

JANUARY 2022

Cancer Medicines *Value in Context*



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Overview

- Game-changing new cancer treatment approaches are contributing greatly to significant reductions in mortality and the pipeline holds enormous promise in addressing great unmet need.
- Too many cancer patients face financial burdens, and these come from a variety of sources including treatment costs, non-medical costs, and shifts in insurance benefit design.
- While most patients with cancer face no out-of-pocket costs for oncology medicines at the pharmacy counter, a small share are burdened with high costs due to increasing use of deductibles and coinsurance.
- Market-based tools are working to contain costs and driving competition between cancer medicines. But broader market distortions driven by hospital consolidation and the 340B program are increasing costs to the system and patients.
- U.S. patients have earlier access to cancer medicines and have many more options for treatment compared to other developed countries. As a result, they have better outcomes.
- Policies should improve patient affordability, reduce market distortions, facilitate the move to a value-driven health care system, and encourage and incentivize new treatments for cancer patients.



01

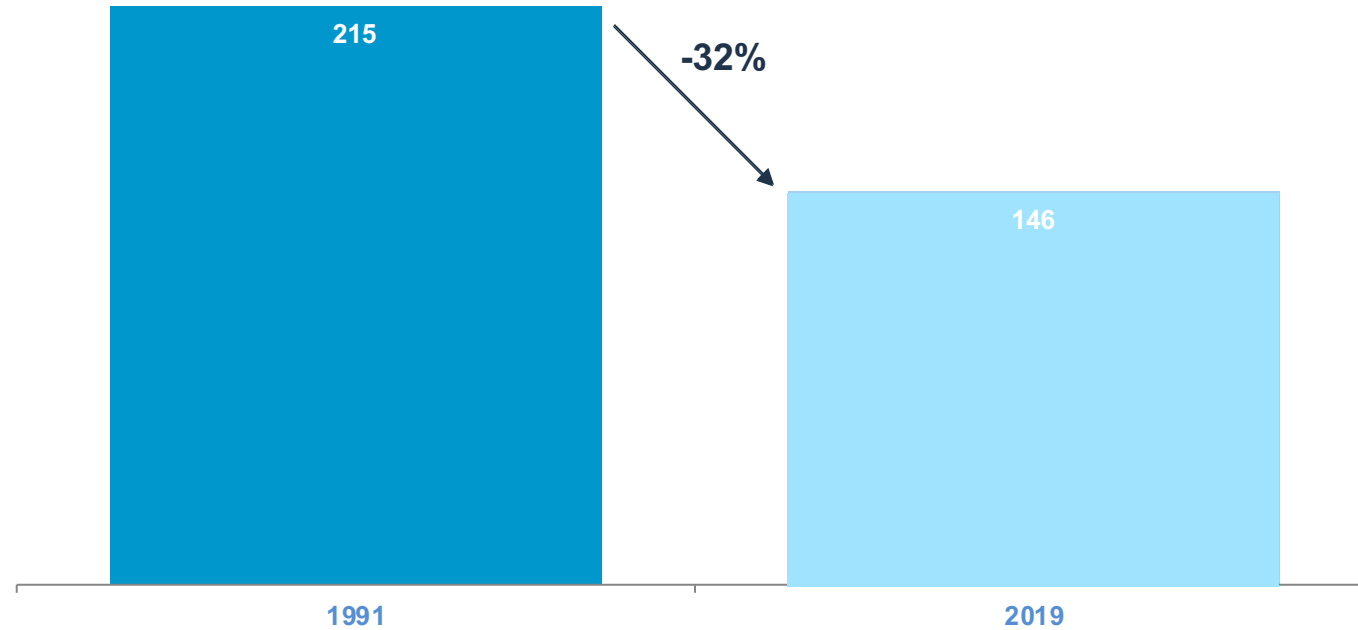
ADVANCES IN CANCER TREATMENT

A range of game-changing new approaches to cancer treatment have become available to patients with a wide range of cancers over the past decade, contributing greatly to significant reductions in mortality and increases in survival.

Since Peaking in the Early 1990s, Cancer Death Rates have Declined 32%

Increases in cancer survival are estimated to translate to 3.5 million avoided cancer deaths since cancer death rates peaked in 1991.

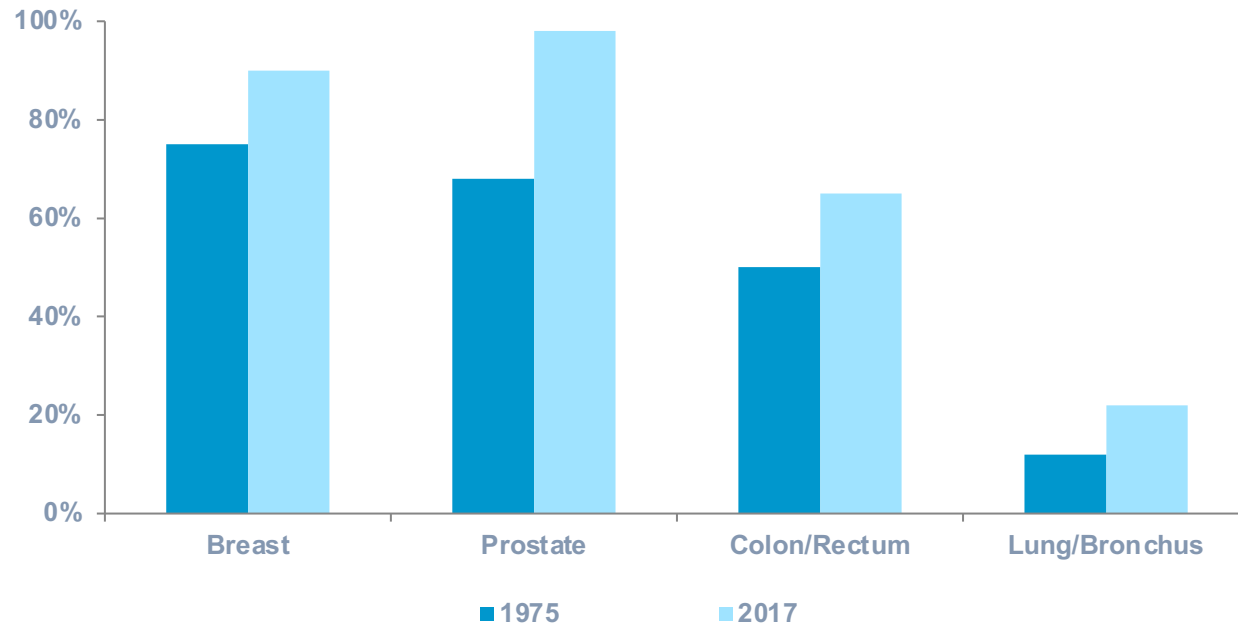
U.S. Death Rates from Cancer (per 100,000)



Five-year Survival Rates Are Increasing for Many Types of Cancer

Across all cancers, today the chances a cancer patient will live 5 years or more is 68%--an increase of 39% since 1975.

5-Year Survival Rates Among the Most Common Cancers, 1975-2017



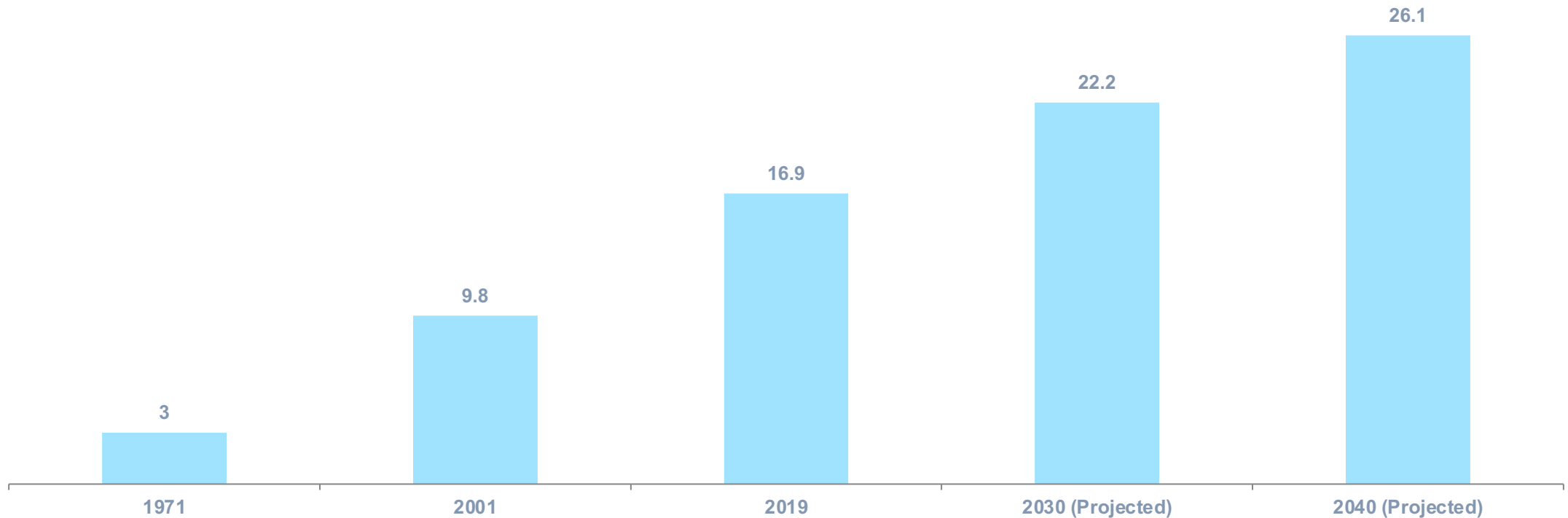
73%

of recent survival gains in cancer are attributable to treatment advances including new medicines.

The Number of Cancer Survivors is Steadily Rising

The continued increase in survival rates, and the corresponding increase in total number of cancer survivors, is in large part attributable to earlier detection and better treatments.

U.S. Cancer Survivors Over Time (millions)



Recent Advances in Cancer Medicines

A new era of innovation is pushing the frontiers of science and having a meaningful impact on the lives of patients with a wide range of cancers.

2010

1st therapeutic vaccine is approved which uses a patient's own immune system cells to treat cancer.

2011

1st immune checkpoint inhibitor is approved which targets certain proteins in order to stimulate the immune system to attack cancer cells. The therapy targets the CTLA-4 protein.

2013

1st antibody drug conjugate is approved which links a cytotoxic drug to a highly selective antibody to target cancer cells while leaving healthy cells unharmed.

2014

2 additional immune checkpoint inhibitors are approved targeting the PD-1 protein and the PD-1 ligand for the 1st time.
Expanded HPV vaccine protects against cancer-causing HPV types that cause 90% of cervical cancer.

2015

1st oncolytic virus therapy uses a modified herpes virus genetically engineered to kill cancer cells.

2017

1st CAR T-cell therapy is approved which involves removing and subsequently returning genetically modified T cells to a patient's body to fight cancer. 2 additional therapies are later approved.

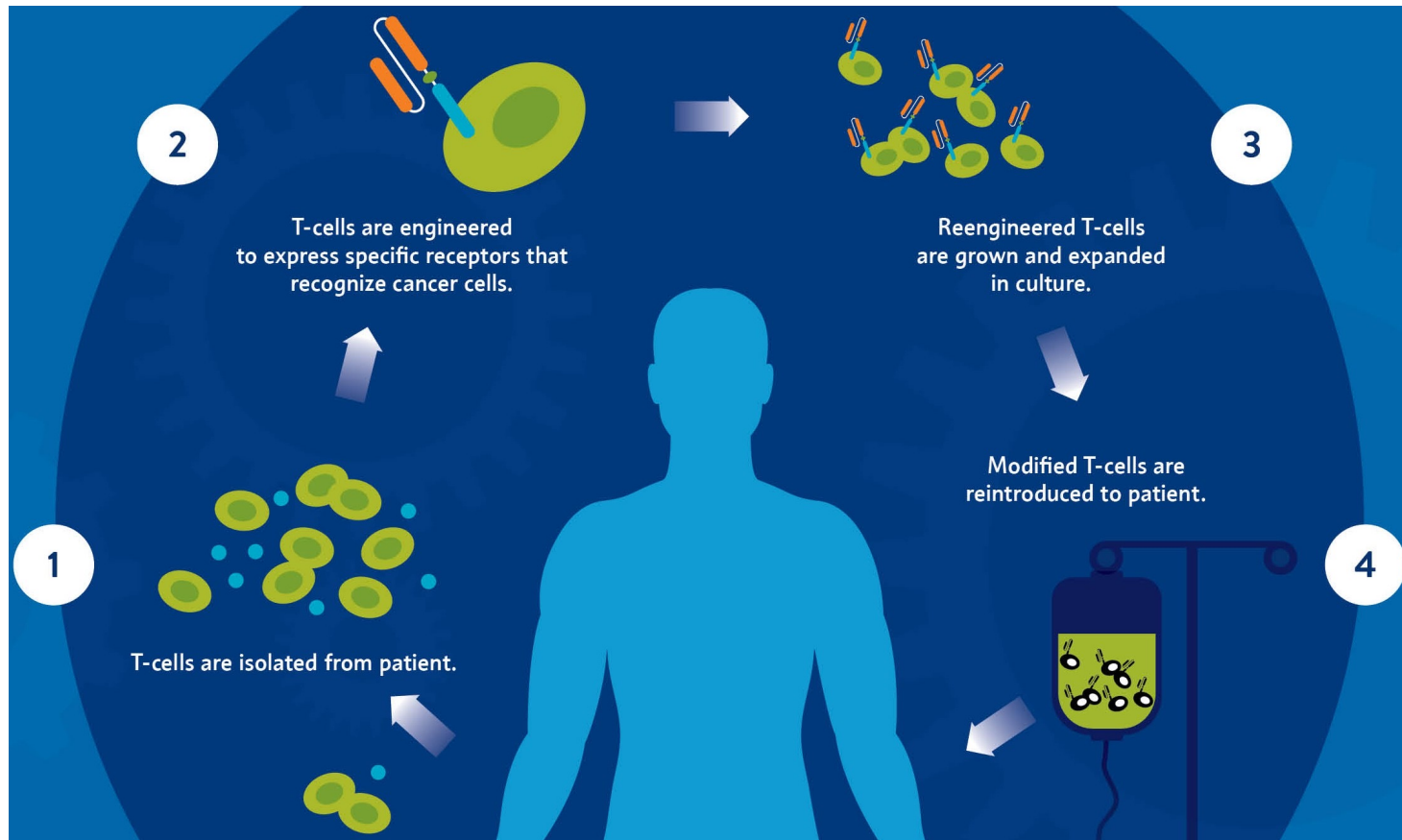
1st tissue-agnostic therapy for tumors with genetic mutations rather than where the cancer originated in the body. 2 additional tissue-agnostic treatments are later approved.

2021

A total of 5 CAR-T-cell therapies are approved to treat a range of cancers, demonstrating unprecedented overall remission rates in clinical trials.

CAR-T Therapy Driving Significant Advancements for Cancer Patients

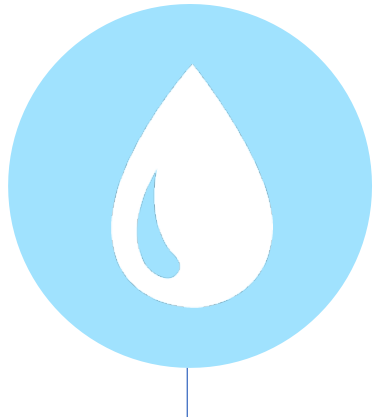
CAR-T is a form of gene modified cell therapy which involves permanently altering a patient's T-cells to recognize, target and kill cancer cells. There are 5 FDA approved CAR-T therapies to treat a range of different cancers.



Treatment Advances Contributing to Improvements in Outcomes for Pediatric Populations

Overall, the mortality rate for all types of cancers among children and teens has dropped by 50% since 1980. Many new medicines along the way have contributed to these improvements across a wide range of cancers.

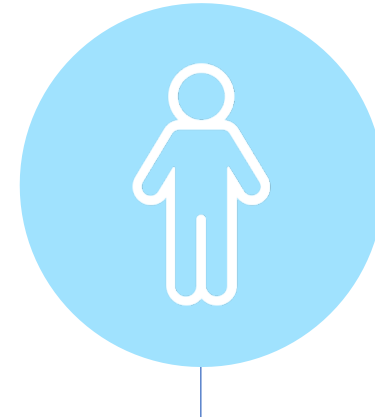
Select Examples of Recent Cancer Drug Approvals for Pediatric Populations



Several CAR-T cell therapies shown to cure some children and adolescents with advanced leukemia, sparing the short and long-term side effects of previous treatments.



A targeted therapy for children with advanced lung cancer and tumors expressing a specific genetic marker.

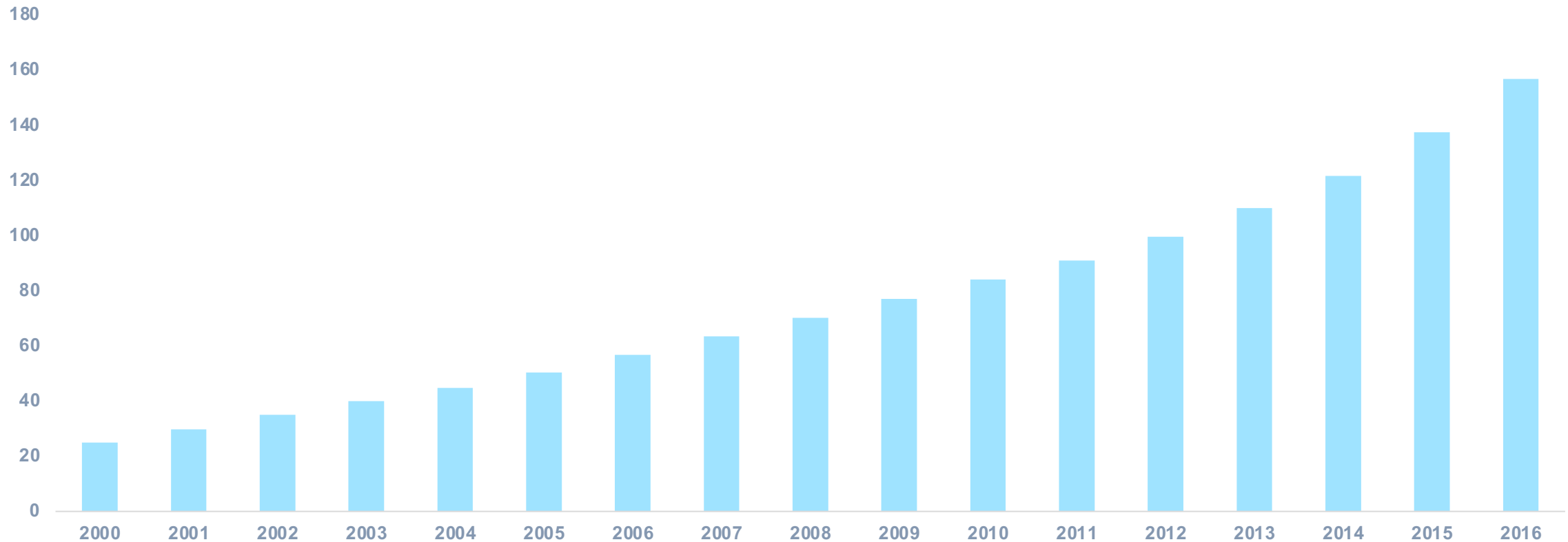


A therapy approved for use in patients 1 year and older with high-risk neuroblastoma, a very rare type of cancer, found in adrenal glands, most often in infancy.

