket costs.



Due to rounding, percentages do not total 100%.

Source: KFF<sup>11</sup>

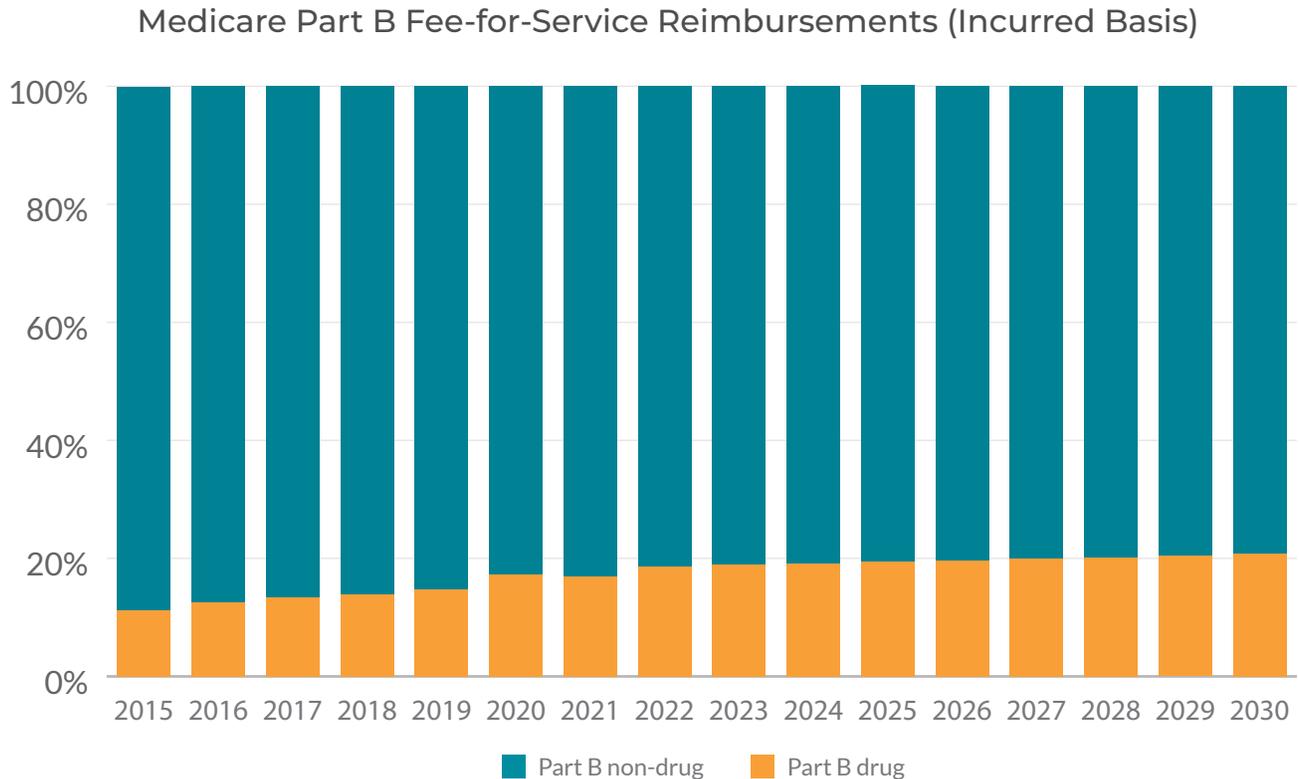
# Part B Drugs Are Are Less Than 5% of Total Government Medicare Spending



Source: MedPAC<sup>12</sup>

# Part B Expenditures Are a Small and Stable Share of Part B Spending

Part B drugs were 10.4% of total Part B expenditures in 2018.

