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Opportunities and Barriers in Pharmaceutical Pricing

The Average Manufacturer Price Final Rule's Effect on Drug Pricing and Contracting (Part 2)

July 13, 2016

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Major Trends in Health Care:
A Life Sciences and Pharmaceutical Perspective

DRIVING FORCES

Breakthrough Science,
"Moon Shot" Initiatives

Personalized Medicine

BIG DATA & ANALYTICS

Technology, Big Data,
Bioinformatics, Analytics

Patient Centered Outcomes
Clinical Trial Design

RESTRAINING FORCES

Affordability for Gov't,
Private Payers

Reputation Issues for
The Pharma Industry

Value-based Payment Models;
Bundled payment;

Impact of Consolidation
Health Plans + PBMs

Pharmaceutical Industry Key Facts

DEVELOPMENT COSTS

Average cost to develop a drug (including the cost of failures):[2]

- 2000s–early 2010s = $2.6 billion
- 1990s–early 2000s = $1.0 billion*
- 1980s = $413 million
- 1970s = $179 million

PERCENTAGE OF SALES THAT WENT TO R&D IN 2013[5]

Domestic R&D as a percentage of domestic sales = 23.4%

Total R&D as a percentage of total sales = 17.9%

ECONOMIC IMPACT OF THE BIOPHARMACEUTICAL SECTOR[6]

Direct jobs = more than 810,000

Total jobs (including indirect and induced jobs) = nearly 3.4 million

APPROVALS

- Medicines approved 2014 = 51[7,8,9]
- Medicines approved since 2000 = more than 500[10,11,12,13,14]
- Only 2 of 10 marketed drugs return revenues that match or exceed R&D costs[17]

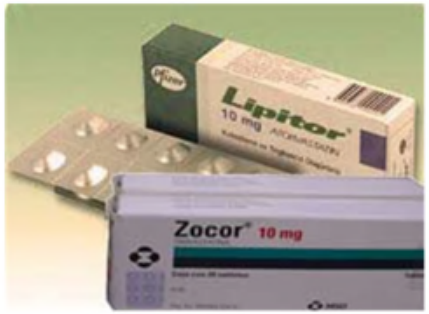
MEDICINES IN DEVELOPMENT

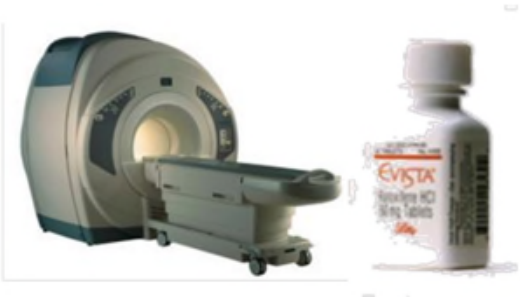
- Medicines in development around the world = 7,000[18]
- Potential first-in-class medicines** in clinical development globally = 70%[19]
- Medicines in development to treat rare disease = More than 450[20]

*Previous research by the same author estimated average R&D costs in the early 2000s at $1.2 billion in constant 2000 dollars (see DiMasi JA, Grabowski, HG. The cost of biopharmaceutical R&D: is biotech different? *Manage Decis Econ*. 2007;28:469-479). That estimate was based on the same underlying survey as the author's estimates for the 1990s to early 2000s reported here ($800 million in constant 2000 dollars), but updated for changes in the cost of capital.

**Note: First-in-class medicines are those that use a different mechanism of action from any other already approved medicine.

Discovery and Innovation

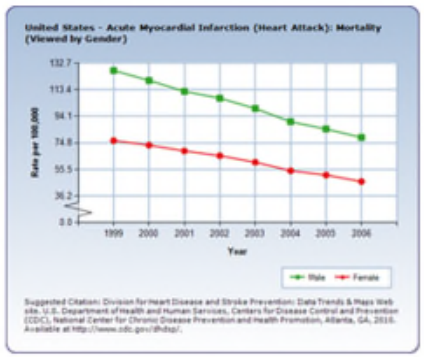


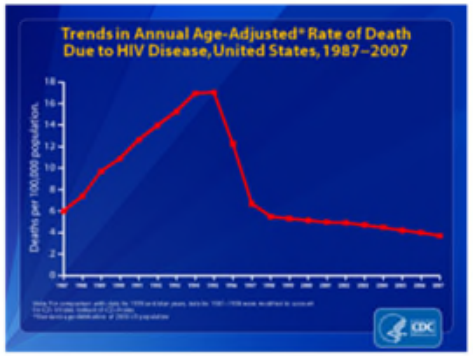


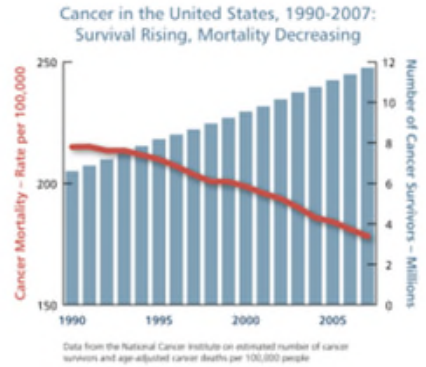
Statins reduce cardiac deaths

Anti-viral drugs transform HIV

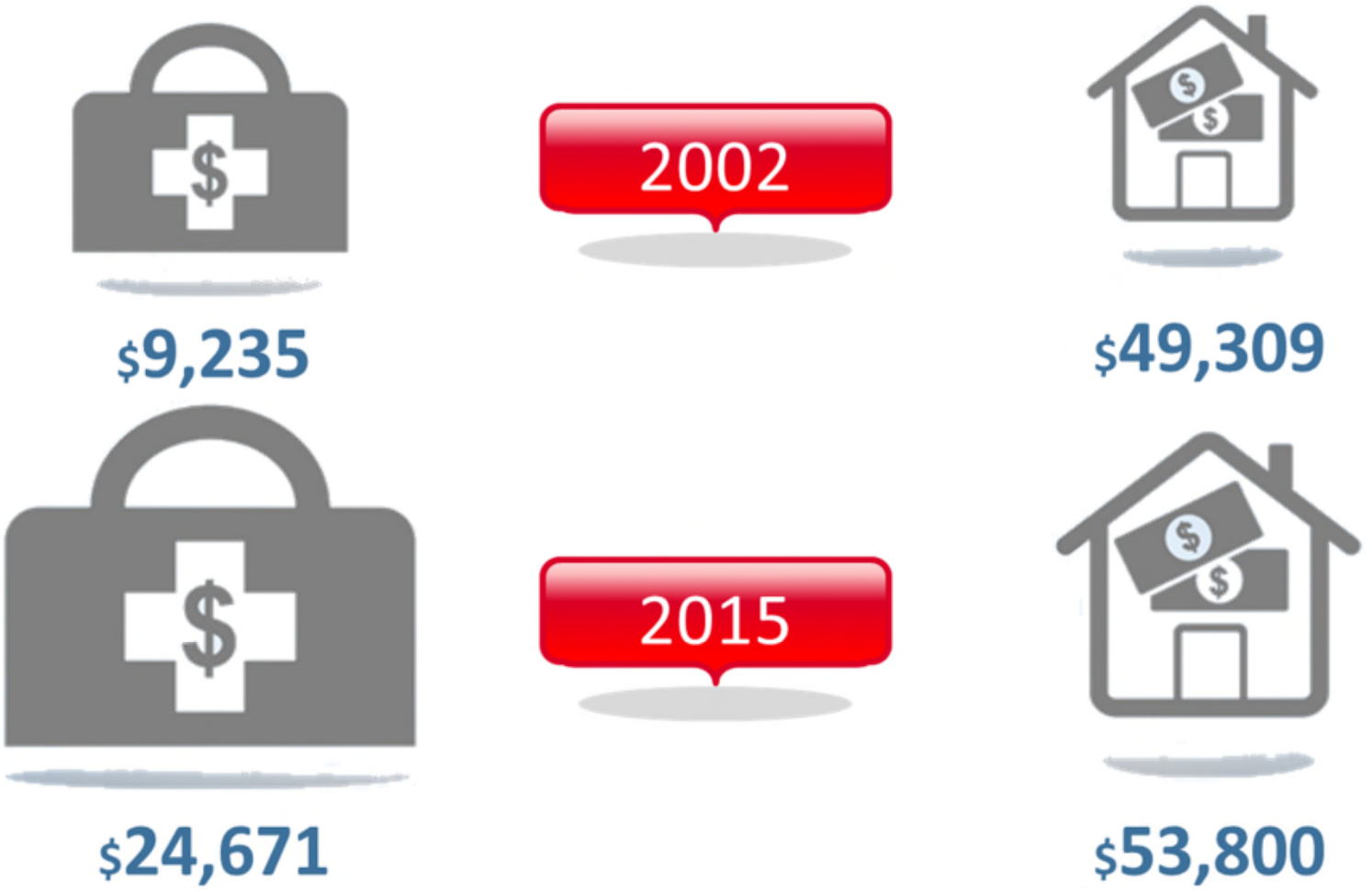
Screening and drugs improve cancer survival