New Cancer Medicines are Associated with Nearly 1.3 Million Avoided Cancer Deaths

Between 2000 and 2016, deaths across the 15 most common tumor types declined by 24%. New cancer medicines are associated with nearly 1.3 million total avoided deaths across these tumor types over this period.

Deaths Averted Associated with New Cancer Medicines* in the U.S. (thousands), 2000–2016**



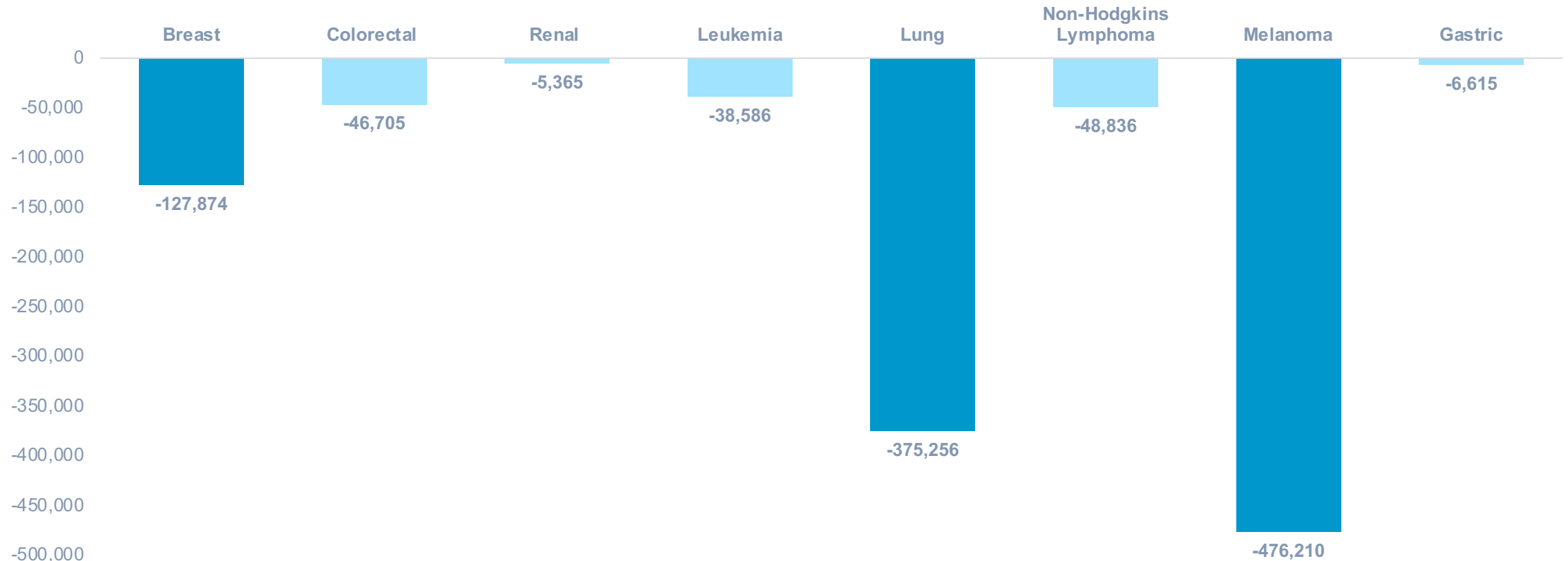
*Results for uterine and liver cancer are not shown as these tumors had no drug approvals from 2000 to 2016.

**106 new drugs were approved in 173 indications from 2000 to 2016 across 15 most common tumor types.

New Medicines Are Associated with Reduced Mortality Across Many Forms of Cancer

New cancer medicines have led to tremendous treatment advances in recent years and are linked to significant avoided deaths across many tumor types, particularly for breast cancer, lung cancer and melanoma.

Change in Total Deaths Associated with New Cancer Medicines in the U.S., 2000–2016* **



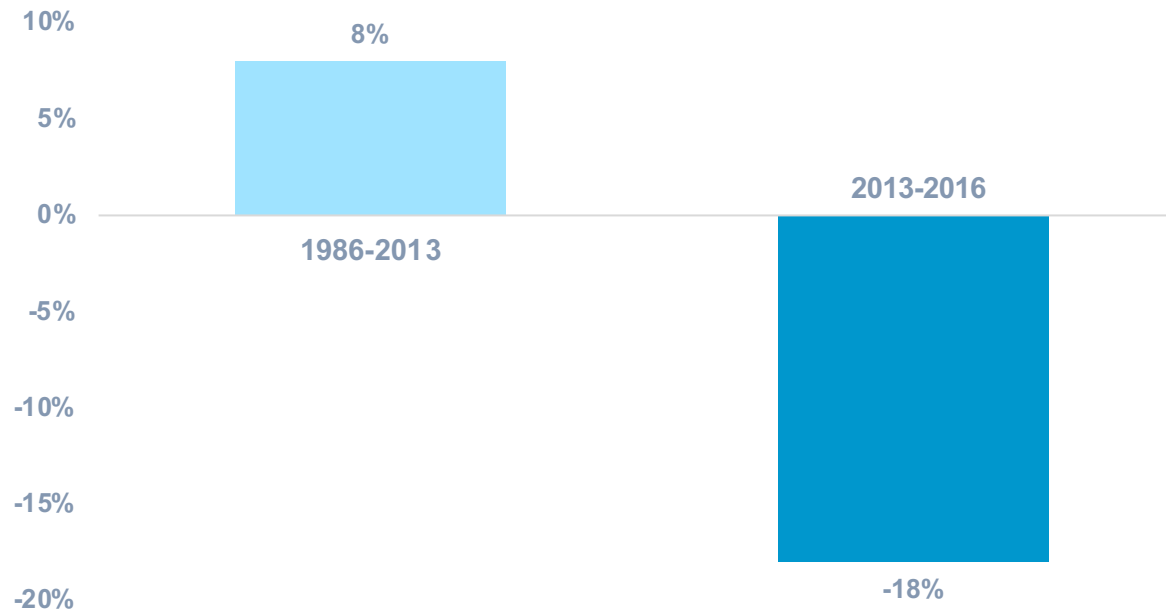
*Results are shown for the 15 most common tumor types with statistically significant results.

**106 new drugs were approved in 173 indications from 2000 to 2016 across 15 most common tumor types.

Treatment Advances Drive Dramatic Death Rate Decline in Melanoma

Following a period of increases in melanoma mortality over several decades, death rates decreased by about 18% between 2013 to 2016—the largest decline ever seen over such a short period, for any kind of cancer. Experts attribute this decline to new treatments, including targeted therapies and immunotherapies, approved for advanced melanoma beginning in 2011.

Melanoma, Change in Death Rates, Among Whites*



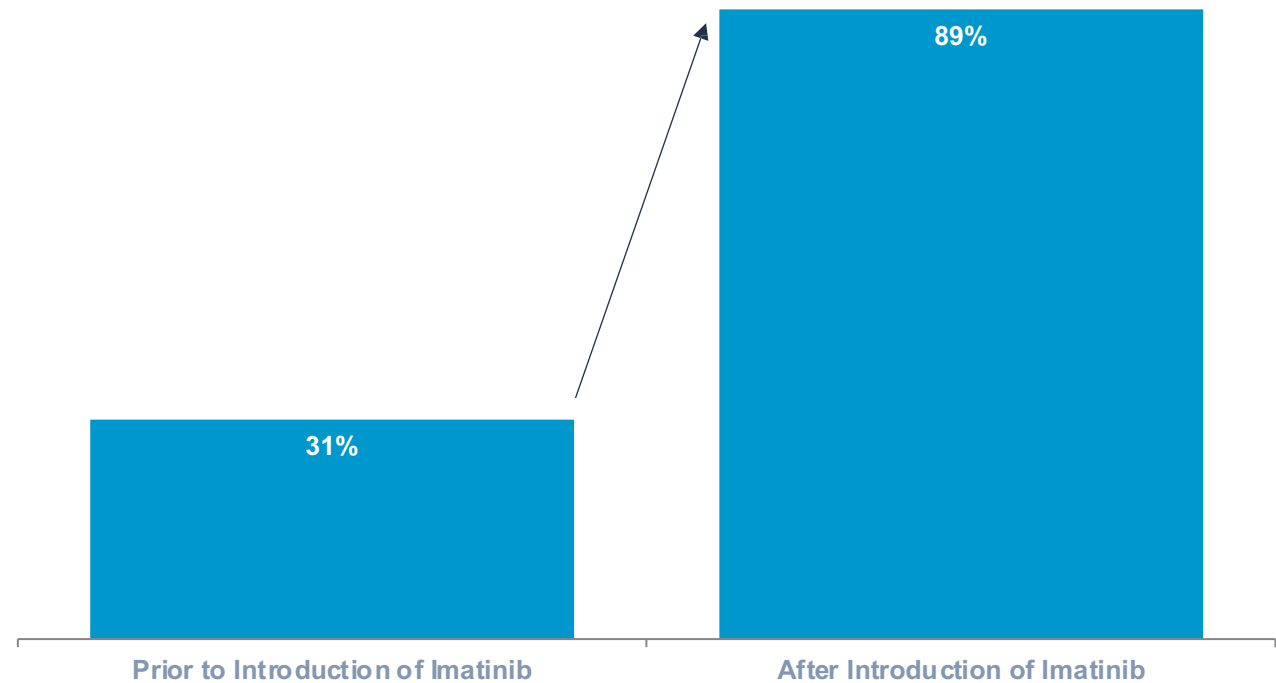
*90% of melanomas occur in white men and women, due to data restraints researchers could only analyze these groups.

Class of Therapies Transform a Form of Leukemia into Chronic Illness for Many Patients

Since the approval of the first tyrosine kinase inhibitor (TKI) for chronic myeloid leukemia (CML), survival rates have improved dramatically, and patients are living close to normal life spans.

- Imatinib—the first TKI—was approved in 2001 to treat CML. While imatinib nearly tripled 5-year survival rates the transformative impact of this class of medicines had yet to be realized.
- After initial approval, continued research revealed that imatinib had a greater impact when initiated earlier in the progression of the disease.
- Today, 4 additional TKIs provide critical options to those developing resistance or intolerance to treatment and are helping patients chronically managing the disease.

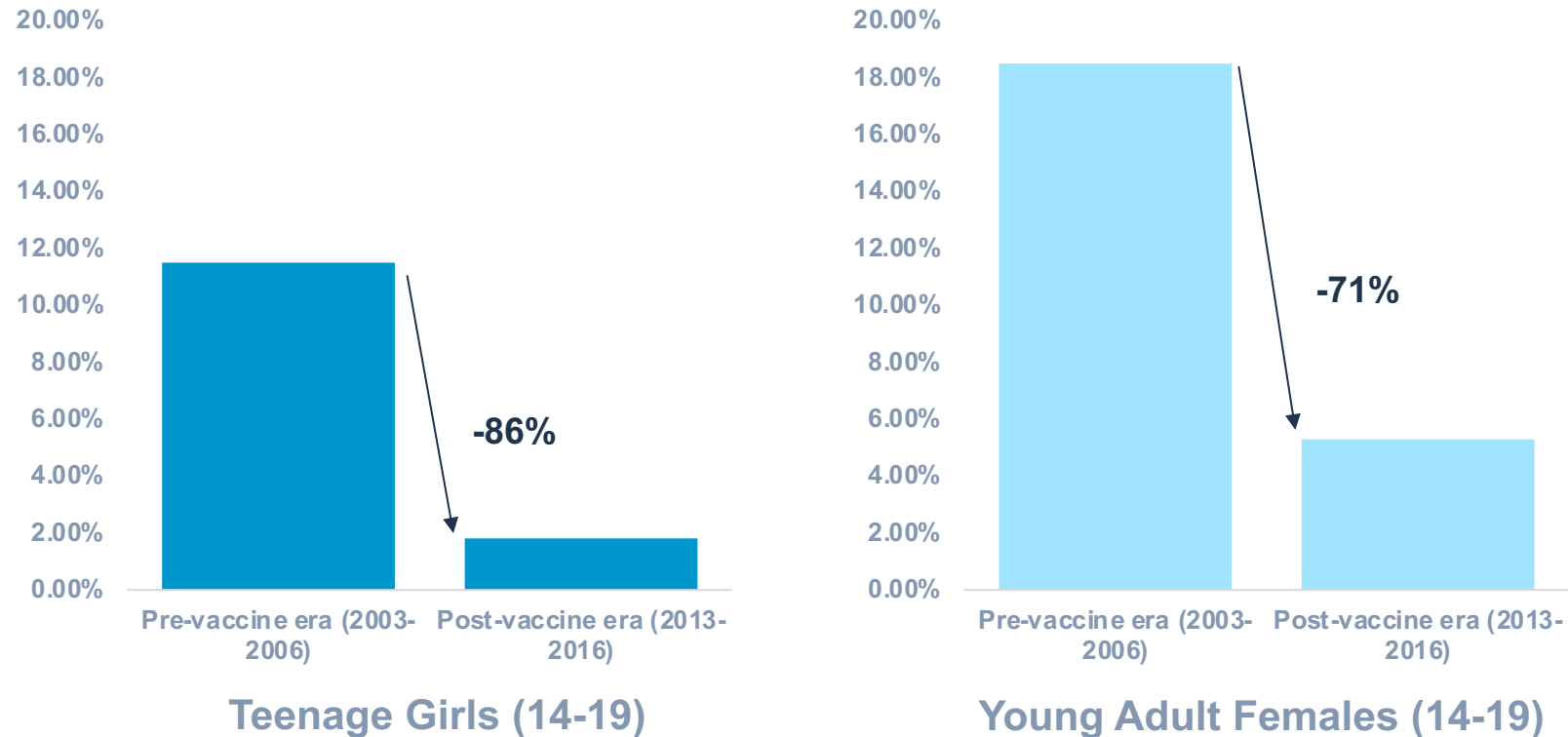
5-Year Survival Rates for CML Patients After Initial Introduction of Imatinib



Vaccines Drive Down Prevalence of Cervical Cancer-Causing HPV Infections

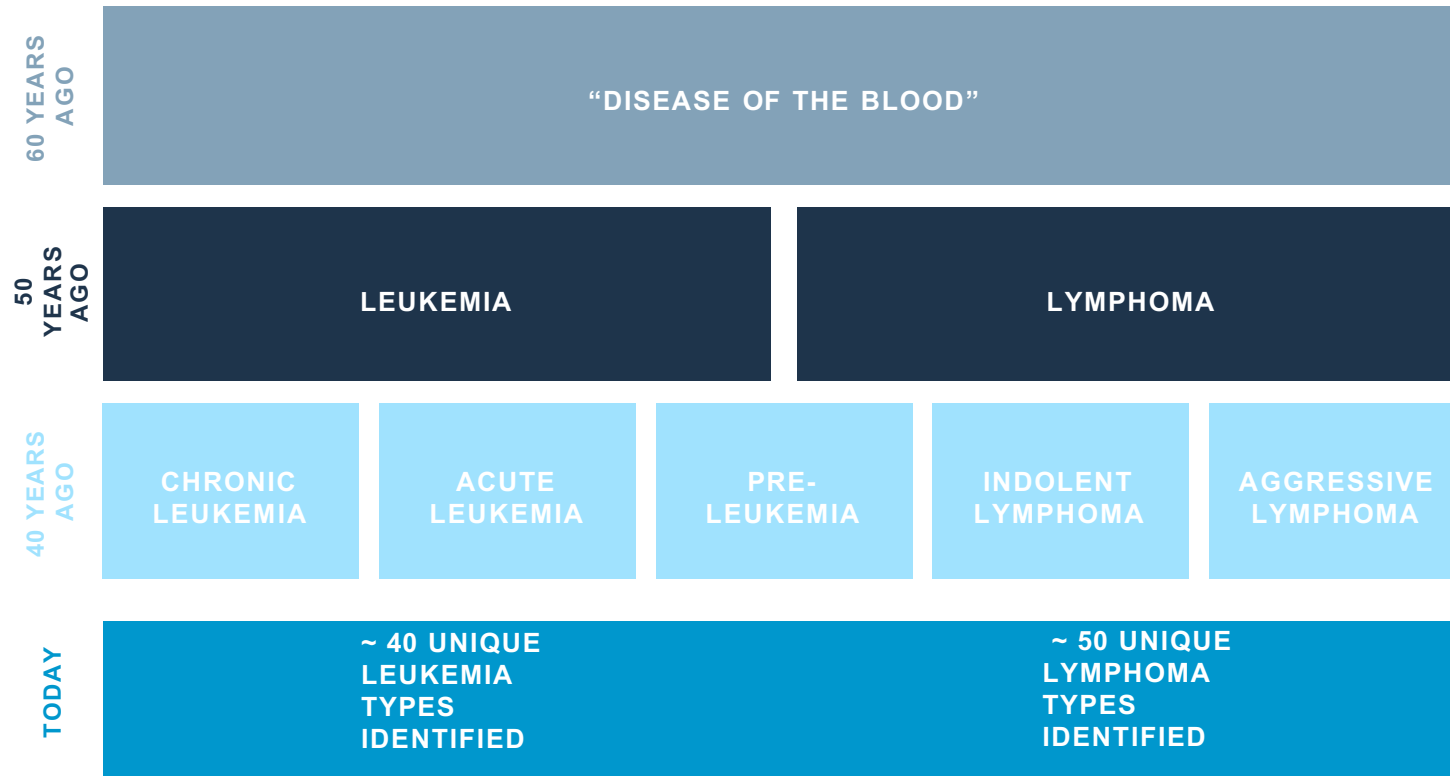
Widespread use of the human papilloma virus (HPV) vaccine has dramatically driven down prevalence of infection in teenage girls and young adult females since the vaccine has been in use in the United States. HPV vaccination has been shown to dramatically reduce the risk of invasive cervical cancer.

Prevalence of HPV Infection Targeted By Vaccine



Transformation in Cancer Diagnosis Has Led to More Precise Treatment

A greater understanding of the molecular basis of disease has transformed what was once known collectively as “disease of the blood,” into multiple subtypes of leukemias and lymphomas, opening up new treatment approaches.