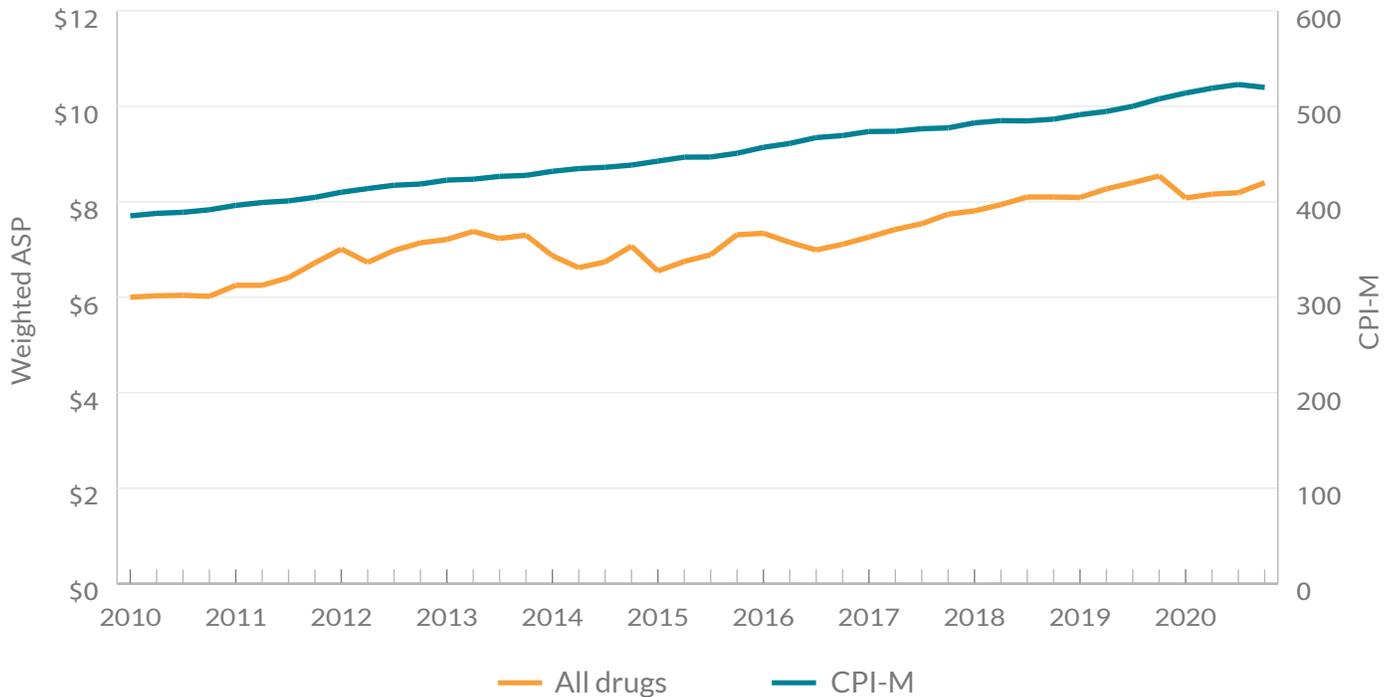


Source: PhRMA analysis of MedPAC and Medicare Trustees data<sup>13</sup>

# ASP Continues to Grow Below Medical Inflation

While medical inflation has been increasing since 2006, the trend of volume-weighted Average Sales Price (ASP) changes for all Medicare Part B drugs has grown more slowly.

Weighted ASP (All Drugs) vs Consumer Price Index-Medical Care (CPI-M)<sup>14\*</sup>