Affordability:
Rising Costs are Unsustainable

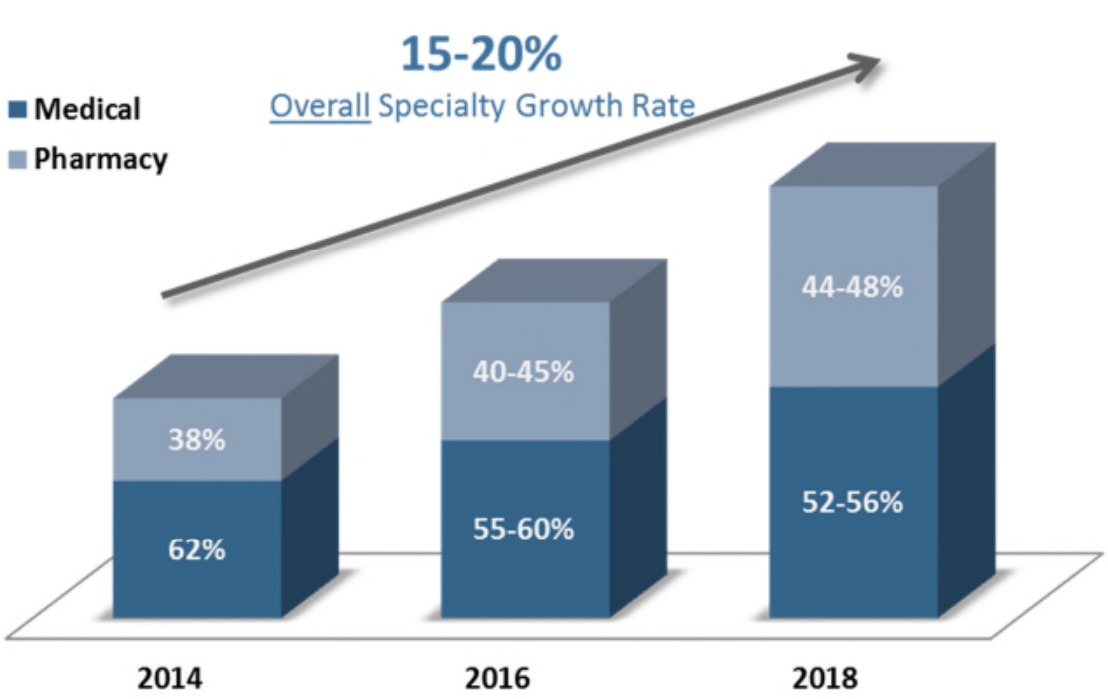


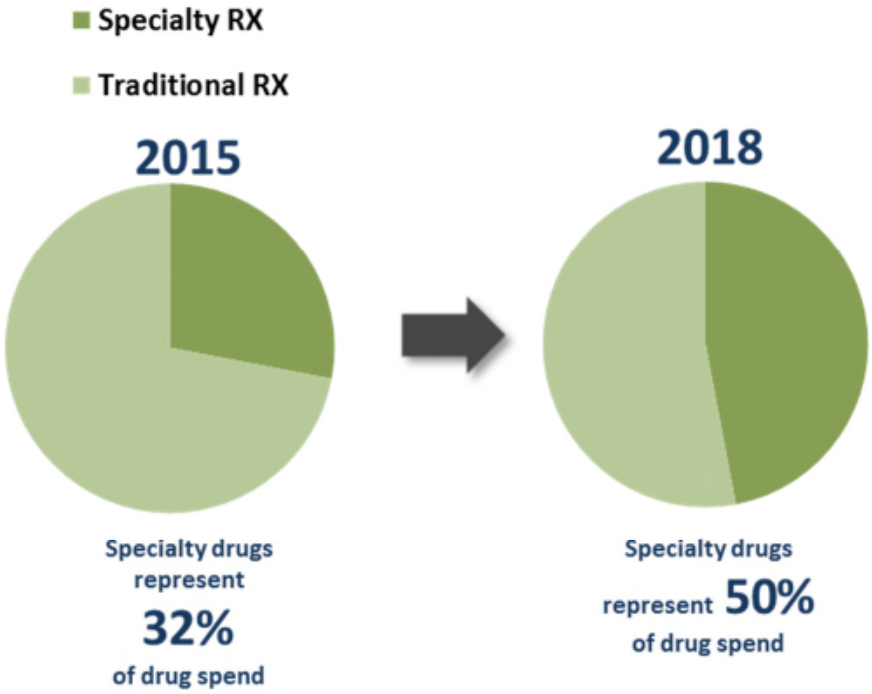
Milliman Medical Index (MMI) vs. Average Household Income

The Impact of Rising Drug Costs to Government, Employers, Health Plans and Consumers

- Increases in drug spending are outpacing all other health care expenditures
  - Specialty drug spending has been increasing at a high teen-low 20% trend since 2013, now representing mid 30% of all drug spending and will reach $400B by 2020
  - Drug spending rose in 2015 to $457B (adjusting for rebates and discounts) representing 16.7% of total health spending in the US (HHS Office of the Assistant Secretary for Planning and Evaluation, ASPE)
- 2014 Xerox/Buck Consulting study: 76.7% of employers spent greater than 16% on drug spending; 5% spent more than 30%
- MedPAC: drug spending accounted for 19.5% of Medicare expenditures in 2013
- Private sector commercial plans: drug costs representing 20-25% of health care premiums