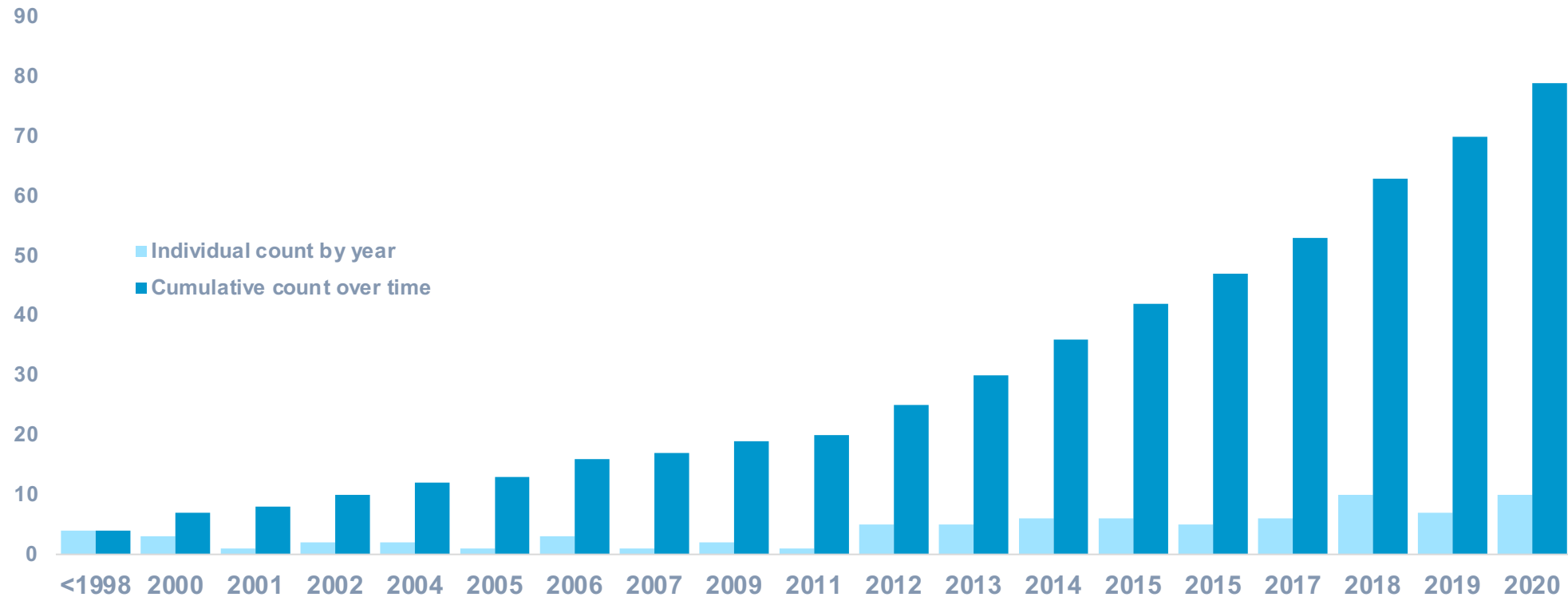


There are nearly 400 medicines in development for a range of blood cancers.

The Role of Personalized Medicines in Oncology is Rapidly Growing

Personalized medicines target the right medicines to the right patient. Predictive biomarkers are characteristics of patients used to determine which patient will respond best to a particular therapy. 59% of oncology medicines launched over the last 5 years in the U.S. require or recommend biomarker testing prior to use.

Number of U.S. Oncology Approvals with Required or Recommended Predictive Biomarker Testing*



Accelerated Approvals Enable Cancer Patients to Access Medicines Sooner Leading to Improved Outcomes

The accelerated approval pathway enables expedited access to medicines that address an unmet medical need for serious or life-threatening diseases like cancer. 85% of therapies approved via this pathway are for cancer patients. Approval may be based on a surrogate endpoint such as a reduction in tumor size, rather than on overall survival, a measure that may take years to confirm. On average, cancer therapies receiving accelerated approval are available to patients 3.4 years sooner than would be achievable through traditional FDA approval

Case Study: Multiple Myeloma

10
Medicines

have been **granted accelerated approval** for multiple myeloma.

90%
Increase

in **5-year survival rates** since the early 1990s.

Improvements in Life Expectancy

are **“greatly due to drugs that were approved under accelerated approval,”** as noted by the FDA.

Notes:

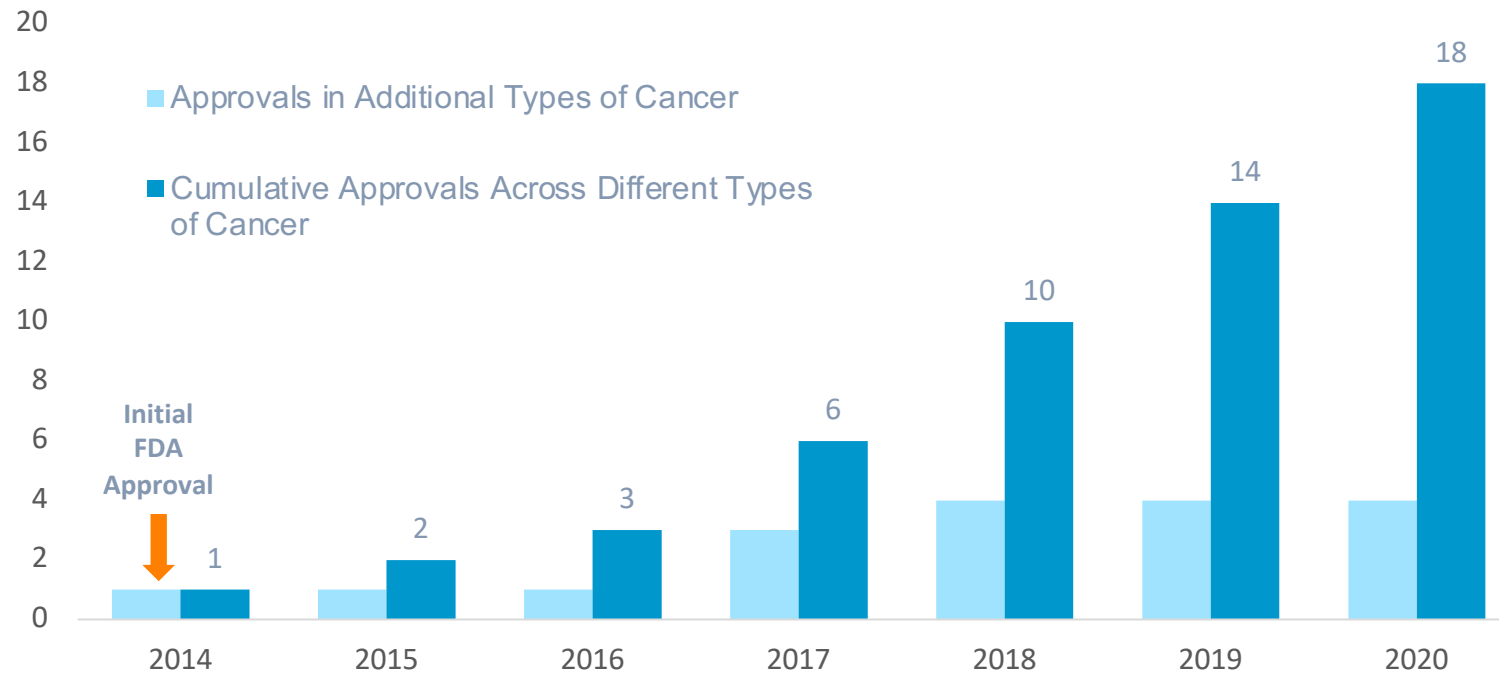
* FDA approval of medicines that use the Accelerated Approval Pathway means the approval is based on a review of the medicine's effect on a “surrogate endpoint” – a marker such as a laboratory measurement, radiographic image, physical sign or other measure – that is reasonably likely to predict long-term clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. FDA then may require that sponsors of accelerated approval products conduct post approval studies to verify clinical benefit.

**The FDA evaluates whether a medicine should receive accelerated approval based on the robustness of scientific support behind the endpoint. As Congress has made clear, the accelerated approval pathway does not alter the “standards of evidence and applicable conditions for approval” for drugs.

Post Approval Research on Existing Medicines is Critically Important to Cancer Treatment

Initial FDA approval is often just the beginning. Additional research may prove a medicine is effective in different forms of cancer or treatment populations, demonstrate greater efficacy when administered earlier in the progression of disease, or is effective in patients with certain genetic characteristics. For example, pembrolizumab was originally approved to treat melanoma. Additional research led to the approval for use in a total of 18 different types of cancers, including for use earlier in the treatment line for many cancers, in children, and as a tissue agnostic therapy.**

Pembrolizumab, Approvals In Additional Types of Cancer Following Initial FDA Approval*



Notes:

* Approvals reflect *initial* drug approvals in the 18 distinct cancers listed on the FDA drug label as of December 31, 2021. Subsequent approvals for use—for example: earlier in the treatment line, in combination with other medicines, or in different treatment populations—are not reflected in this data.

** Tissue agnostic therapies are approved for use in patients with tumors expressing a certain genetic feature, regardless of the tissue in the body in which the tumor originated.

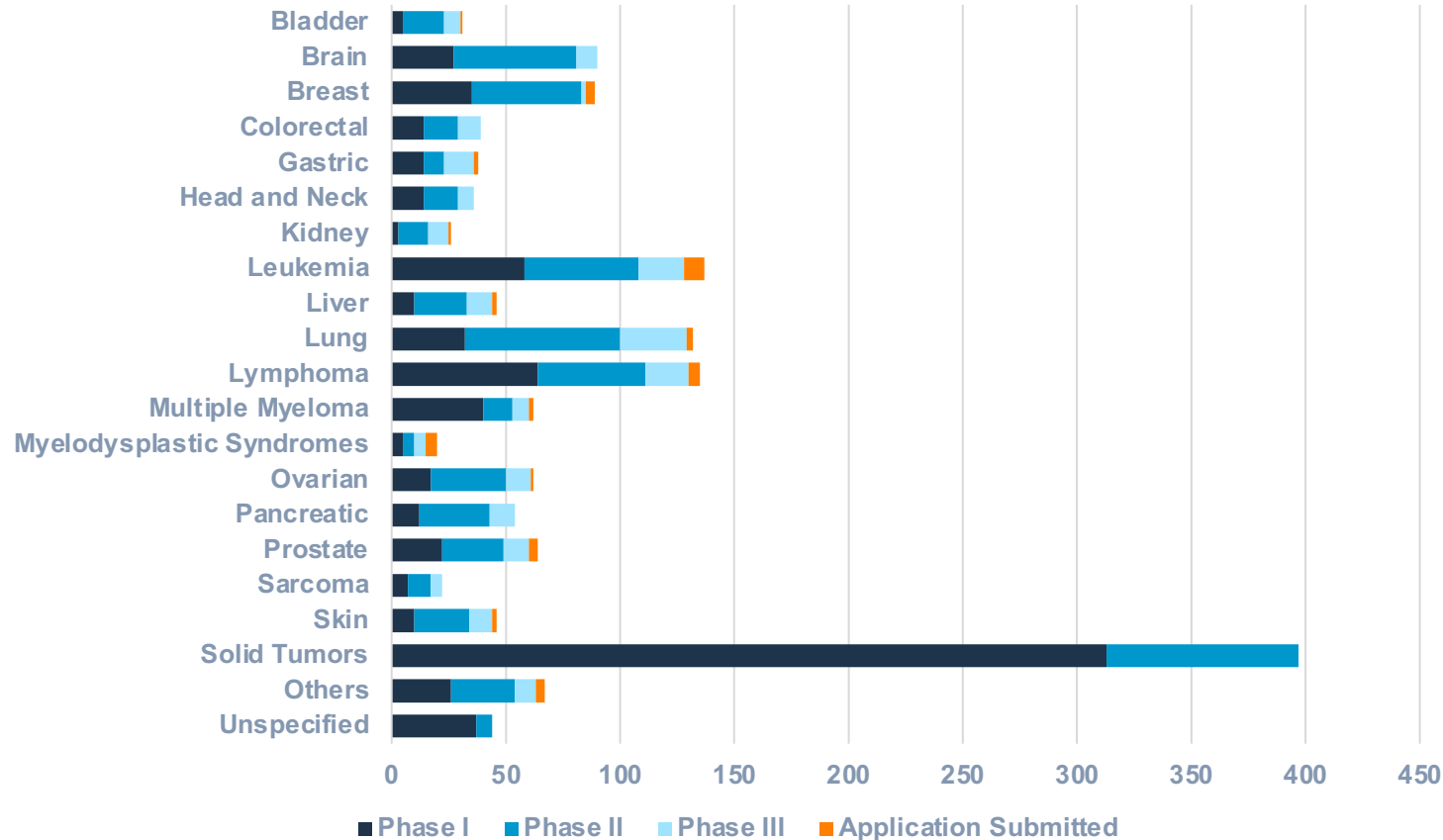
02

PROMISE IN THE PIPELINE

Cancer progress has been truly remarkable in recent years. But there remains significant unmet need. The current pipeline holds enormous promise in improving treatment outcomes for patients with a wide range of cancers. But as researchers explore new frontiers and discover more about the hundreds of diseases we collectively call cancer, the more complexity is uncovered.

Promise in the Pipeline: More than 1,300 Medicines in Development for Various Cancers

Medicines and Vaccines in Development for Cancer by Type, December 2020



“There has never been a more promising time in history for the cancer field... The rapid pace and broad scope of the progress we are making against cancer are extraordinary and we are now poised to deliver the next wave of lifesaving breakthroughs.”

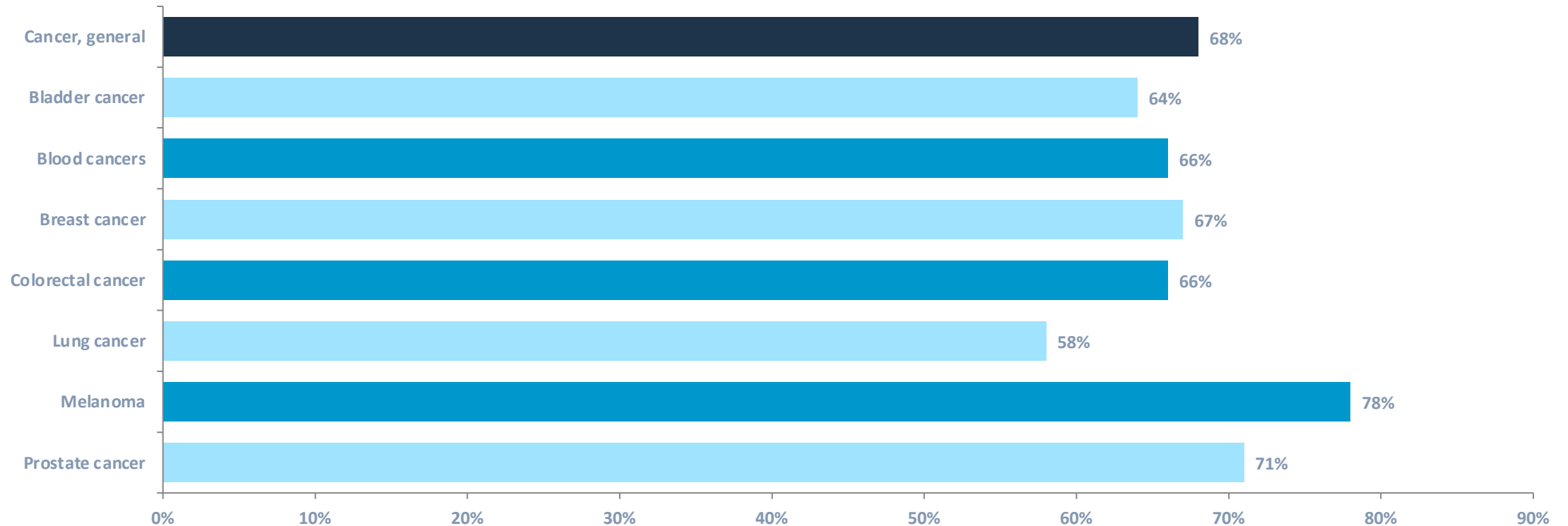
—Margaret Foti, PhD, MD (hc), Chief Executive Officer of the American Association of Cancer Research

*Some medicines may be in more than one therapeutic category.
Sources: PhRMA, Medicines in Development for Cancer, December 2020.

New Approaches to Treating Cancers Represent the Majority of Medicines in the Oncology Pipeline

Researchers are using novel approaches to attack cancer at the molecular level. An average of 68% of drugs in the oncology pipeline have the potential to be first-in-class medicines.

Percentage of Projects in Development that are Potentially Novel Approaches in Selected Cancer Areas, 2020



Biopharmaceutical Researchers are Pushing the Frontiers of Science

The cancer pipeline is ripe with innovative therapeutic options.



Gene editing involves manipulation of DNA at particular locations in order to treat a specific cancer.

Oncolytic viral therapies zero in on cancer cells, replicate and cause them to rupture.

Immunotherapies help target and kill cancer cells by unleashing the immune system. (e.g., CAR-T, checkpoint inhibitors).

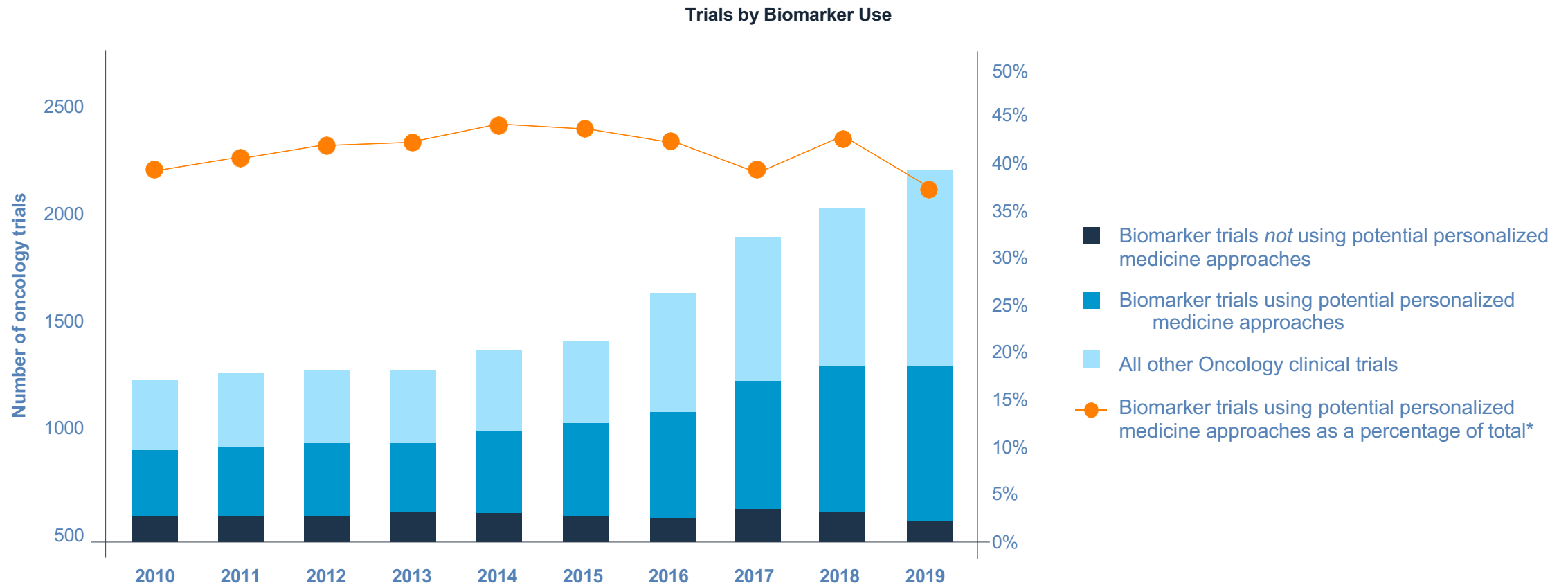
Antibody Drug Conjugates target specific cancer cells with cytotoxic agents without harming normal cells.

“In the next 10 years, I expect that scientific discoveries will ignite another revolution in cancer treatment and further improve outcomes for patients with cancer.”

—Antoni Ribas, MD, PhD
President, AACR,
Professor of Medicine, Surgery, and
Molecular and Medical Pharmacology, UCLA

Biopharmaceutical Companies are Increasingly Researching More Targeted Cancer Therapies

The use of biomarkers in oncology clinical trials, which help predict patients who will benefit from cancer treatments has grown in recent years. This growth is driven by biomarker trials using potential personalized medicine approaches, which have more than doubled since 2010, representing 42% of oncology trials in 2019.