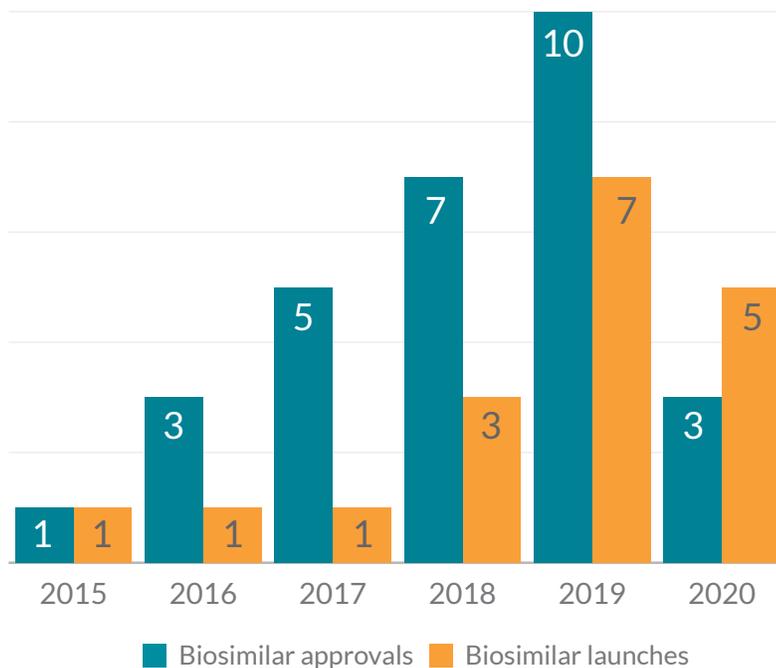


\*2020 Weighted ASP numbers are projections.

Source: The Moran Company<sup>14</sup>

# Biosimilar Uptake Drives Growing Savings in Part B

Biosimilar Approvals and Launches by Year<sup>15</sup>



## BIOSIMILAR UPTAKE AND SAVINGS POTENTIAL<sup>16</sup>

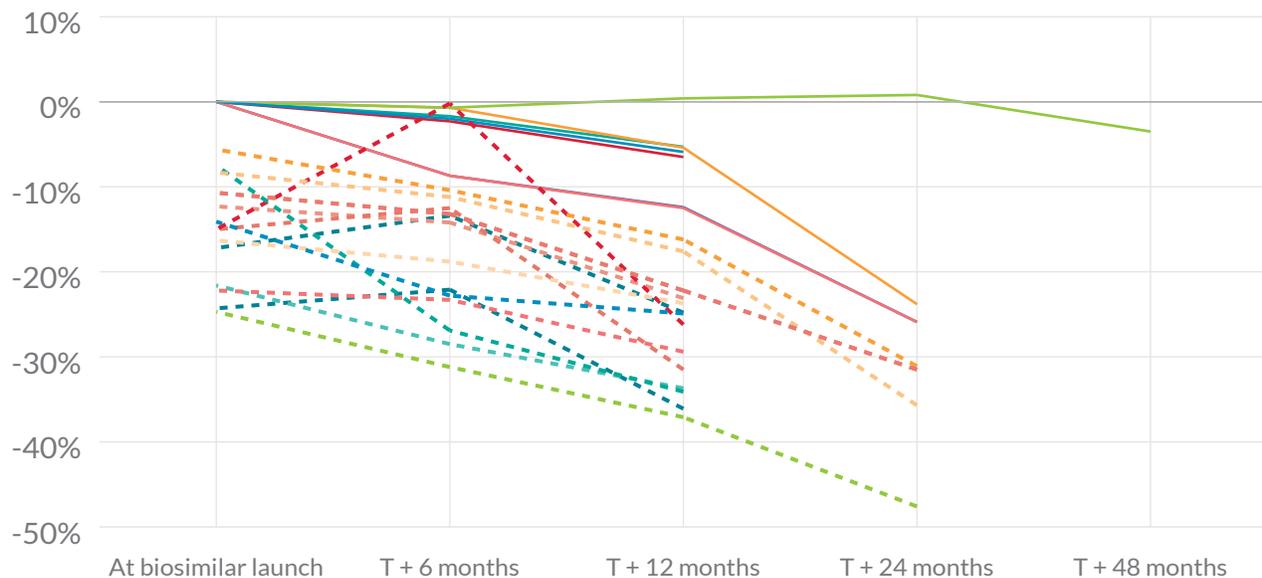
- In the past 5 years, the Food and Drug Administration has approved increasing numbers of biosimilars for physician-administered drugs.
- Biosimilars are anticipated to save more than \$100 billion in aggregate over the next 5 years.
- Savings are attributable to physician-administered drugs in the Medicare Part B program.

Sources: Fish & Richardson<sup>15</sup>; The IQVIA Institute<sup>16</sup>

# Average Sales Prices of Oncology Medicines Drop Substantially Following the Introduction of Biosimilars

Following the launch of a biosimilar, substantial drops occur in the Average Sales Price of oncology originator products.