Specialty Pharmacy and Medical Drug Spend is Growing Rapidly





Pharmacy and Medical Specialty spend will likely **double**

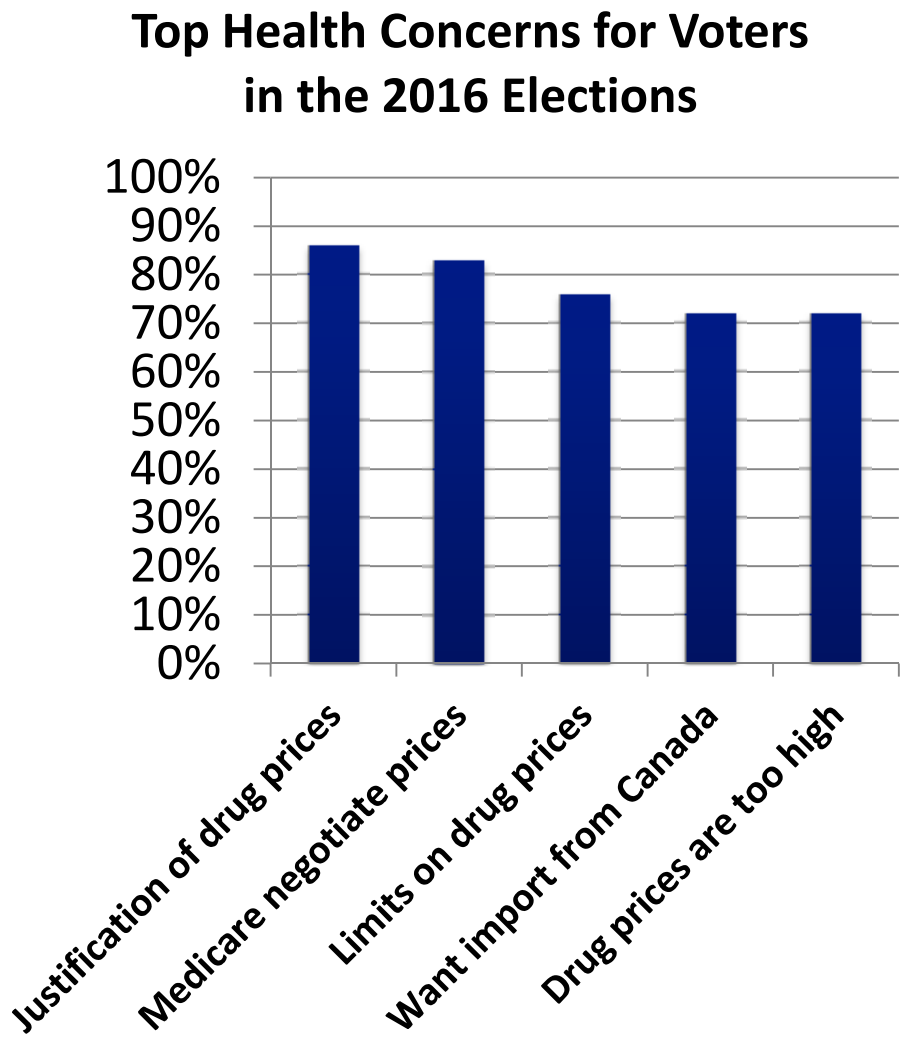
Almost Half of pharmacy drug spend will be specialty drugs

Total drug spending in 2015: $457B;
specialty drug spend expected to be $400B+ by 2020

A View From Consumers

- People want full access to new treatments
- 50-70% of Consumers take drugs on a regular basis
- 27% did not fill an Rx because of costs
- There is no out of pocket limit for Medicare part D

74% believe drug companies place profits before people



Source: Kaiser Family Foundation

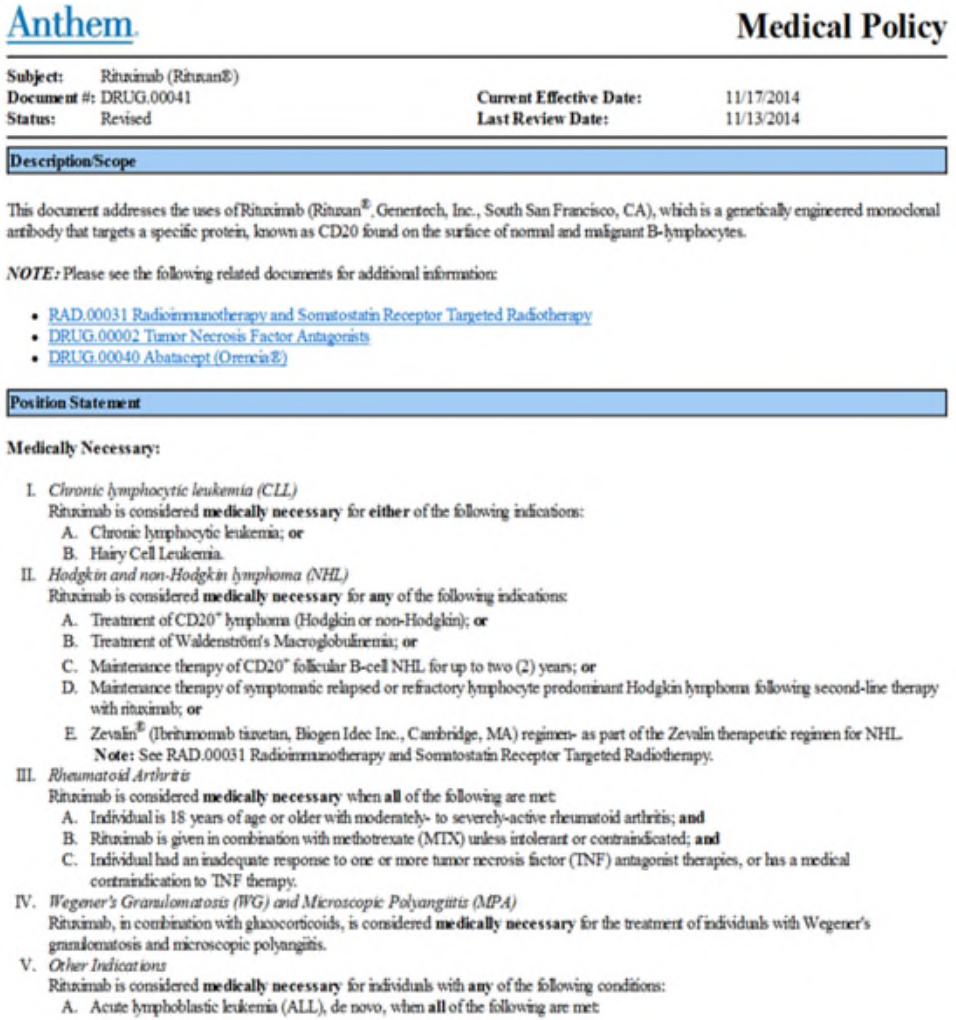
Rising Attention to the Impact of Drug Costs to the Government, Employers, Health Plans and Consumers

"We in the United States end up paying the highest prices for drugs in the entire world. The drug companies are free to charge us whatever they choose to charge us"

"The drug companies probably have the second or third most powerful lobby in this country, They get the politicians, and every single one of them is getting money from them…. When it comes to negotiate the cost of drugs, we are going to negotiate like crazy"

Private Sector: Medical Policy Transparency

- All policies available via Plan websites
- Accessible by network physicians
- Includes background, coding, and definitions
- Detailed rationale
- References to:
  - Peer-reviewed journals
  - Other authoritative publications
- Comprehensive revision history



Anthem

Medical Policy

Subject: Rituximab (Rituxan®)
Document #: DRUG.00041
Status: Revised
Current Effective Date: 11/17/2014
Last Review Date: 11/13/2014

Description/Scope

This document addresses the uses of Rituximab (Rituxan®, Genentech, Inc., South San Francisco, CA), which is a genetically engineered monoclonal antibody that targets a specific protein, known as CD20 found on the surface of normal and malignant B-lymphocytes.

NOTE: Please see the following related documents for additional information:

- RAD.00031 Radioimmunotherapy and Somatostatin Receptor Targeted Radiotherapy
- DRUG.00002 Tumor Necrosis Factor Antagonists
- DRUG.00040 Abatacept (Orencia®)

Position Statement

Medically Necessary:

I. *Chronic lymphocytic leukemia (CLL)*
Rituximab is considered **medically necessary** for **either** of the following indications:
A. Chronic lymphocytic leukemia; **or**
B. Hairy Cell Leukemia.