Note: Trials using personalized medicine approaches use pharmacogenomic (PGX) patient stratification, i.e., trials incorporating pharmacogenomic and/or pharmacogenetic analysis to stratify patients for predictive response, safety, or dosing. Source: IQVIA. "Supporting Precision Oncology: Targeted Therapies, Immuno-Oncology, and Predictive Biomarker-Based Medicines," 2020.

Cancer Researchers Build on Knowledge Gained from Setbacks to Advance New Treatments

The more researchers discover about the hundreds of diseases that we now know make up cancer, the more complexity and challenges are uncovered. As a result, the process is fraught with many setbacks. For every medicine that successfully makes it to patients, there are many more investigational medicines that fail. But these so called “failures” inform new avenues of research and pave the way for future medicines.



MELANOMA

- 158 unsuccessful medicines
- 12 new medicines



BRAIN CANCER

- 122 unsuccessful medicines
- 3 new medicines



LUNG CANCER

- 268 unsuccessful medicines
- 32 new medicines

*Setbacks and advances from 1999 to 2019

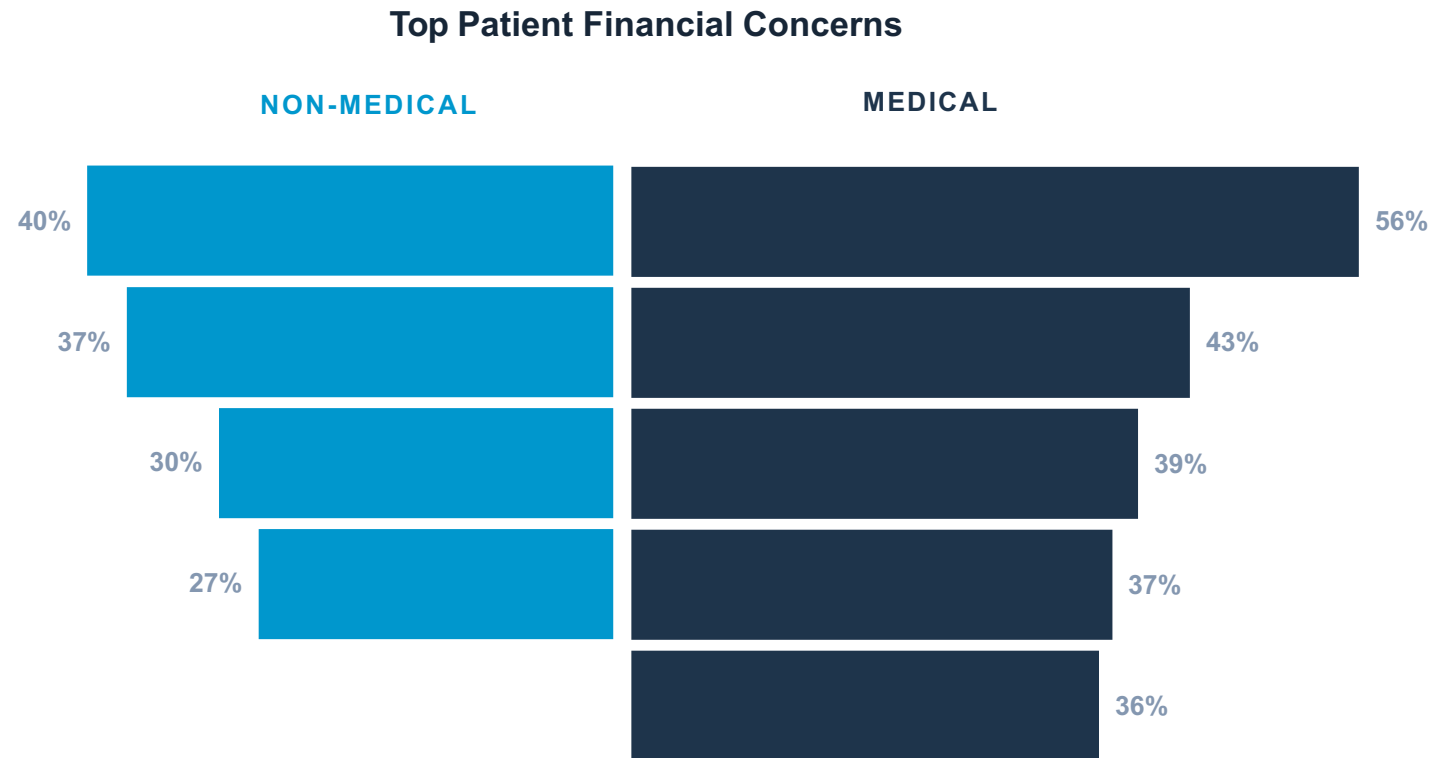
03

CANCER PATIENT FINANCIAL BURDEN

Today, too many cancer patients face financial burdens, which are driven by a range of medical and non-medical costs and shifts in insurance benefit design. While most patients with cancer face no out-of-pocket costs for oncology medicines at the pharmacy counter, a small share of patients are burdened with high out-of-pocket costs for their medicines due to increasing use of deductibles and coinsurance which shifts more costs onto patients. Patient assistance programs play a critical role in helping many cancer patients afford their cancer medicines and preventing abandonment and treatment delays.

Multiple Factors Contribute to the Financial Burden Faced by Cancer Patients

Physician services, transportation expenses, and the inability to work, among other things, drive the cost burden on cancer patients – often more so than prescription drugs. Although 42% of patients indicate that medical expenses were the primary driver of their financial difficulties, more than 40% of cancer patients say medical and non-medical expenses contribute equally to their financial difficulties



A Cancer Diagnosis Impacts Productivity and Employment for Patients and Caregivers

Loss of employment and decreased earnings, which may result from working less hours or taking unpaid leave, are associated with greater risk and severity of financial hardship.



PATIENTS

67%

of patients who were employed full-time when diagnosed either **stopped working** or **reduced their work hours**.



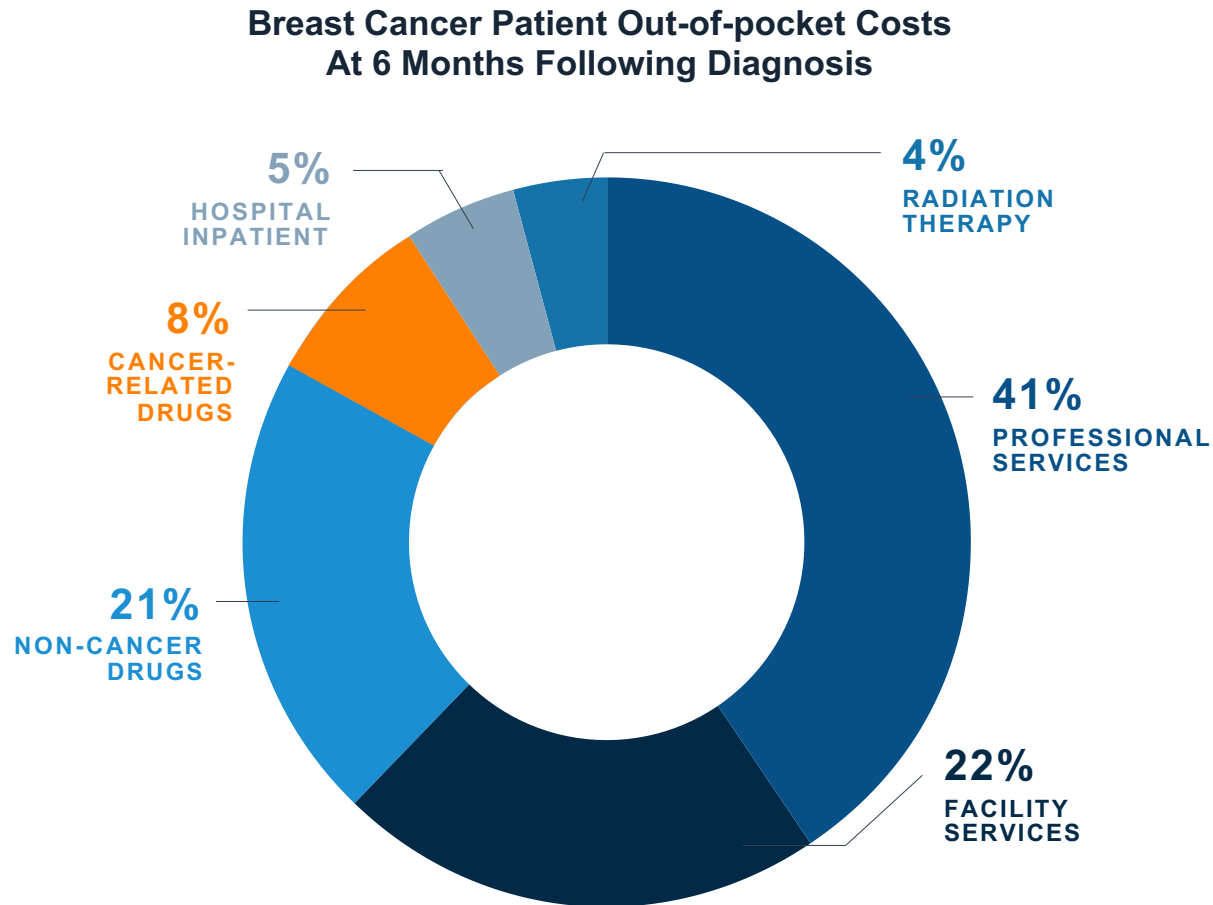
CAREGIVERS

>25%

of caregivers made **extended employment changes**.

Many Factors Contribute to Cancer Patient Out-of-Pocket Costs

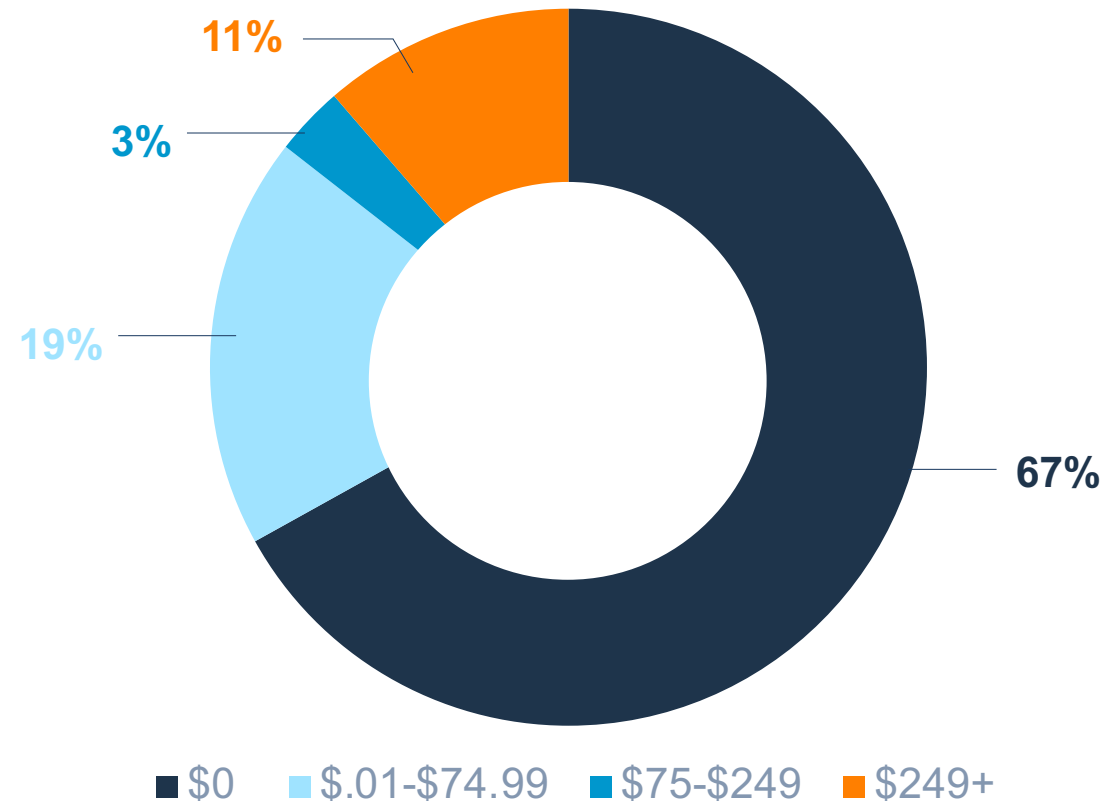
At 6 months post-diagnosis, 60-70% of out-of-pocket costs are driven by physician and facility care for commercially insured patients with breast, lung and colorectal cancer on average.



A Small Share of Patients Face High Out-of-Pocket Costs for Oncology Medicines

Two-thirds of prescriptions for brand oral oncology medicines have no patient out-of-pocket costs. However, about 11% of prescriptions cost patients \$250 or more out of pocket.

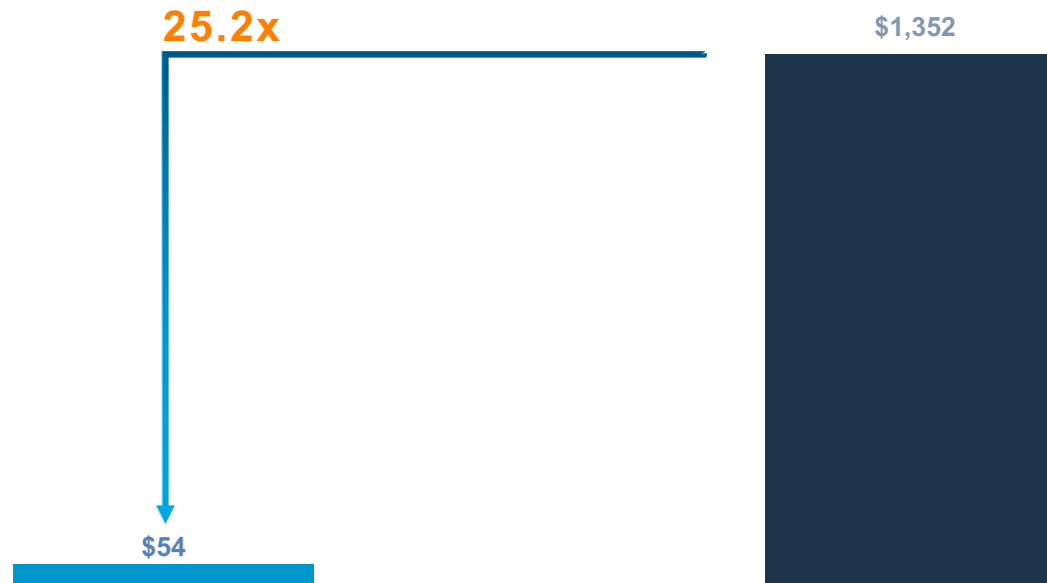
Final Out-of-Pocket Cost Distribution for Brand Oral Oncology Brand Prescriptions Across All Payer Types, 2019



Increasing Use of Coinsurance and Deductibles Shifts More Costs onto Patients with Cancer

Final annual out-of-pocket costs for patients taking brand oncology medicines was 25.2 times greater on average for patients with deductible or coinsurance spending than those with only copay cost sharing

**Final Annual Average Out-of-Pocket Costs
for Patients Taking Oncology Brand
Medicines, 2019***

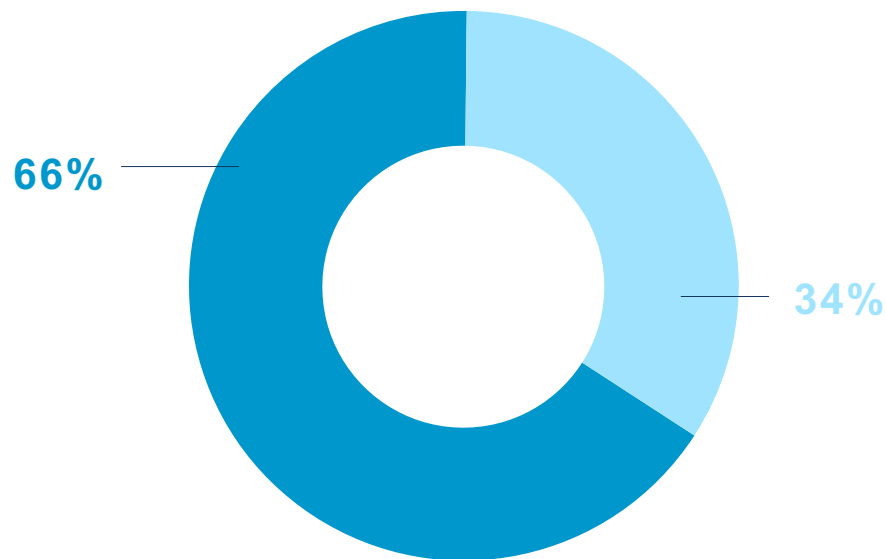


*Reflects final annual average out-of-pocket spending for patients taking condition-specific brand medicines.
Source: IQVIA, Medicine Spending and Affordability in the United States, August 2020.

A Small Share of Patients Account for the Majority of Out-of-Pocket Spending on Cancer Medicines

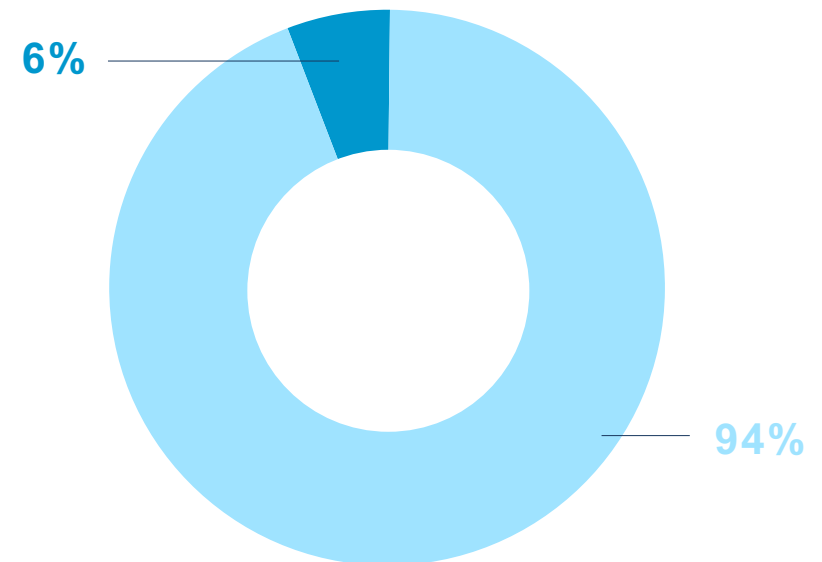
In 2019, 34% of patients across all payers had coinsurance and deductible spending for brand oncology medicines. But these patients represented 94% of total out-of-pocket spending on these medicines.