ASP Changes Over Time for Oncology-Related Reference Products and Biosimilars (Including Supportive-Care Products), as of July 2021



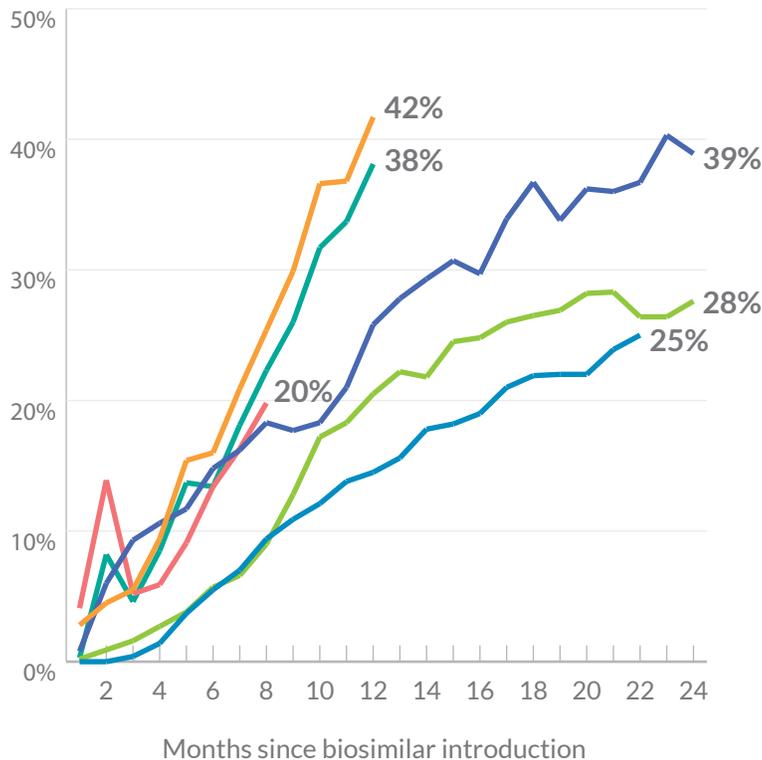
Each line represents a separate product.

Source: Xcenda<sup>17</sup>

# Oncology Medicines Face Robust Competition From Biosimilars

Biosimilars are achieving significant market uptake, with the 3 most recently launched biosimilars achieving between 20% and 42% of market share within their first year. In 2020, biosimilar ASPs for oncology medicines were as much as 45% less than the originator.

Oncology Biosimilar Share of Volume Since Launch



Originator Biologic and Biosimilar Launch Date:	ASP Difference:*
Oncology monoclonal antibody July 2019	<b>-22.7%</b>
Oncology monoclonal antibody July 2019	<b>-11.4%</b>
Oncology monoclonal antibody November 2019	<b>-24.7%</b>
Supportive oncology therapy July 2018	<b>-45.1%</b>
Supportive oncology therapy September 2018	<b>-23.8%</b>
Supportive oncology therapy November 2016	<b>-26.9%</b>

\*Percentage price difference between originator ASP and biosimilar ASP, July 2020

Source: The IQVIA Institute<sup>18</sup>

# Part B Continues to Evolve to Control Costs

## Increasing numbers of beneficiaries

are now opting to enroll in Medicare Advantage.



## 50% of top-40 drugs

are expected to see biosimilar competition in the next 10 years.



## Growing share of providers

are participating in alternative payment models, like the Oncology Care Model.



# Solutions to Strengthen Medicare Part B

PhRMA supports reforms that enable Medicare beneficiaries to benefit more from the lower prices negotiated by large commercial purchasers in the market, while protecting physician care quality. Under this approach, manufacturers would provide a price concession in the form of a rebate to Medicare, called a “market-based adjustment,” based on prices that fall below the ASP.

## LOWERS COSTS FOR PATIENTS



Could reduce out-of-pocket costs for Medicare beneficiaries who have cost-sharing exposure

## PRESERVES PHYSICIAN PAYMENT



Would limit physician financial and administrative burden

## BRINGS MEDICARE PRICES CLOSER TO COMMERCIAL PRICES



Would bring prices paid by Medicare closer to what is paid in the commercial market

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