II. *Hodgkin and non-Hodgkin lymphoma (NHL)*
Rituximab is considered **medically necessary** for **any** of the following indications:
A. Treatment of CD20+ lymphoma (Hodgkin or non-Hodgkin); **or**
B. Treatment of Waldenström's Macroglobulinemia; **or**
C. Maintenance therapy of CD20+ follicular B-cell NHL for up to two (2) years; **or**
D. Maintenance therapy of symptomatic relapsed or refractory lymphocyte predominant Hodgkin lymphoma following second-line therapy with rituximab; **or**
E. Zevalin® (Ibritumomab tiuxetan, Biogen Idec Inc., Cambridge, MA) regimen- as part of the Zevalin therapeutic regimen for NHL.
Note: See RAD.00031 Radioimmunotherapy and Somatostatin Receptor Targeted Radiotherapy.

III. *Rheumatoid Arthritis*
Rituximab is considered **medically necessary** when **all** of the following are met:
A. Individual is 18 years of age or older with moderately- to severely-active rheumatoid arthritis; **and**
B. Rituximab is given in combination with methotrexate (MTX) unless intolerant or contraindicated; **and**
C. Individual had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies, or has a medical contraindication to TNF therapy.

IV. *Wegener's Granulomatosis (WG) and Microscopic Polyangiitis (MPA)*
Rituximab, in combination with glucocorticoids, is considered **medically necessary** for the treatment of individuals with Wegener's granulomatosis and microscopic polyangiitis.

V. *Other Indications*
Rituximab is considered **medically necessary** for individuals with **any** of the following conditions:
A. Acute lymphoblastic leukemia (ALL), de novo, when **all** of the following are met:

Evidence-Based Pharmaceutical Decisions

- Two-step process evaluates quality and outcomes first…then cost
- Clinical Review Committee
  - Evaluates research & FDA information
  - External expert physician decisions
  - Classifies into categories
    - o Favorable
    - o Comparable
    - o Insufficient Evidence
    - o Unfavorable
- Value Assessment Committee
  - Conducts pharmacoeconomic review
  - Determines tier and formulary position to support care and value

How Anthem Chooses Drugs for the Drug List (Formulary)

Why doesn't Anthem cover all the drugs approved by the FDA?

The FDA (Food and Drug Administration) decides if drugs can go on the market. The FDA:

- makes sure a drug does what it is supposed to do and is safe.
- approves each drug for a specific use.

But the FDA does not compare drugs to find out which drug is best for a specific health condition. That's why Anthem is always reviewing the latest research.

Why does Anthem have a drug list (formulary)?

For most health problems there are several drug options. Anthem's goal is to provide benefits for the best drug options for each health issue. The list of covered drugs is called a formulary. Using drugs that work well at a good price makes wise use of everyone's health care dollars.

Why does my drug coverage change?

Anthem changes the drug list (formulary) to keep it up-to-date. New brand-name and generic drugs come on the market all the time. After the drugs are on the market, researchers look at how well they work in everyday situations. This means that we are learning more each day about which drugs work best.

Who decides which drugs are on the drug list (formulary)?

The Pharmacy and Therapeutics (P&T) Committee decides which drugs are on the drug list (formulary).

- This committee includes an independent group of 30 doctors, pharmacists and specialists.
- These clinicians are not employees of Anthem. They give unbiased opinions about the benefits and risks of the drugs.

How does Anthem use medical research?

Anthem gathers up all the medical research findings about a specific drug or group of drugs (drug class). The findings come from researchers around the world.

- Effectiveness research looks at how well each drug works.
- Safety research looks at the side effects of the drug and if there is a chance of serious problems (risks).
- Some medical research compares different drugs for the same condition. It compares how well the drugs work and their side effects. This research may find that some drugs work better than other drugs. Or, this research may find that many drugs work well to treat the same health condition.
- This research is published in medical journals (like the *New England Journal of Medicine*). We regularly search these journals to keep up-to-date.
- Anthem also looks at the details about how each research study was done. We check to see that the researchers used careful methods and good science.
- We write a report about the research and how well it was done. This medical research report is the most important information we bring to the P&T Committee.

See the chart on the next page for details about how the P&T Committee makes changes to the drug list (formulary).

Anthem starts with an independent review of the research.

Anthem. Health. Join In.

Government Sector: HHS Focus on Drug Spending

- In November 2015, HHS convened a ***Pharmaceutical Forum*** for consumers, providers, employers, manufacturers, health insurance issuers, representatives from state and federal government, and other stakeholders to discuss ideas to address the rising cost of prescription drugs by:
  - Increasing access to information
  - Driving innovation
  - Strengthening incentives and promoting competition
  - Improving patient access to affordable prescription drugs
  - Developing innovative purchasing strategies
  - Incorporating value-based and outcomes-based models into purchasing programs

- *See* http://www.hhs.gov/hhs-pharmaceutical-forum/index.html

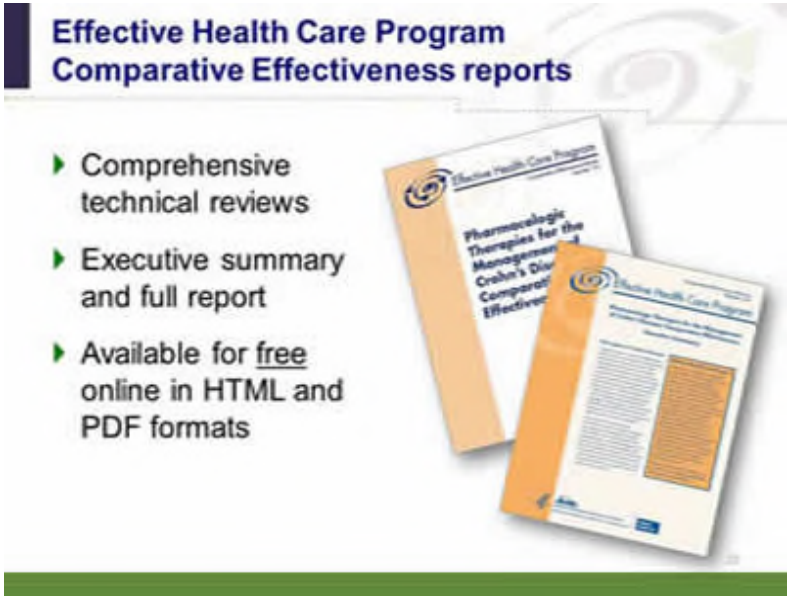
Medicare Drug Spending Dashboard

- In December 2015, CMS released an online dashboard looking at Medicare prescription drug costs for both Part B and Part D
  - The dashboard intends to increase transparency around drug spending, but does not provide information on the clinical or financial value of a drug
- The dashboard includes the following categories of drugs:
  - Drugs with high spending on a per user basis
  - Drugs with high spending for the program overall
  - Drugs with high unit cost increases in recent years
- 80 drugs are included on the dashboard, representing 33 percent of all Part D spending and 71 percent of all Part B drug spending in 2014

- *See* https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/

Medicare Drug Spending Dashboard (cont.)