Share of Patients with Deductible and Coinsurance Spending on Brand Oncology Medicines



- Patients without Deductible and Coinsurance Spending
- Patients with Deductible and Coinsurance Spending

Share of Final OOP Spending on Brand Oncology Medicines by Benefit Design

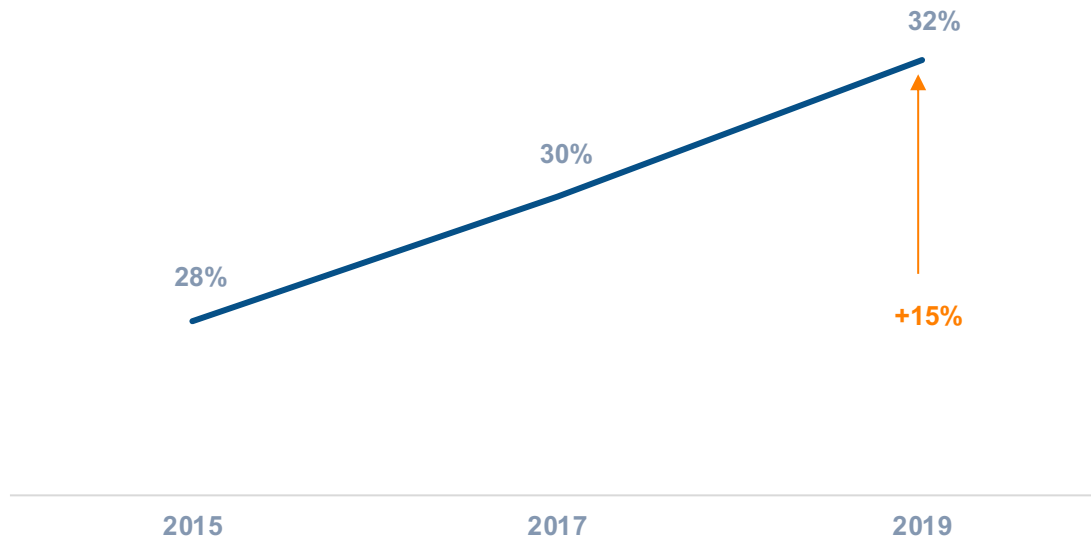


- Spending without Deductible or Coinsurance Spending
- Spending in the Deductible or with Coinsurance

An Increasing Share of Patients Taking Brand Cancer Medicines Use Cost-Sharing Assistance to Help Pay Out-of-Pocket Costs for their Medicines

Manufacturer cost sharing assistance helps commercially insured patients who otherwise might struggle to afford their out-of-pocket costs

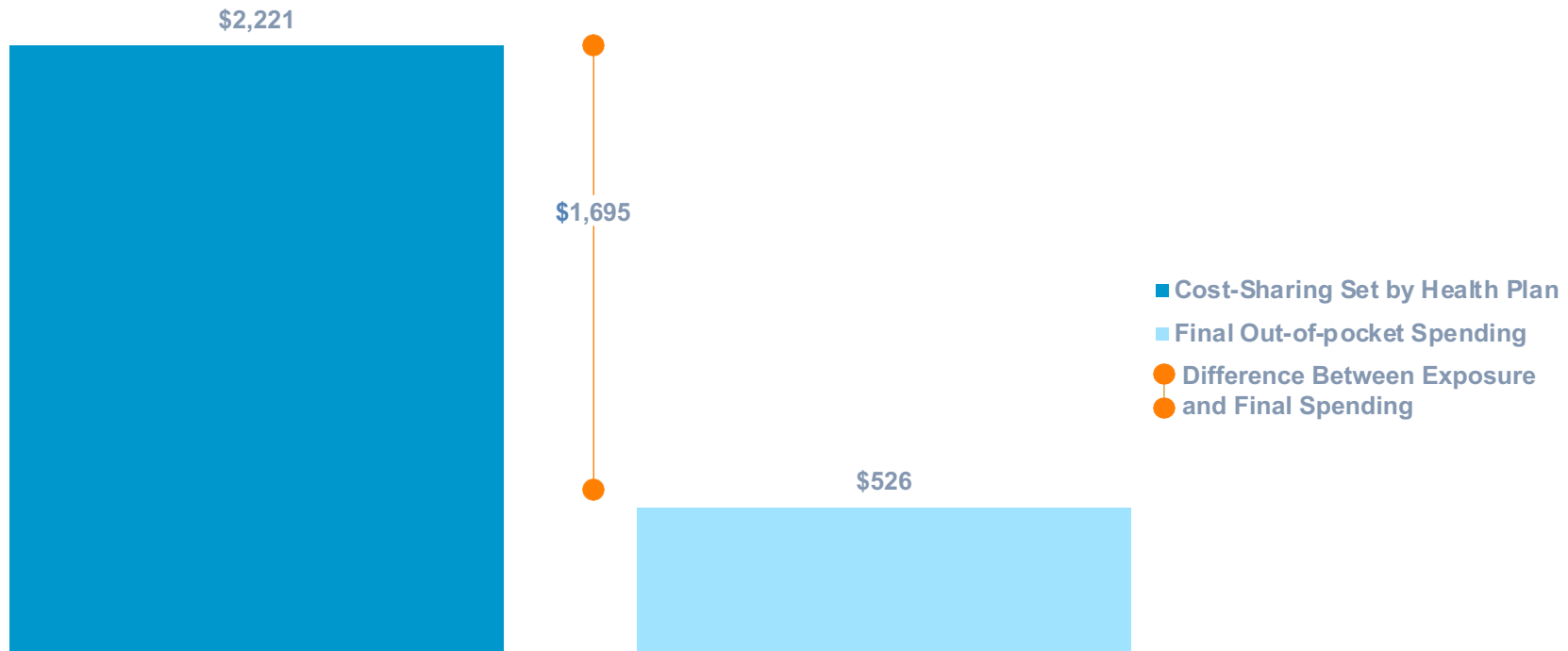
Share of Patients Taking Brand Cancer Medicines Using Cost Sharing Assistance to Fill One or More Prescriptions



1-in-3 patients taking brand cancer medicines used cost-sharing assistance in 2019.

Patient Spending on Brand Cancer Medicines Would Have Been 4x Higher Without Cost-Sharing Assistance

Average Initial Exposure and Final Annual Out-of-Pocket Spending for Patients Taking Brand Oncology Medicines Who Used Cost Sharing Assistance, 2019*



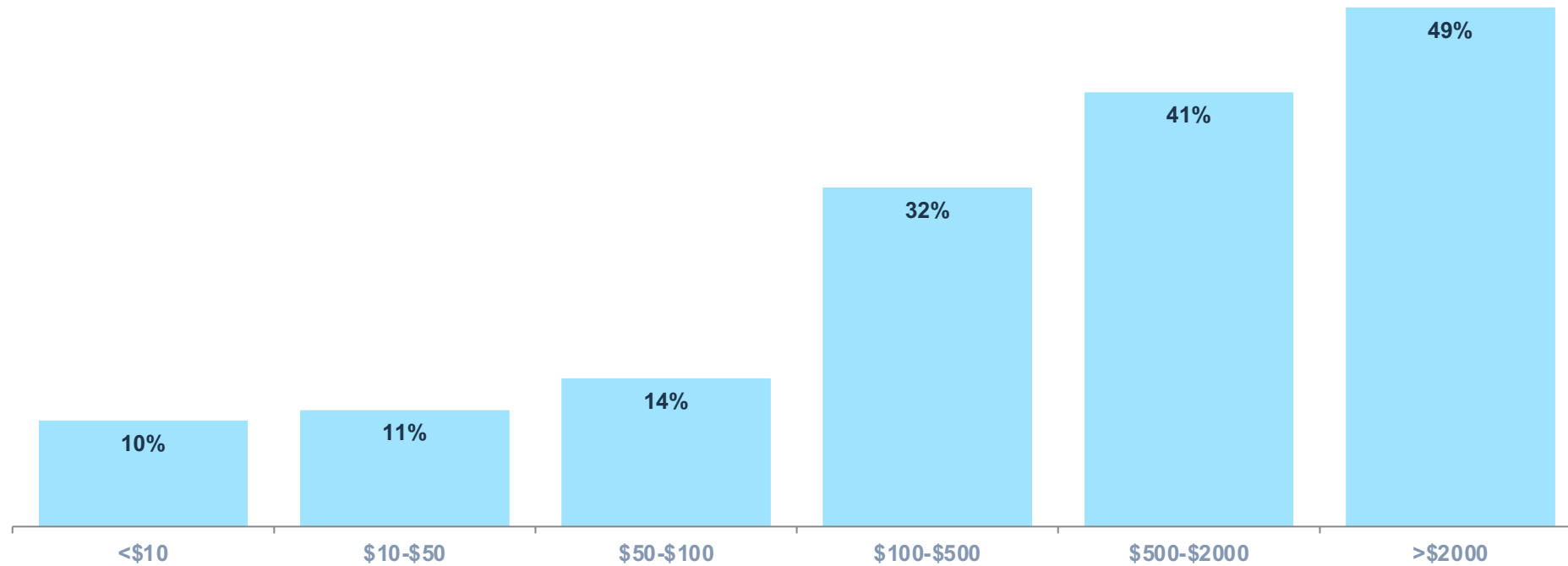
*Includes out-of-pocket spending for condition-specific brand medicines only. Out-of-pocket exposure measures the amount health plans required patients to pay. Difference between initial and final out-of-pocket spending represents the savings from use of cost-sharing assistance.

Source: IQVIA, U.S. Market Access Strategy Consulting, July 2020.

High-Cost Sharing Can Lead to Abandonment or Delays in Cancer Treatment

Patients with highest cost sharing were 5 times more likely to abandon treatment than patients with the lowest cost sharing.

Oral Oncolytic Abandonment Rate by Patient Out-of-Pocket Amount



04

CANCER COSTS IN CONTEXT

Despite an increase in new medicines becoming available to patients in recent years driving significant improvements in health outcomes, spending on cancer medicines has remained a small and steady share of overall cancer and overall health care spending.

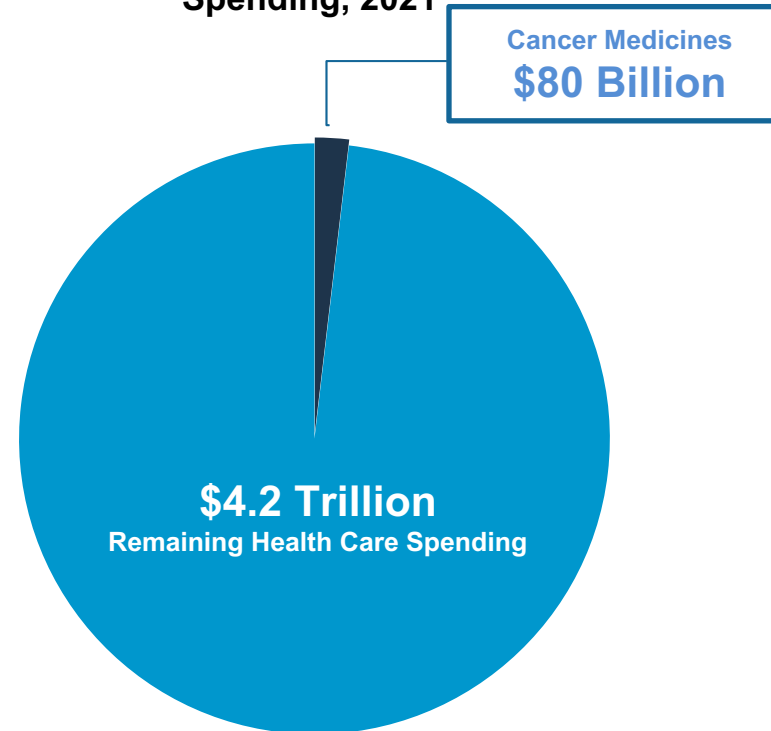
Market-based mechanisms are working to control costs in our health care system. Payers are able to leverage cost-containing tools, like formulary exclusions and utilization management techniques, to drive competition between cancer medicines. The market is also shifting to new payment models as it continues to evolve and adapt.

Additionally, generics and an increasing number of biosimilars are driving significant competition and savings in the oncology market today. Looking ahead, competition is expected to continue to make headroom for tomorrow's innovative treatments.

Spending on Cancer Medicines Represents Less than 2% of Overall Health Care Spending

Despite an increase in new medicines becoming available to patients in recent years driving significant improvements in health outcomes, spending on cancer medicines has remained a small and steady share of overall cancer and overall health care spending.

Projected Spending on Cancer Medicines as a Portion of Total U.S. Health Care Spending, 2021*



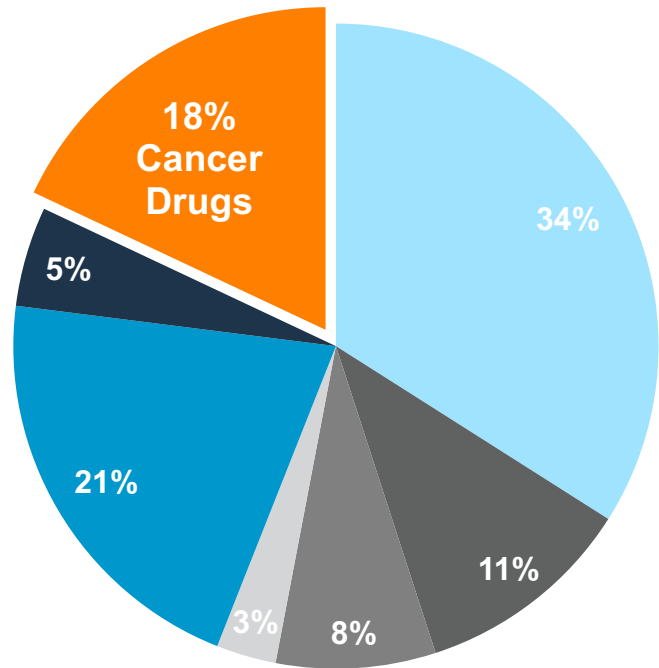
*Cancer medicine spending reflects invoice spending, which does not account for rebates and discounts

Sources: IQVIA Institute. The Use of Medicines in the U.S. May 2021.; Centers for Medicare & Medicaid Services (CMS). National health expenditure projections 2019-2028: forecast summary. Published March 2020. Accessed March

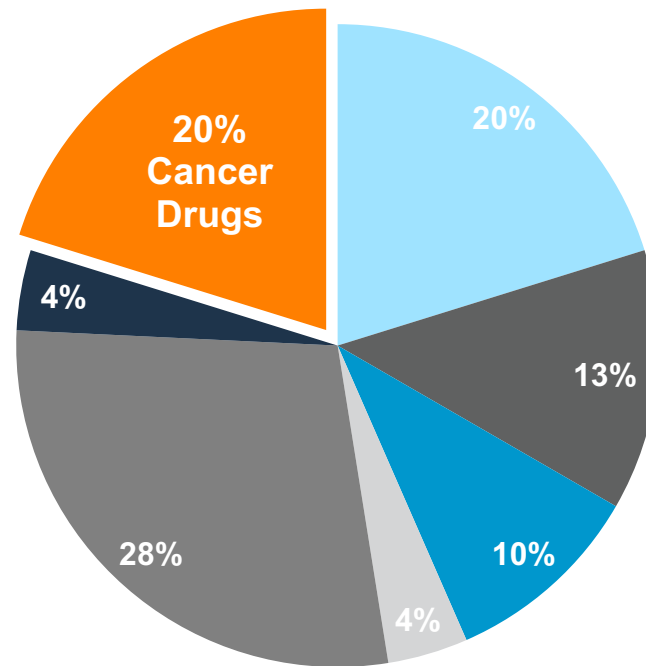
2020. <https://www.cms.gov/files/document/nhe-projections-2019-2028-forecast-summary.pdf>.

Cancer Medicines Represent About 20% of Overall Spending on Cancer Care

Medicare, Actively Treated Cancer Population



Commercially Insured, Actively Treated Cancer Population

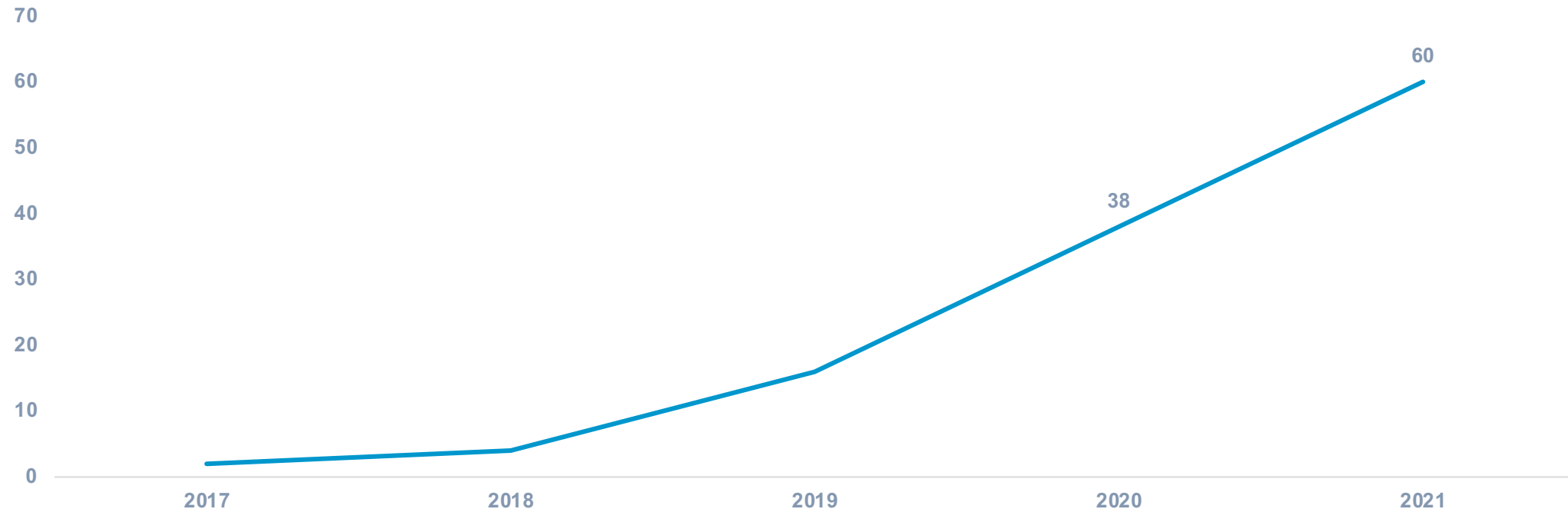


- Hospital Inpatient
- Cancer Surgeries
- Radiology
- Radiation Oncology
- Other Out Pt Services
- Professional Services
- Cancer Drugs

PBMs Increasingly Use Formulary Exclusions to Drive Competition Between Cancer Medicines

The use of formulary exclusions have increased rapidly in recent years, increasing at an annual rate of 93% since 2017. Formulary exclusions can affect therapies dispensed in retail pharmacies as well as physician administered cancer therapies. Physician administered cancer treatments accounted for nearly half of excluded products in 2021.