- For all drugs included on the dashboard, CMS displays relevant spending, utilization, and trend data and also includes information on the drug product descriptions, manufacturer(s), and clinical indications
  - CMS is prohibited from publicly disclosing information on manufacturer rebates or other price concessions
- The dashboard also includes links to Evidence-based Practice Center ("EPC") reports on the effectiveness and harms of the drugs when used by certain populations for specific conditions



- CMS intends to update the dashboard on a regular basis and release a similar list for ***Medicaid*** this year

Clinical and Cost Effectiveness Research

- **Patient-Centered Outcomes Research Institute ("PCORI")**
  - Created by the ACA as a federally-funded, nonprofit corporation focused on the synthesis and dissemination of ***comparative clinical effectiveness research*** findings
  - Focused on funding research related to:
    - Specific drugs, devices, and procedures
    - Alternatives, such as medical and assistive devices and technologies
    - Behavior change, including the use of behavioral or financial incentives
    - Organizational models and policies within and across healthcare systems (e.g., patient-centered medical homes, clinical protocols such as standing orders, clinical pathways)
    - Communication and/or dissemination strategies
  - To date, PCORI has 780 funded research projects and program projects listed on its public website
    - Only a limited number of funded studies relate to drug treatment, medication adherence, and drug treatment outcomes

CER Promotes Value and Innovation

Collaboration amongst health care system stakeholders is central to making CER work

Address unsustainable health care costs

Limited resources threaten innovation

Help patients choose more effective treatments

Fewer unnecessary services = health system savings

Quality first, then affordability

Superior treatments deserve our nation's investment

Comparable treatments should be chosen on value

Selectively effective personalized treatments should be managed by physicians and patients

Remove inappropriate/ineffective treatments

Clinical and Cost Effectiveness Research (cont.)

- **Institute for Clinical and Economic Review ("ICER")**
  - Non-profit organization that conducts ***comparative cost-effectiveness analyses*** and develops "value-based price benchmarks" for treatments, tests and procedures
  - Current focus on assessing the cost of new drug treatments in comparison to existing treatments
    - In July 2015, ICER announced the creation of a new program, the Emerging Therapy and Assessment Pricing ("ETAP") Program, specifically focused on drug cost-effectiveness research
    - Through the ETAP Program, ICER intends to conduct a number of new drug assessments in 2016, including drugs used to treat diabetes, asthma, primary biliary cirrhosis, Duchenne Muscular Dystrophy, non-small cell lung cancer, multiple sclerosis, and psoriasis and psoriatic arthritis

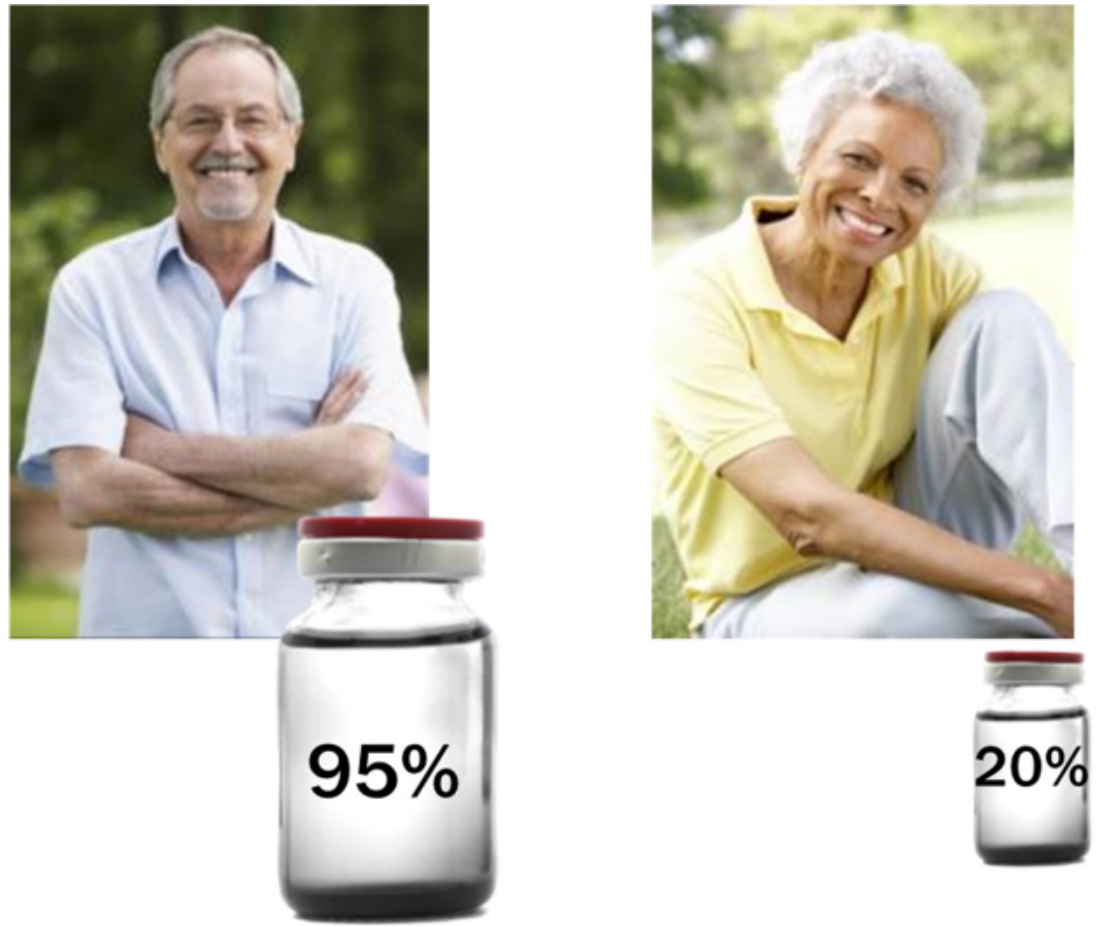
California Technology Assessment Forum: Sovaldi ROI

$100M-200M

1-year cost per 1,000 patients

"Even at a **20-YEAR HORIZON**, if all patients infected with Hepatitis C are treated with new regimens, the cost offset will only cover approximately **TWO-THIRDS** of initial drug cost."

Express Scripts: Paying for Results by Indication



Can we define the relative value of a single drug?