Number of National Formulary Exclusions in Oncology (Top National Payers, Commercial Payers), 2017-2021

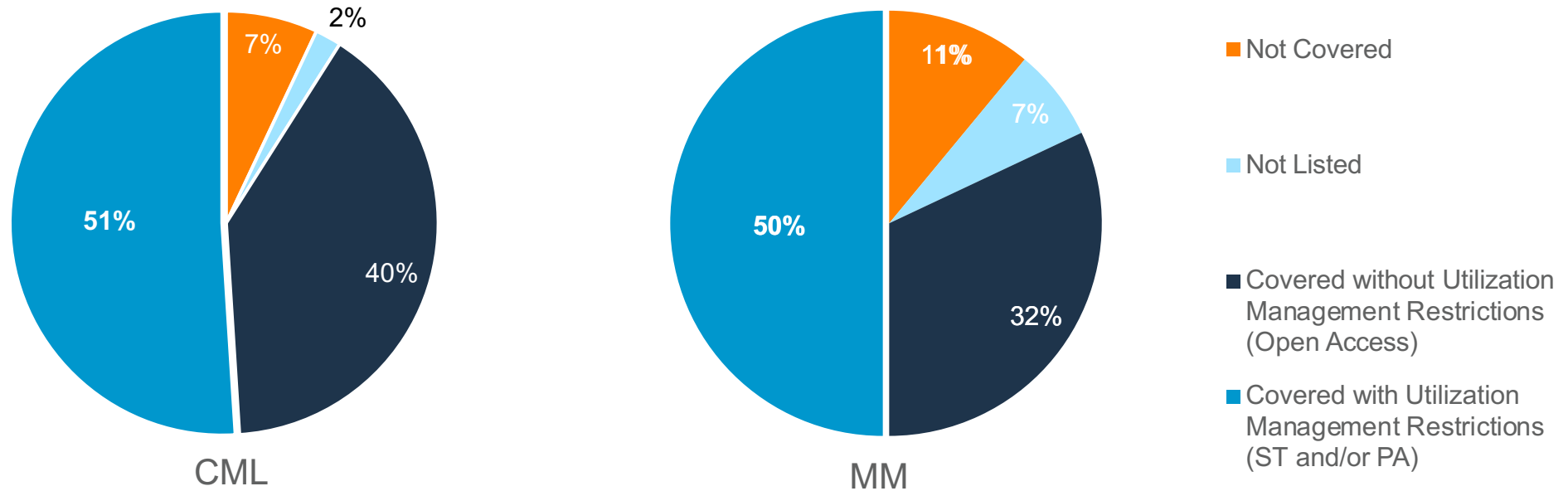


Notes: National Payers include Aetna, CVS Caremark, Cigna, Express Scripts (the PBM subsidiary of Cigna), OptumRx (the PBM subsidiary of UnitedHealthcare), and Prime Therapeutics.
Source: IQVIA, [Controlling Cancer Care: The Emergence of Formulary Exclusions in Oncology](#), 2021

Payers Increasingly Use Utilization Management Tools to Limit Access to Cancer Medicines

Half of brand multiple myeloma (MM) and chronic myelogenous leukemia (CML) medicines in the commercial market face step therapy (ST) and/or prior authorization (PA) restrictions. Between 2014 and 2020, use of ST in commercial plans increased 311% for brand MM medicines and 150% for brand CML medicines. Over this same period, use of PA increased 173% and 448% for MM and CML brand medicines, respectively.

Coverage of Brand Medicine to Treat CML and MM in the Commercial Market, 2020



Notes:

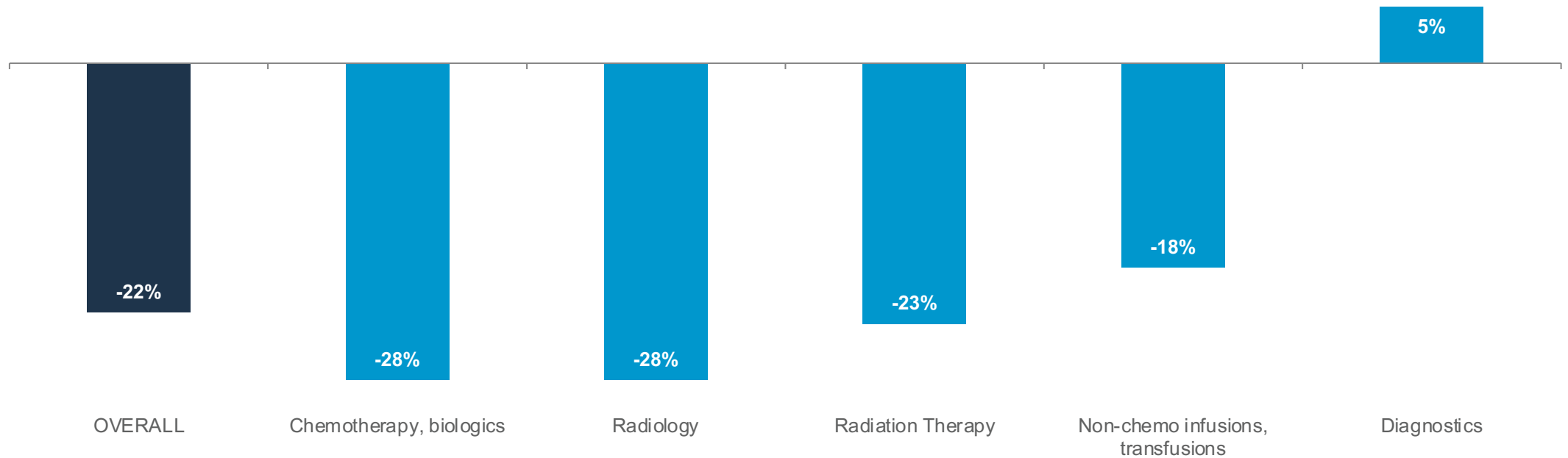
Prior authorization requires patients to obtain approval from the health plan before a medication is covered. The process can be lengthy, with several stages of back-and-forth between the insurer and provider before the insurer approves or rejects the request. Step therapy requires patients to try 1 or more alternative medications to treat their condition before the plan covers the drug originally prescribed by the provider.

Not Listed denotes when a plan did not list a product on its formulary. However, the drug may or may not still be covered based on the given plan's policy for not listed drugs. Total may not sum to 100% due to rounding.

Plans and Providers Rapidly Adopting Clinical Pathways

Clinical pathways are care plans that provide specific guidance on interventions and consider the benefits and harms of alternative care options, often taking the cost of therapy into account. Non-small cell lung cancer patients treated according to a clinical pathway incurred lower drug and total costs.

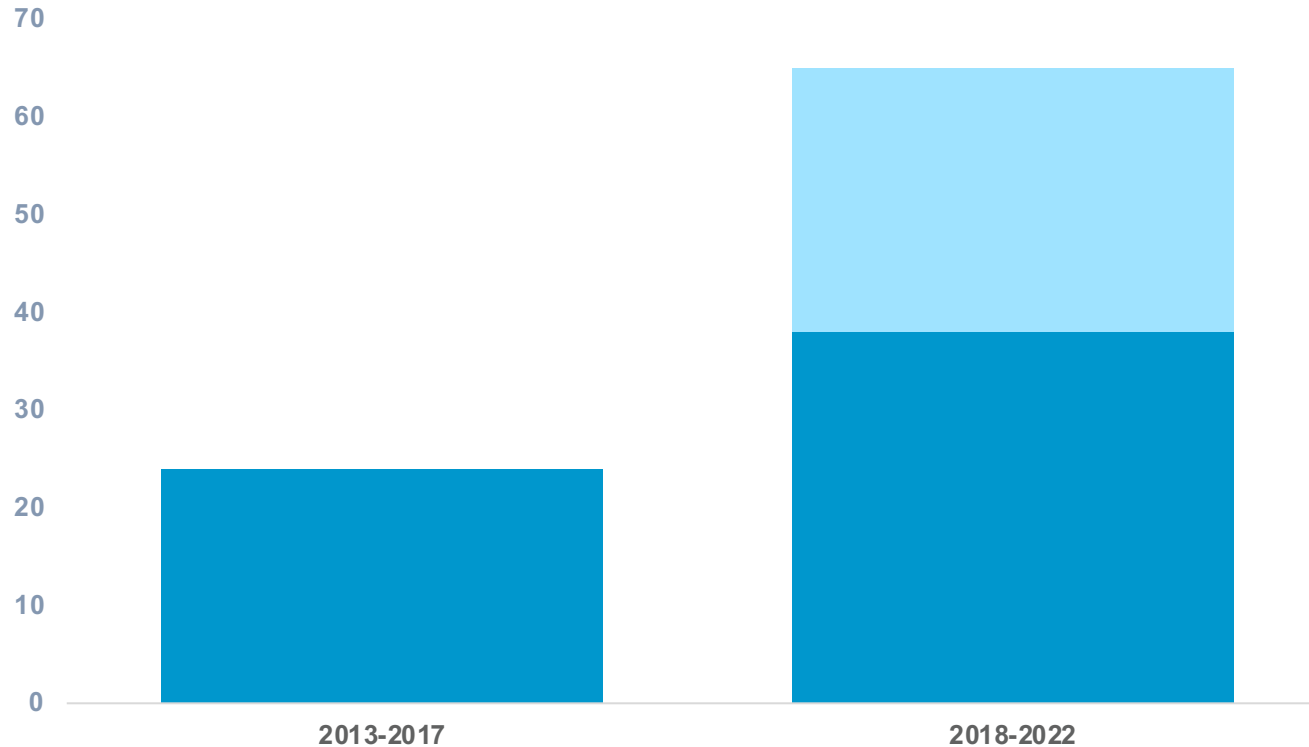
12-Month Savings with Lung Cancer Clinical Pathway



Manufacturers and Insurers Pursuing Outcomes-Based Contracts in Oncology

Shared risk or outcomes-based contracts (OBCs) between health insurers and manufacturers are becoming more common across diseases, including oncology.

Number of Private Sector Risk-Sharing Contracts Publicly Announced



More than **40%** of the 65 outcomes-based contracts projected between 2018-2022 are expected to be in oncology.

Biosimilars are Increasingly Driving Competition and Containing Costs in the Market for Cancer Medicines

There are 33 biosimilars approved in the U.S. and 18 are commonly used by cancer patients. More recently launched biosimilars are reaching greater market uptake far more quickly than earlier launched biosimilars. Experts predict the biosimilar marketplace will continue to drive savings and create headroom for spending on new and innovative treatments entering the market.

Annualized Savings from Biosimilars, 2020:



\$65 BILLION

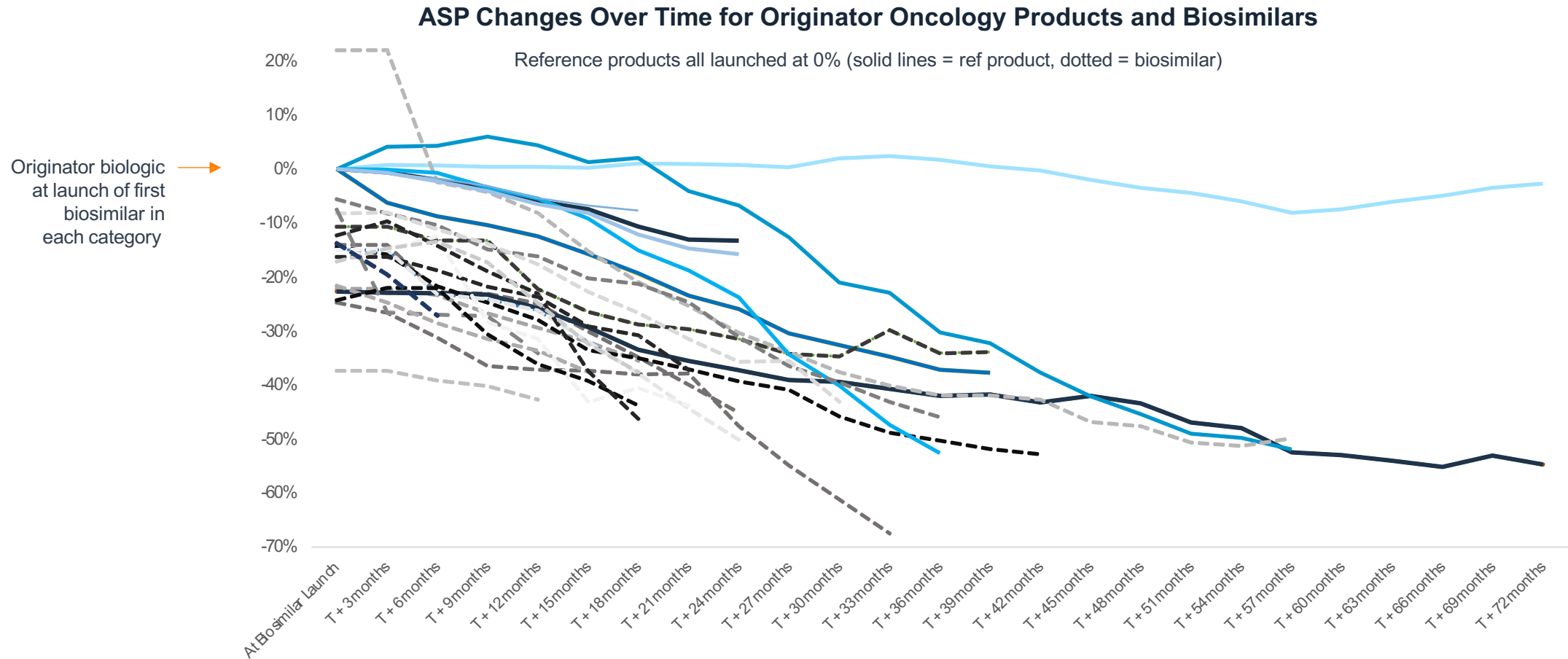
Projected Savings from Biosimilars Between 2020 and 2024:



\$100 BILLION

Prices of Biologics Used in Oncology Decline Substantially Following the Introduction of Biosimilars

In 2021, Average Sales Price (ASP) prices for biosimilars used in oncology were 15%-45% less than brand biologic prices at the time of the first biosimilar launch. ASPs for oncology biosimilars have been decreasing annually at a rate between 9% and 19%.



Biosimilar Competition is Driving Savings in Medicare Part B

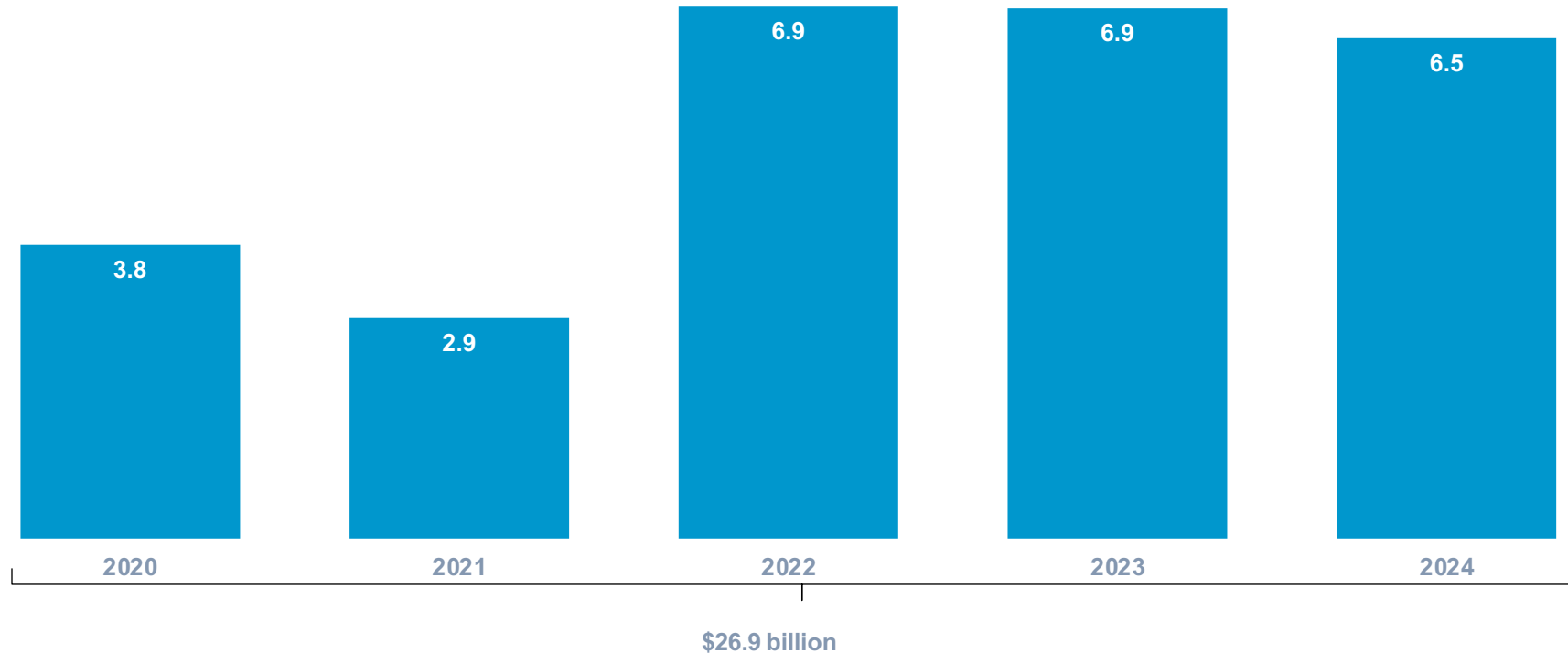
According to the Medicare Payment Advisory Commission, competition is leading to price reductions from *both* physician-administered biosimilars and branded biologics used in oncology, leading to lower costs for patients and Medicare.

Trends in Medicare Part B Payment Rates for Brand Biologics and their Biosimilar Products

	First Biosimilar Entry	Percent Change in Brand Biologics' ASP Since Biosimilar Entry (through 2021 Q1)	Biosimilars' Payment Rate as a Percent of Brand Biologic's Payment Rate (2021 Q1)	Biosimilar Market Share (2020 Q3)
Brand Biologic A and Biosimilars	2015 Q3	-6%	44%-56%	77%
Brand Biologic B and Biosimilars	2016 Q4	-46%	94%-115%	16%
Brand Biologic C and Biosimilars	2018 Q3	-35%	97%-116%	27%
Brand Biologic D and Biosimilars	2018 Q4	-28%	97%	47%
Brand Biologic E and Biosimilars	2019 Q3	-8%	75%-79%	41%
Brand Biologic F and Biosimilars	2019 Q3	-8%	74%-90%	40%
Brand Biologic G and Biosimilars	2019 Q4	-4%	74%-75%	24%

Cancer Medicines Face Growing Competition from Generics and Biosimilars

Global Oncology Sales at Risk of Reduction Due to Estimated Loss of Exclusivity
(Billions of U.S. Dollars)*



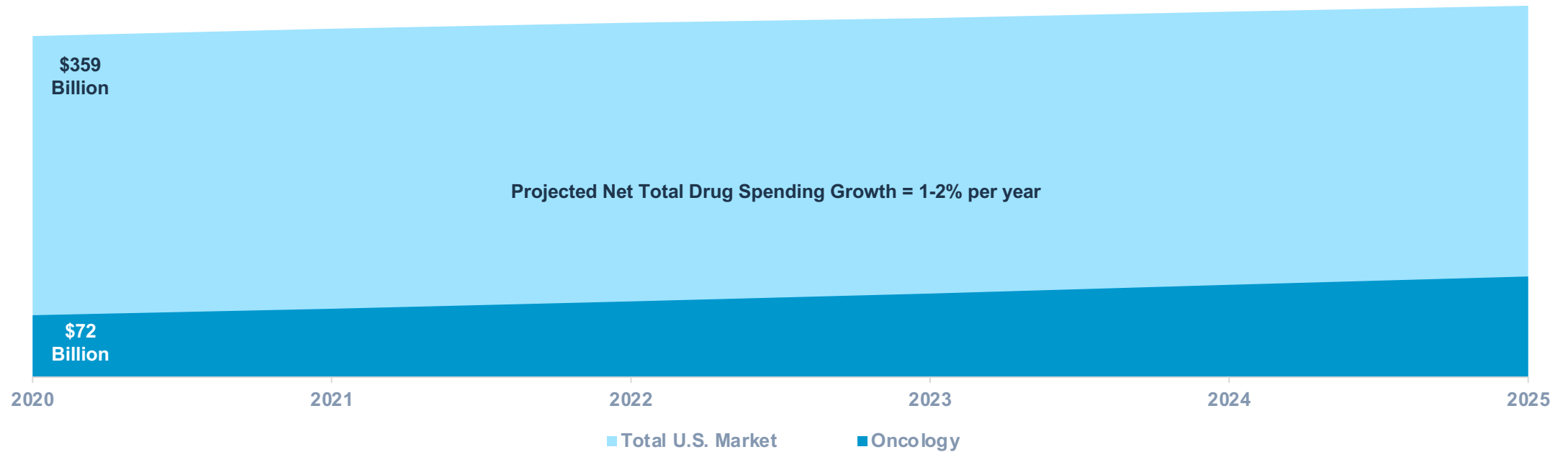
*Pre-Expiry spending is the actual and estimated spending in the 12 months prior to loss of exclusivity (LOE) and is shown for developed markets only. Estimates are based on patent expiry dates or expected generic/biosimilar availability, and historic analogues where available. Biologics and small molecules are modeled separately. Biologic brand sales at risk are based on any non-original biologic competitor, regardless of approval type.