Center for Medicare and Medicaid Innovation

Section 3021 of Affordable Care Act

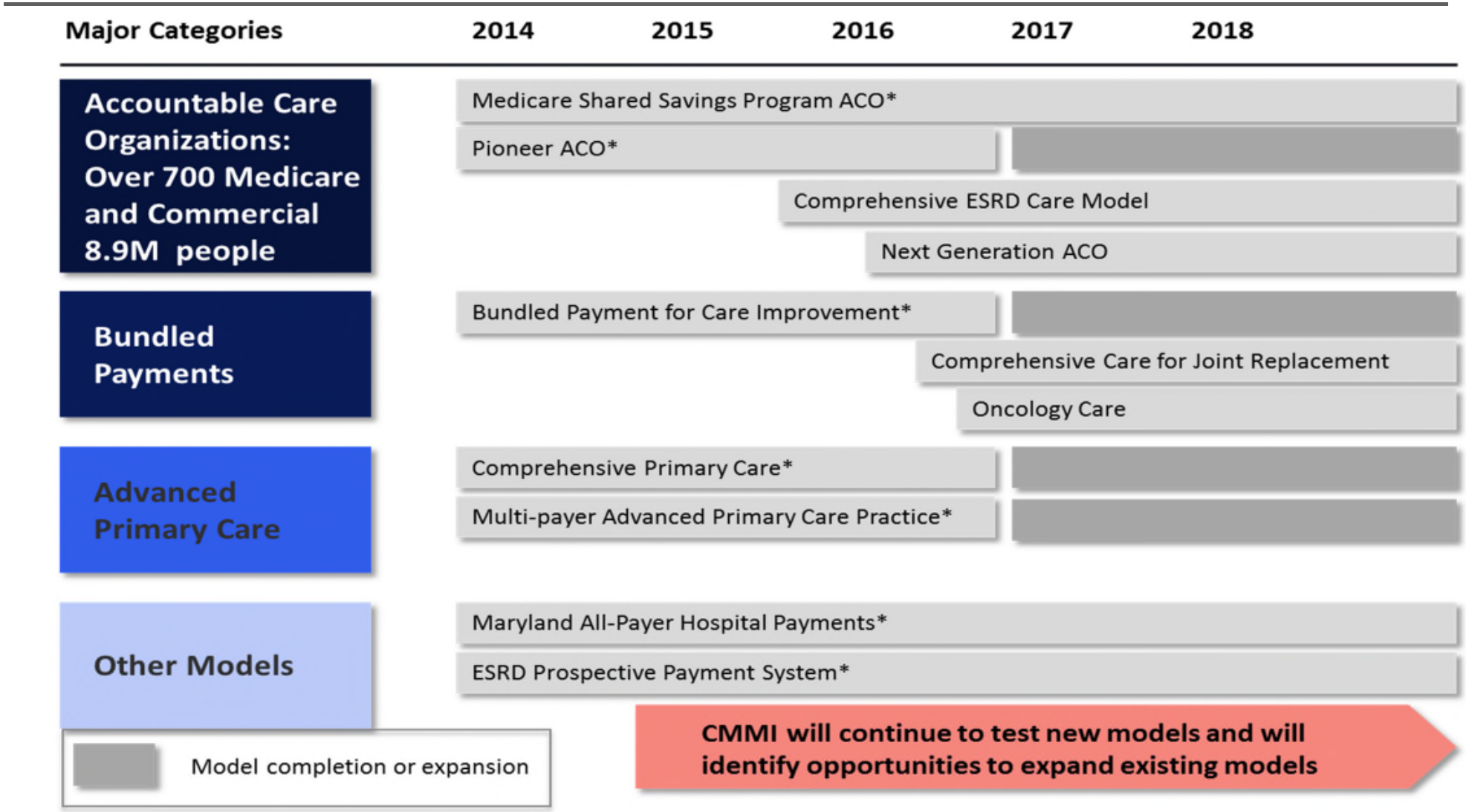
"The purpose of the [Center] is to test innovative payment and service delivery models to **reduce program expenditures…while preserving or enhancing the quality of care** furnished to individuals under such titles"

Three scenarios for success

1. **Quality improves; cost neutral**
2. **Quality neutral; cost reduced**
3. **Quality improves; cost reduced (best case)**

If a model meets one of these three criteria and other statutory prerequisites, the statute allows the Secretary to expand the duration and scope of a model through rulemaking

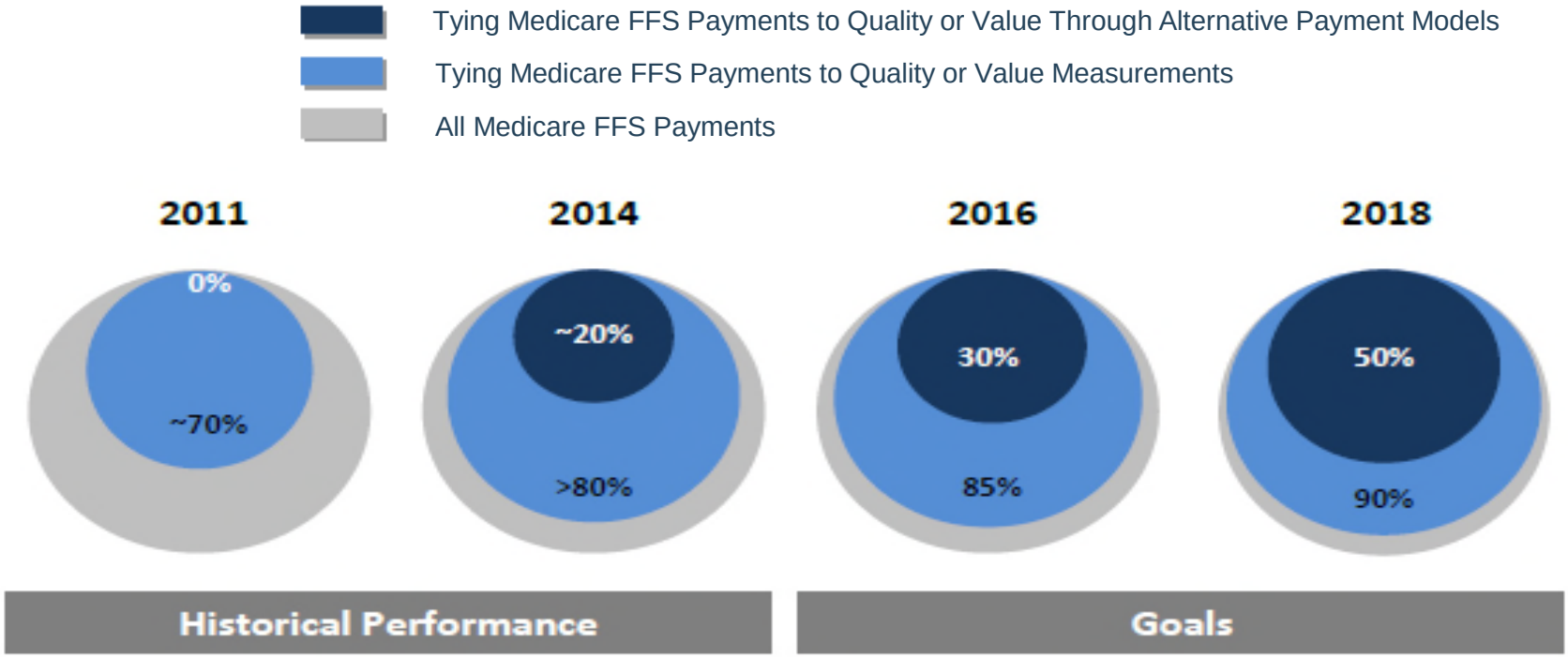
CMMI Payment Reform Demonstrations



* MSSP started in 2012, Pioneer started in 2012, BPCI started in 2013, CPC started in 2012, MAPCP started in 2011, Maryland All Payer started in 2014 ESRD PPS started in 2011