Sources: IQVIA Market Prognosis, National Sales Perspectives, QuintilesIMS Institute, December 2020. Includes small and large molecules.

Overall Drug Spending Growth Expected to be Moderate as Cancer Progress Continues

Last year, biosimilars brought oncology medicine spending growth below 10% for the first time in seven years. Looking forward, biosimilars are expected to slow spending growth at similar levels over the next 5 years.

Projected Cancer Drug Spending as a Portion of Total Drug Spending, U.S. \$ Billions



*Cancer medicine spending reflects invoice spending, which does not account for rebates and discounts Sources: IQVIA Institute. The Use of Medicines in the U.S. May 2021.

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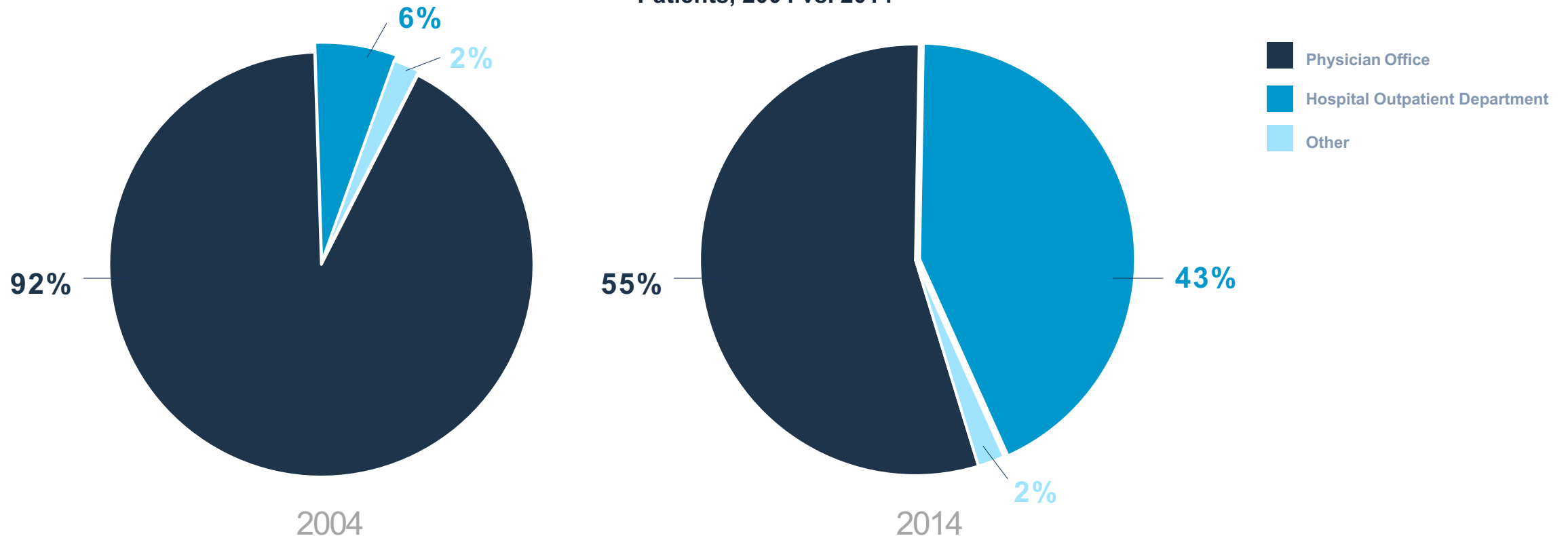
HOSPITAL MARKET DISTORTIONS

While competition is working well to contain costs in many ways, there are broader market distortions driven by hospital consolidation that are increasing cancer spending. As hospitals consolidate by buying physician practices and merging with other hospitals, they are able to leverage their size and lack of competition to demand large mark-ups on the prices of medicines and higher reimbursement from commercial payers. Greater profit potential, or “spread,” on 340B discounted drugs fuel trends in consolidation—which experts agree increase costs across the healthcare system.

Hospital Consolidation Shifts Care to More Expensive Settings for Cancer Patients

The share of physicians employed by a hospital or health system has increased from 41.8% in 2012 to 50.2% in 2020. This has led to a shift in site-of-care from community-based physician practices to more expensive hospital outpatient departments—particularly for cancer patients.

Shift in Site-of-Care for Infused Chemotherapy Among Commercially Insured Patients, 2004 vs. 2014

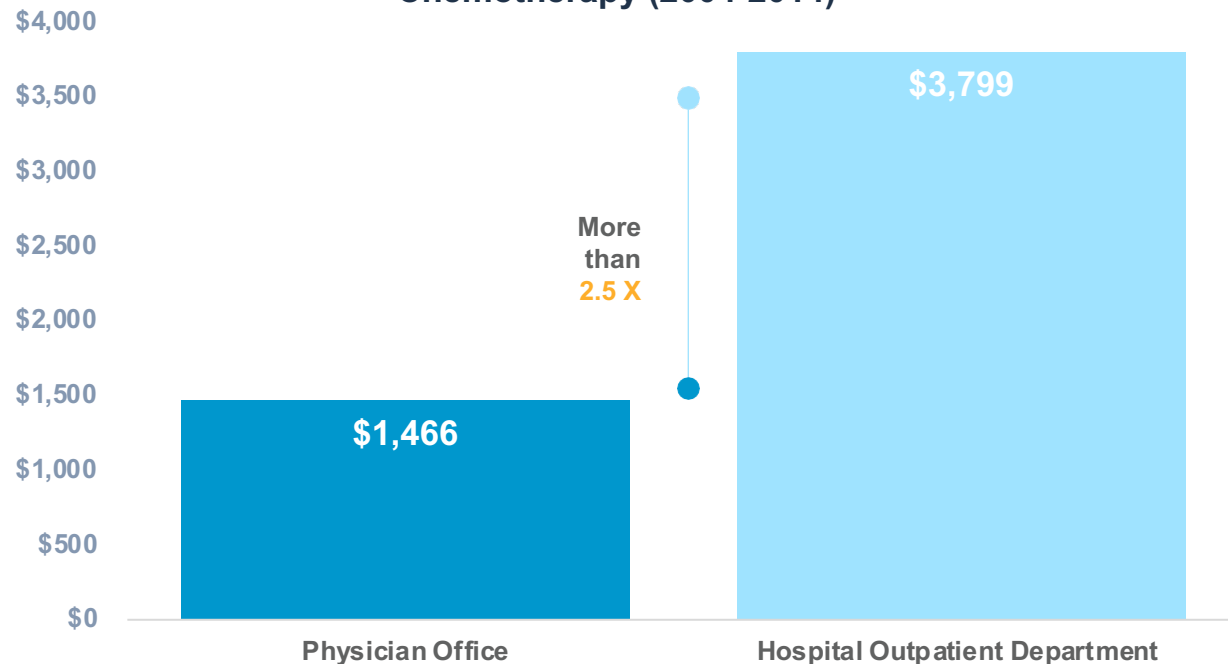


Source: American Medical Association. "Recent Changes in Physician Practice Arrangements: Private Practice Dropped to Less Than 50 Percent of Physicians in 2020," May 2021. Winn AN, Keating NL, Trogon JG, Basch EM, Dusetzina SB. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA oncology. 2018 Apr 1;4(4):580-1. Available online at: <https://jamanetwork.com/journals/jamaoncology/fullarticle/2673075>.

Hospitals are Paid More than Physician Offices for Cancer Medicines Due to Market Power

As hospitals and health systems rapidly consolidate, through the purchase of community-based oncology practices, they demand higher payments from commercial payers for providing equivalent services previously delivered in less-expensive, physician offices.

Average Drug-Level Commercial Spending on Infused Chemotherapy (2004-2014)



“If you want our beds, you have to take our prices for oncology treatment.”

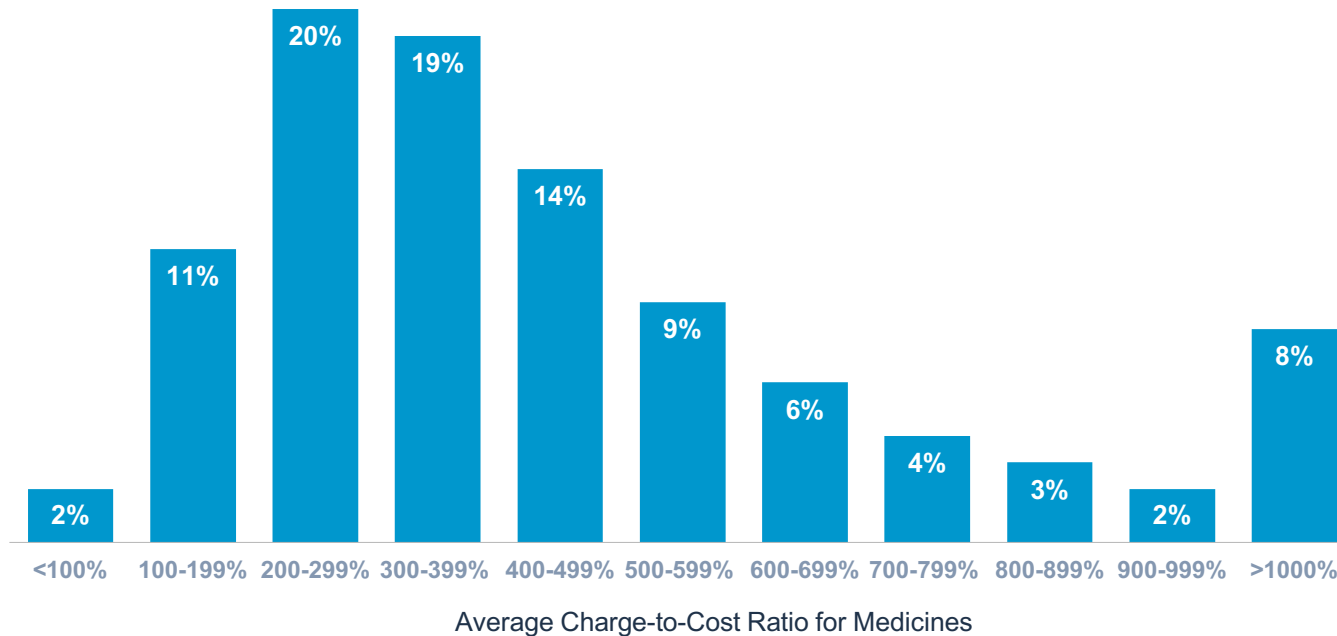
—Lee Newcomer, United Healthcare (speaking of large hospital system demands)

Source: Winn AN, Keating NL, Trogon JG, Basch EM, Dusetzina SB. Spending by Commercial Insurers on Chemotherapy Based on Site of Care, 2004-2014. JAMA oncology. 2018 Apr 1;4(4):580-1. Those who pay have a say: A view on oncology drug pricing and reimbursement. The Oncologist. 2016 Jul 1;21(7):779-81.

Hospitals Markup Medicine Prices Nearly 5 Times, Including Many Cancer Medicines

Hospitals markup medicine prices, on average, nearly 500%. The amount hospitals receive after negotiations with commercial payers is, on average, more than 250% what they paid to acquire the medicine.

Percentage of Hospitals by Average Level of Markup for Medicines*



*Percentages in chart may not add up to 100% due to rounding.
Average Sales Price

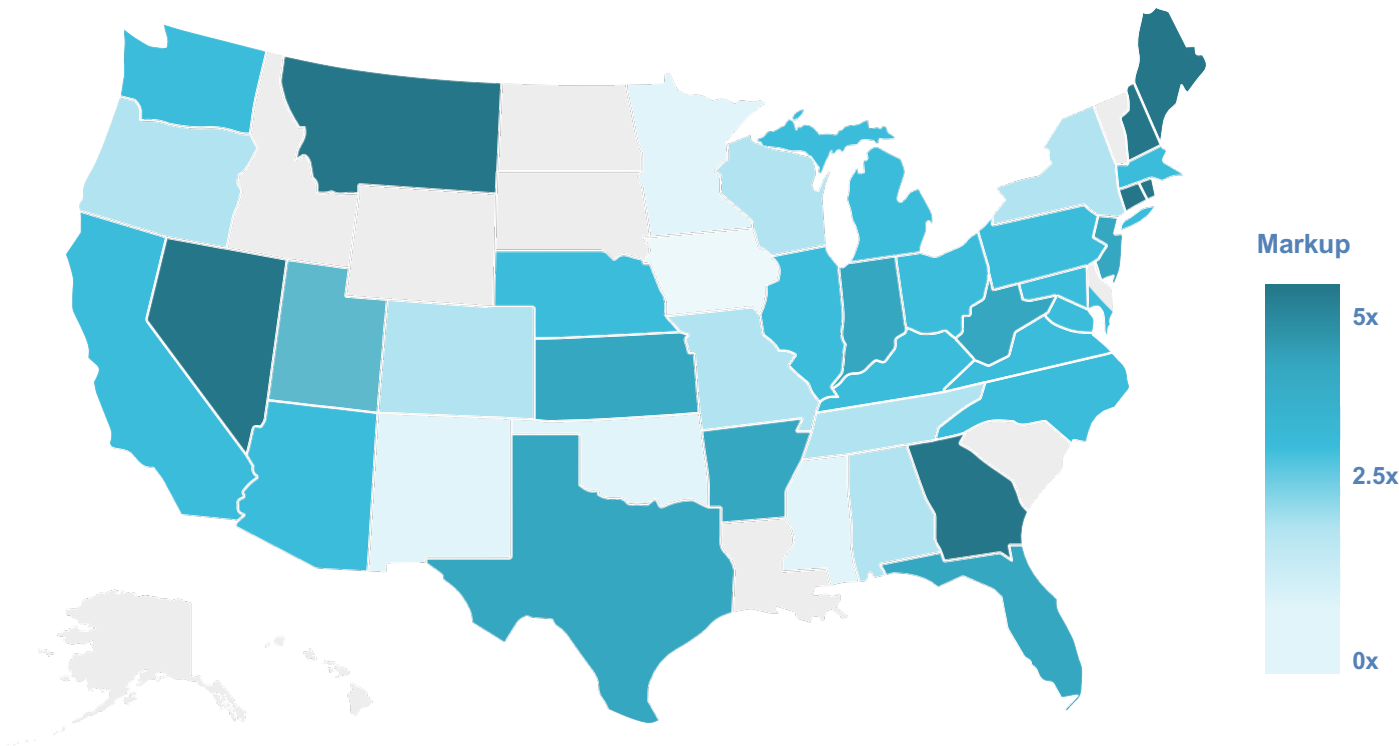
**ASP:

Nearly 1-out-of-5 hospitals marks up medicines to 700% or more of their acquisition costs.

*On a medicine with an ASP** of \$150, this could result in a charge of \$1,050 or more.*

Hospitals Can Markup Cancer Medicines Prices Nearly 5 Times More than Physician Office Prices Depending on Where Patients Live

Cost Differences for Oncology Medicines by State: Comparison of Prices for Similar Treatments in Physicians' Offices (PO) versus Hospital Outpatient Departments (HOPD)



*Authors were unable to report markup data for the ten states in grey

“If the healthcare system is consolidated, consumers don’t have anywhere else to go...Even if they see the prices of a given hospital, they’re limited in terms of how much they can ‘shop’ across providers.”

—Sunita Desai, PhD, NYU, School of Medicine

Employers Could Reduce Drug Costs by Nearly Half by Shifting Patients to Lower Cost Sites of Care

For the top infused cancer medicines, hospitals are paid nearly 2 times more than physician offices for the same cancer medicines.

Given...

Nearly
50%

Of oncology therapy occurs in hospital
outpatient departments

Employers could save...

Nearly
\$10,000

Per Cancer Patient Annually

And cut costs by..

45%

By shifting patients to physician office
settings or negotiating site neutral payments
without affecting quality of care

340B Program Profit Incentives Fuels Hospital Consolidation and Increases Costs for Cancer Patients

The 340B program requires that manufacturers provide deep discounts on medicines to qualifying hospitals and safety net clinics and allows providers to keep any spread between the 340B price and reimbursement for medicines bought at the 340B price. Greater profit margins on 340B discounted medicines, particularly cancer medicines, without requirements to reinvest savings in care for vulnerable or uninsured patients, fuels hospital acquisition of community-based physician practices and shifts care to more expensive hospital outpatient settings.

340B Hospitals are reimbursed by commercial insurance, on average:

3X

what they paid to acquire a medicine.

“Financial gains for [340B] hospitals have not been associated with clear evidence of expanded care or lower mortality among low-income patients.”

—S Desai, PhD and JM McWilliams MD, PhD

“[The 340B program] will ultimately end up increasing health care costs for everyone, as patients are shifted from cheaper, community-based care to more expensive hospital settings....”

—ST Parente, PhD and M Ramlet

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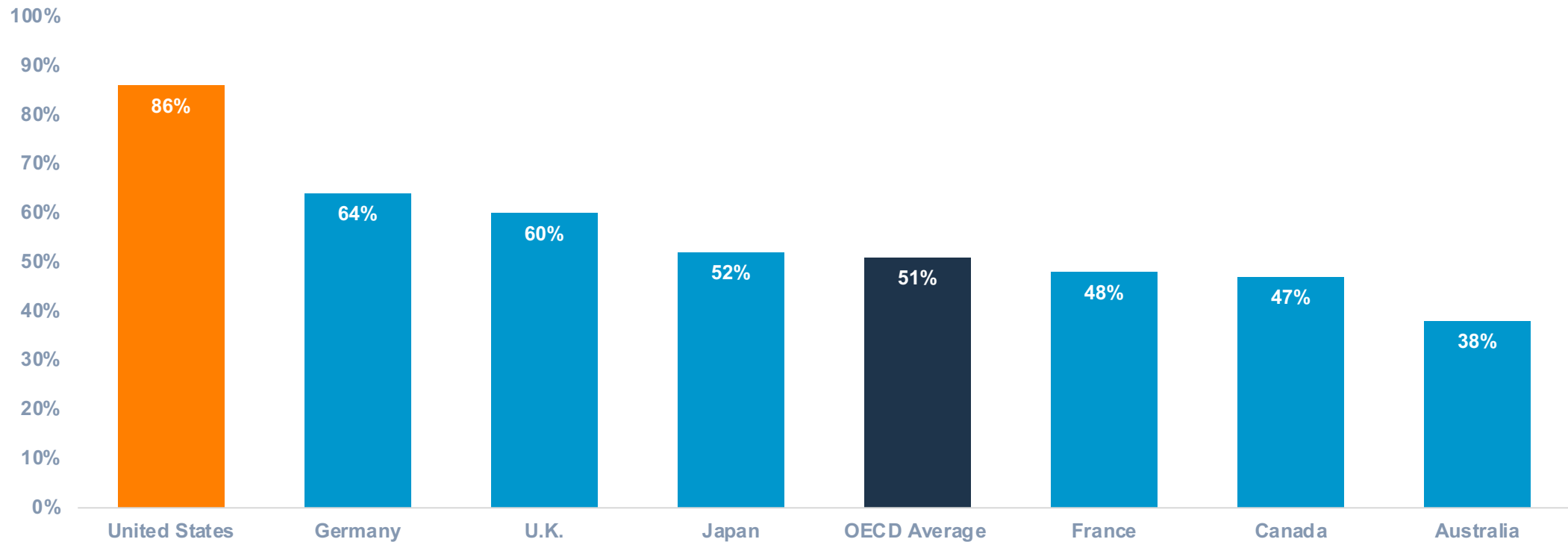
U.S. SYSTEM IN CONTEXT

America leads the world in biopharmaceutical innovation. Government price-setting policies threaten our innovative ecosystem and would discourage continued investment in R&D and the development of new treatments while restricting and delaying access to cancer medicines that patients need, leading to worse outcomes.