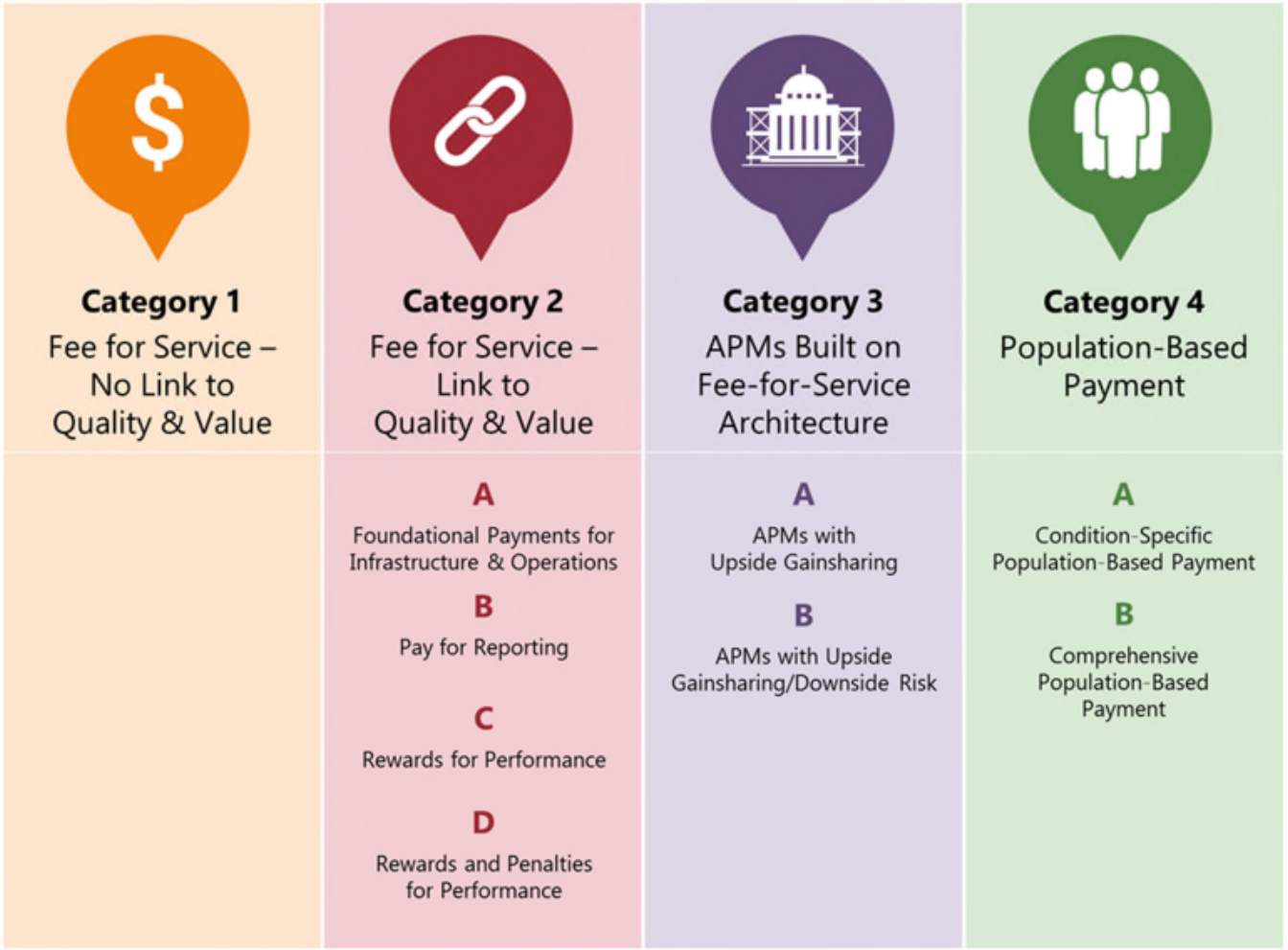
Shifting Medicare Payments from Volume-Based to Value-Based

- In January 2015, HHS Secretary Burwell announced measurable goals and a timeline for moving Medicare payments from traditional, fee-for-service to alternative payment models that are based on quality or value
- HHS goals for the transformation of Medicare payments:

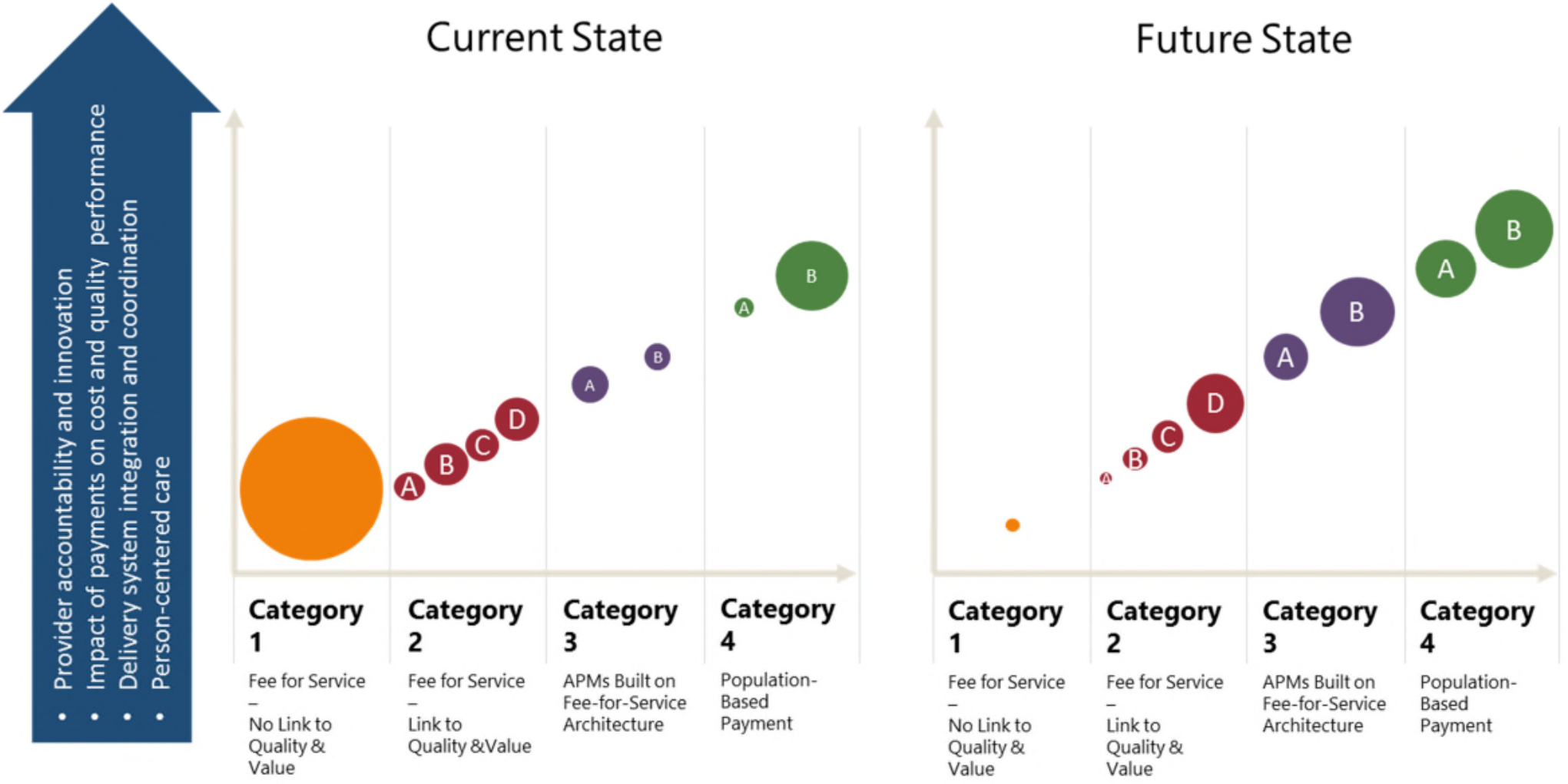


Source: Patrick Conway, MD, MSc, CMS, Health System Transformation (May 17, 2016)

Alternative Payment Models Framework



Learning and Action Network's Goals for Payment Reform



The Beginning of Payment Innovation
Code of Hammurabi: P4P in 1750 B.C.

Ancient Mesopotamian statutes specified differential, outcome-based physician compensation:

If a physician make a large incision with an operating knife and cure it, or if he open a tumor (over the eye) with an operating knife, and saves the eye, he shall receive ten shekels in money.

If a physician make a large incision with the operating knife, and kill him, or open a tumor with the operating knife, and cut out the eye, his hands shall be cut off.

— Code of Hammurabi, c. 1750 B.C.