Many New Oncology Medicines Available to U.S. Patients are Not Available in Other Countries

Government price setting and coverage restrictions in other countries lead to reduced availability of new treatments

Availability of New Cancer Medicines Launched in OECD Countries, 2011 – 2020*




*New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2011 and December 31, 2020. OECD average excludes the U.S.

Source: PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Australia Therapeutic Goods Administration (TGA) and Health Canada data. April 2021.

Many New Oncology Medicines Available to U.S. Patients are Not Available in Other Countries

Government price setting and coverage restrictions in other countries lead to reduced availability of new treatments across a range of different cancers.

Percentage of New Cancer Medicines Available in the United States vs. OECD* Countries by Cancer Type (of 112 new cancer medicines launched from 2011 to the end of 2020)*

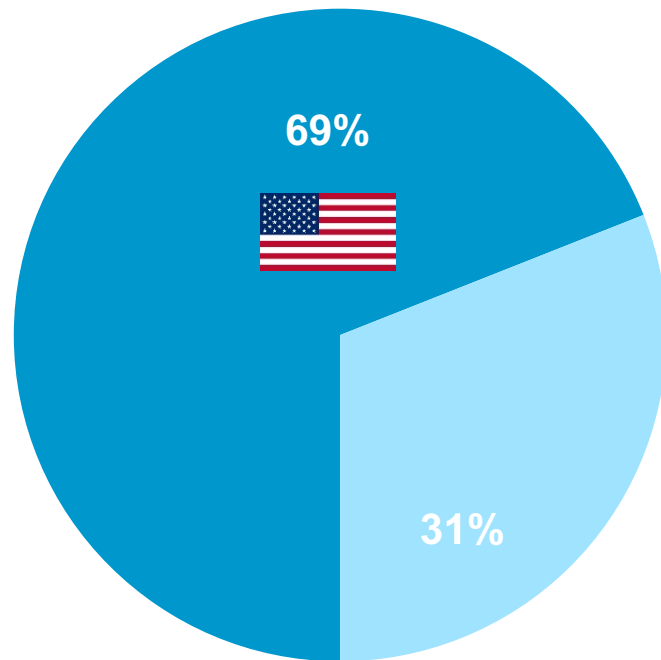
	Blood	Breast	Gastro-intestinal	Lung	Female Reproductive	Skin	Urological	Other
US 	93%	100%	100%	96%	100%	100%	90%	100%
OECD	45%	64%	65%	65%	67%	73%	64%	58%

Source: PhRMA analysis of IQVIA Analytics Link, National Cancer Institute, U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) data. June 2021.
 Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2011 and December 31, 2020. Chile, Colombia, Costa Rica, Greece, Iceland, Israel, and Luxembourg removed due to data limitations.*OECD average excludes the United States.

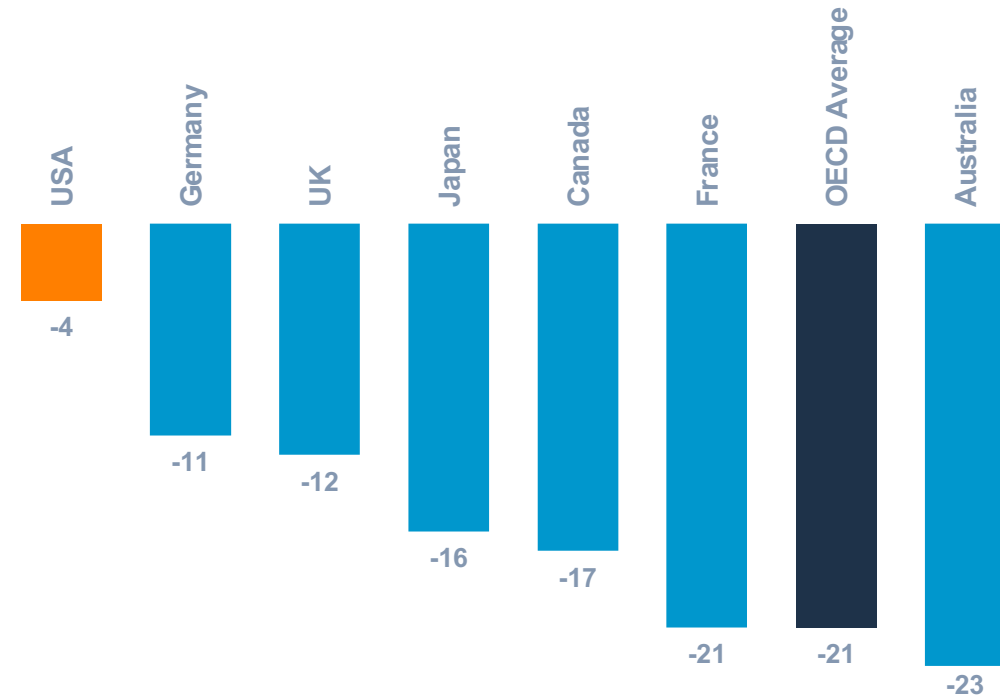
U.S. Patients have Access to Cancer Medicines Nearly Two Years Earlier than Other Countries on Average

To the extent that patients in other developed countries have access to medicines, they have to wait longer to access those medicines compared to patients in the United States.

First Global Launch of New Cancer Medicines by Country



Average Months of Delay in Availability of New Cancer Medicines Launched in OECD Countries from 2011 to the end of 2020



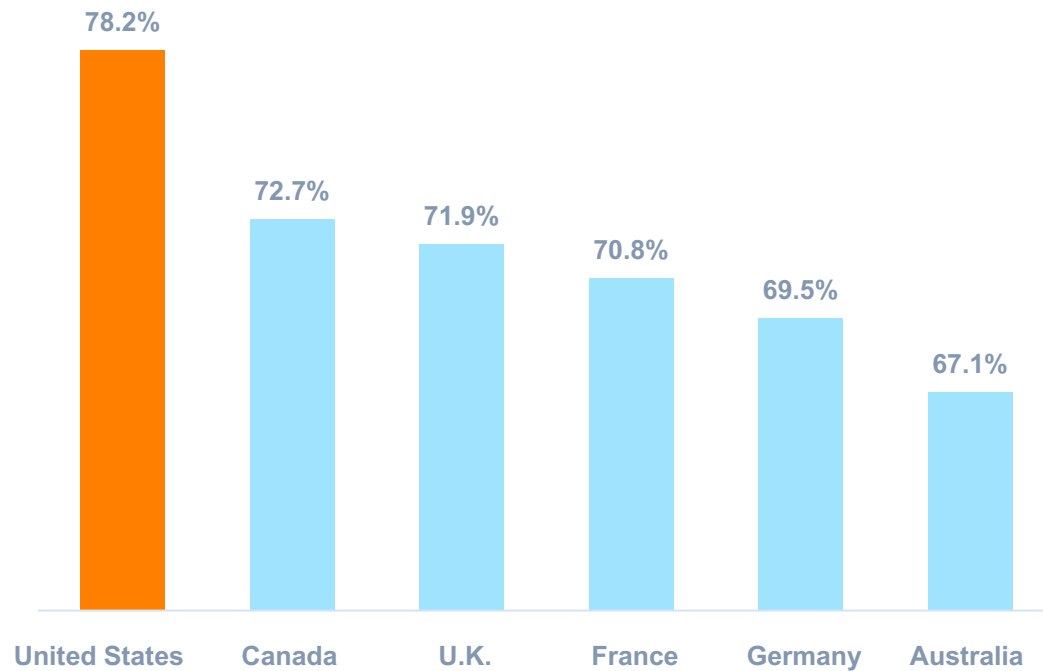
Source: PhRMA analysis of IQVIA Analytics Link and U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), Japan Pharmaceuticals and Medical Devices Agency (PMDA), Australia Therapeutic Goods Administration (TGA) and Health Canada data. April 2021.

Note: New active substances approved by FDA, EMA and/or PMDA and first launched in any country between January 1, 2011 and December 31, 2020. OECD average excludes the US.

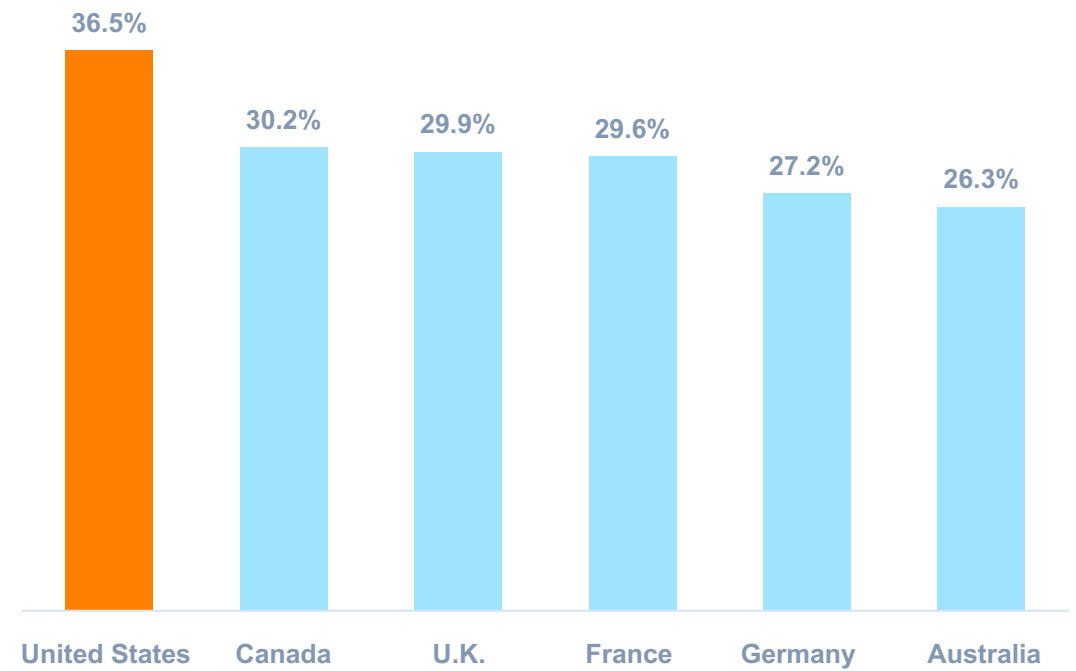
U.S. Patients Have Better Outcomes in Cancer

Cancer survival rates are higher in the U.S., where patients have timely access to cancer medicines than in other developed countries.

Pediatric Brain Cancer 5-Year Survival Rate (2010-2014)



Brain Cancer (Adult) 5-Year Survival Rate (2010-2014)

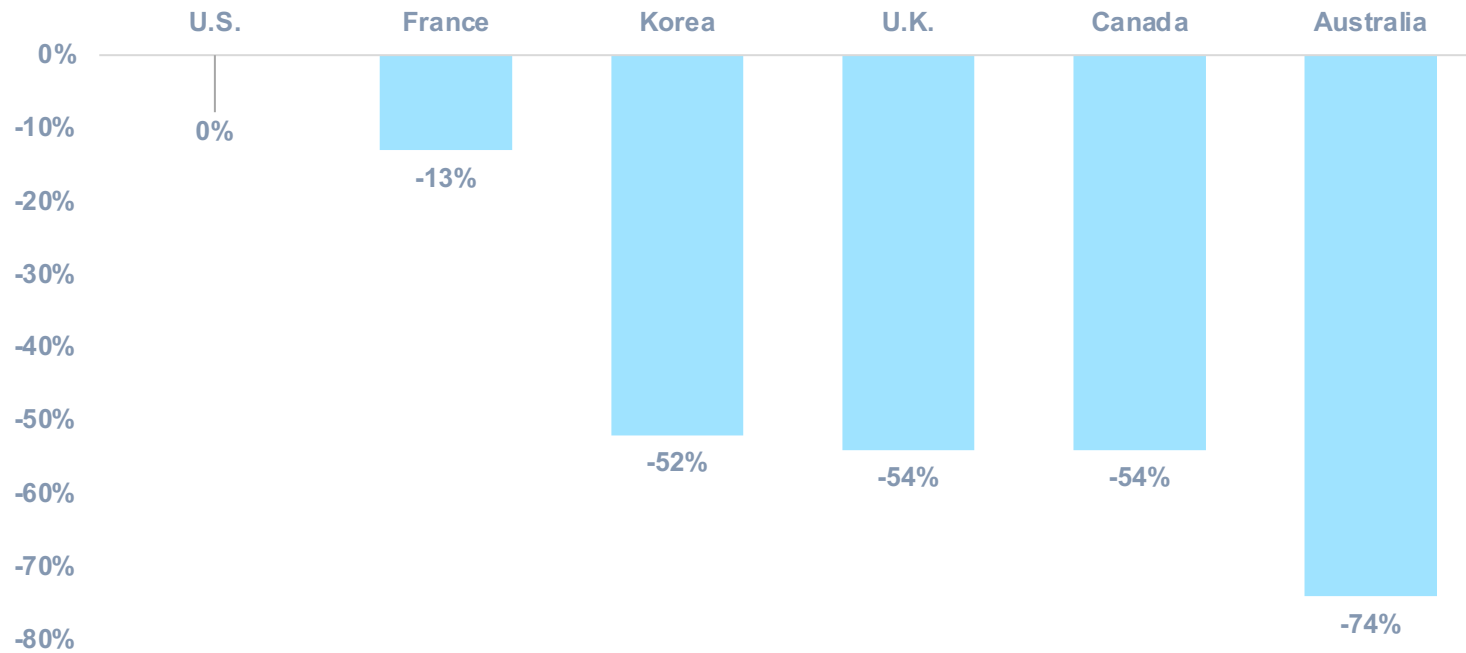


Source: Allemani C, Matsuda T, Di Carlo V, et al. Global surveillance of trends in cancer survival 2000-14 (CONCORD-3): analysis of individual records for 37 513 025 patients diagnosed with one of 18 cancers from 322 population-based registries in 71 countries. Lancet. 2018;391(10125):1023-1075.

Lung Cancer Patients Experience Better Survival Under the Market Access Policies in the U.S.

American patients with lung cancer would have poorer outcomes if they had the same access to medicines seen in other countries that use government price setting. This is in part because patients in other countries do not have access to all medicines available in the U.S.

Survival Gains Lost Under Different Access Schemes



07

SOLUTIONS TO ADVANCE PROGRESS FOR CANCER PATIENTS

We need solutions that address the patient affordability challenges that some patients are facing today. To do that we also need to reduce the market distortions driven by hospital consolidation and the 340B program that increase costs for patients and the health care system.

America leads the world in biopharmaceutical innovation. To continue to advance the latest innovations in cancer treatment to patients, we need a policy framework that incentivizes and rewards innovation and recognizes the value that medicines provide to patients.

Advancing Solutions for Cancer Patients

AFFORDABILITY

While most patients with cancer face no out-of-pocket costs for oncology medicines at the pharmacy counter, a small share are burdened with high costs due to increasing use of deductibles and coinsurance.

MARKET DISTORTIONS

Competition is working to control costs in the oncology market today, but we need solutions that reduce the broader market distortions that are driven by hospital consolidation and the 340B program that drive up costs for medicines and health care services.

VALUE

To ensure patients have access to the latest innovations in cancer treatment, we need a system that fully accounts for the value that new medicines bring to cancer patients and the health care system.

INNOVATION

To continue to advance new treatments for cancer patients, we need to support a policy and regulatory framework that allows innovation to thrive.

Improving Affordability for Patients with Cancer

INSURANCE NEEDS TO WORK LIKE INSURANCE:

SOLUTIONS

COVER MORE MEDICINES FROM DAY ONE

- Patients managing chronic conditions should have at least some of the cost of their medicines covered by insurance from day one.

MAKE COST-SHARING MORE PREDICTABLE

- Encourage the use of fixed dollar-copays instead of coinsurance
- Place a limit on the max amount that a patient will be asked to pay out-of-pocket

MAKE COUPONS COUNT

- Ensure cost-sharing assistance counts towards deductibles and out-of-pocket maximums.

IMPROVE AFFORDABILITY IN MEDICARE:

SOLUTIONS

MEDICARE PART D

- Cap annual out-of-pocket costs, lower cost-sharing overall and allow patients to spread costs throughout the year in Part D

MEDICARE PART B

- Implement a market-based adjustment in Part B which could lower out-of-pocket costs for some beneficiaries.

Reducing Market Distortions that Drive Up Cancer Spending

MARKET DISTORTIONS:

CONSOLIDATION

As hospitals consolidate by buying physician practices and merging with other hospitals, they are able to leverage their size and lack of competition to demand large mark-ups on the prices of medicines and higher reimbursement from commercial payers.

THE 340B PROGRAM

Experts agree the greater spread on 340B discounted drugs fuels consolidation and increases costs across the healthcare system.

SOLUTIONS

Ensuring patients benefit more directly from the 340B discounts provided by manufacturers and that hospitals participating in the program are held accountable for how they use 340B discounts can help address market distortions created by the program.

Facilitating the Move to a Value-Driven Healthcare System

SOLUTIONS

DECISION SUPPORT TOOLS

Advance scientifically rigorous, patient-centered decision support tools (such as clinical pathways, value frameworks, and shared decision-making).

EVIDENCE

Close gaps in the evidence base across the continuum of cancer care, via organizations like the Patient-Centered Outcomes Research Institute, manufacturer research partnerships, and expanding and harnessing electronic health datasets such as clinical data registries.

IMPROVE QUALITY MEASURES

Expand capacity to measure and incentivize value by closing gaps in performance and quality measurement for cancer patients.

ALTERNATIVE PAYMENT MODELS

Evaluate and scale holistic, patient-centered payment models such as oncology patient-centered medical homes

INNOVATIVE CONTRACTS

Clarify regulations and barriers that may prevent innovative contracts between manufacturers, payers, and providers to encourage innovative solutions that can address issues with affordability and accessibility for both payers and patients without jeopardizing future medical advances.

Advancing New Treatments for Cancer Patients

America leads the world in biopharmaceutical innovation because our unique innovation ecosystem is supported by a policy framework that incentivizes and rewards innovation. To continue to advance new cancer treatments we need:

Strong
**INTELLECTUAL
PROPERTY**
protections



A well-functioning,
science-based
**REGULATORY
SYSTEM**



**COVERAGE
AND PAYMENT**
policies that support
and encourage
medical innovation