Medicare Access and CHIP Reauthorization Act (MACRA)

- Federal legislation was enacted in April 2015 that repeals the Sustainable Growth Rate ("SGR") formula under the Medicare Physician Fee Schedule
  - The Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA") eliminates the negative update to physician payments through application of the SGR, and instead provides for annual updates of 0.5% for a 5-year period (starting July 1, 2015 through the end of 2019)
  - In 2019 and subsequent years, physician payments will be tied to quality performance through the new Merit-Based Incentive Payment System ("MIPS") and through participation in alternative payment models ("APMs")
- May 9, 2016 – CMS issued a proposed rule implementing MIPS and APM incentives under the new "Quality Payment Program"
  - Available at https://federalregister.gov/a/2016-10032
  - Final Rule expected on or around November 1, 2016

MACRA Physician Payment Reforms – MIPS

- For payments starting in 2019 (based on performance starting in 2017), MIPS streamlines multiple existing quality programs to link fee-for-service payments to quality and value
  - Current Meaningful Use, Value-Based Modifier, and Physician Quality Reporting System programs sunset at the end of 2018
- A MIPS composite performance score will be calculated for eligible clinicians based on four weighted performance categories:
  - Quality
  - Resource Use
  - Clinical Practice Improvement Activities ("CPIA")
  - Advancing Care Information ("ACI")
- Based on a clinician's MIPS composite performance score, that clinician will receive positive, negative, or neutral adjustments to their Medicare Part B base payment rate
  - +/- 4% (2019), +/- 5% (2020), +/- 7% (2021), +/- 9% (2022 and beyond)

Where Do Drugs Fit Within MIPS?

Quality

- Percentage of patients prescribed a specific medication for prevention or treatment of specific conditions
- Avoidance of inappropriate use of certain drugs (e.g., antibiotics)
- Evaluation for risk of opioid misuse
- Documentation of current medications
- Medication reconciliation post-discharge
- Medication management

Resource Use

- In the future, CMS intends to consider how best to ***incorporate Part D costs*** into the ***resource use*** performance category

CPIA

- Patients participating in specific drug management or monitoring programs
- Patients with established treatment goals for specific drug regimens
- Medication management and medication reviews
- Clinician participation in/consultation of state prescription drug monitoring program
- Participation in antibiotic stewardship program

ACI

- E-prescribing using certified electronic health record technology
- Drug interaction and drug-allergy checks
- Medication orders using computerized provider order entry (alternate proposal)

MACRA Physician Payment Reforms – APMs

- From 2019-2024, participants in advanced APMs are eligible for an annual lump-sum bonus of 5% of estimated Medicare payments for the preceding year
  - The bonus payment would be in addition to any shared savings bonuses or fees that the physician receives for participating in the advanced APM
- Advanced APMs must require participating providers to:
  - Take on "more than nominal" financial risk (or participate in certain patient-centered medical homes)
  - Report quality measures that are comparable to the measures adopted under MIPS
  - Use certified EHR technology
- Providers must receive a "significant share" of their revenue through participation in an advanced APM to be eligible for the 5% bonus

Medicare Part B Drug Payment Model

- On March 8, 2016, CMMI announced a proposal to test new models to pay for prescription drugs under Medicare Part B
  - Today, Medicare Part B generally pays physicians and hospital outpatient departments the average sales price ("ASP") of a drug, plus a 6 percent add-on
  - The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value
- The proposed model also would test ***value-based purchasing arrangements***
- All providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model, although not all would be part of each test proposed by CMMI

Medicare Part B Drug Payment Model – Value-Based Purchasing Arrangements

- CMMI proposes to test five value-based purchasing arrangements for Part B drugs:
  - ***Discounting or eliminating patient cost-sharing***: goal is to improve beneficiaries' access and appropriate use of effective drugs
  - ***Feedback on prescribing patterns and online decision support tools***: create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications
  - ***Indications-based pricing***: test variations in the payment for a drug based on its clinical effectiveness for different indications
  - ***Reference pricing***: test the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products
  - ***Risk-sharing agreements based on outcomes***: allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments

Feedback on Proposed Medicare Part B Drug Payment Model

- The proposed model has been met with vast criticism and calls to withdraw the proposal
  - Bipartisan letter from more than 240 House members call for demo to be withdrawn; Senate Finance Committee members similarly call for withdrawal
  - Concerns include:
    - Patient access to appropriate medicines
    - Impact on quality of care
    - Inappropriate expansion of CMMI authority
    - Overly broad size and scope
  - Dr. Patrick Conway from CMS testifies at Senate Finance Committee Hearing on June 28, 2016
- Supporters of the proposed model have suggested that tweaks are needed
  - Suggestions include:
    - Creating an ombudsman program to monitor beneficiary and provider experiences
    - Requiring a monitoring and corrective action plan from CMS to deal with unintended consequences
    - Establishing a multi-stakeholder advisory panel to provide input on potential mid-course corrections
    - Limiting the size and scope of the demonstration
    - Providing an exceptions process for small and rural providers

What Key Stakeholders Said About the Proposal

"…we are gravely concerned that CMS has issued a Proposed Rule that will diminish Medicare providers' ability to obtain Part B therapies, and in turn, threaten patient access to needed medicines. Given these concerns, and the significant deviation of CMS's proposed approach from the statutory requirements and congressional intent with respect to Center for Medicare & Medicaid Innovation (CMMI) demonstrations, **BIO strongly urges the Agency to withdraw the Proposed Rule in its entirety**. In its place, CMS should establish an inclusive dialogue with stakeholders to identify discrete opportunities for Part B changes in an evidence-based manner and work collaboratively to develop any future demonstration programs with a scope and approach that align with Congress's intent in authorizing CMMI."

BIO Public Comment Letter (May 9, 2016)

" …we are very concerned with the broad changes CMS proposes to make to the Medicare program, which would require physicians and their patients to participate in an almost nationwide model that will limit access to Part B medicines based on an unsupported hypothesis that the current payment methodology is leading to inappropriate care. The policies proposed by CMS-including a reduction in ASP payment rates and use of relative effectiveness and cost-effectiveness standards to impose new 'value-based' price regulation on Part B drugs-are fundamentally flawed and would present a significant risk to patient access and care quality; accelerate the shift to more expensive, hospital-based sites of care, thereby increasing costs to Medicare and its beneficiaries; and replace individualized doctor-patient decision-making with centralized government judgments of which treatment options are clinically appropriate or 'valuable' for individual patients. Additionally, the proposed model has serious legal defects and raises constitutional concerns. **Because of this, we strongly urge CMS to withdraw the proposed rule**."

PhRMA Public Comment Letter (May 6, 2016)

Value-Based Reimbursement for Drugs

	TRADITIONAL DISCOUNTING	CONDITIONAL COVERAGE	VALUE-BASED ARRANGEMENTS
General Description	Drug price is established prior to coverage and fixed for the benefit year	Coverage contingent on certain short-term health outcome or evidence collection target	Reimbursement is tied to clinical or process outcome at the individual patient level
Key Inputs	Negotiated discount or rebate	Pre-determined goal for a defined patient population (e.g., short-term treatment goal such as persistence)	Pre-determined goal for a defined patient population (e.g., 1% reduction in HbA1c, performance versus competitor, delay in disease progression)
Key Outcomes	Varies (e.g., flat pricing, volume of drug purchased)	Attainment of treatment goals or collection of additional evidence through research	Patient-level clinical or process outcome (may occur after benefit year ends)
Example	• Market share-based rebating or price-volume arrangements • Utilization cap or manufacturer-funded treatment initiation	Coverage with evidence development or conditional treatment continuation	Manufacturer provides rebate on products purchased for patients who fail to achieve desired outcome

DEGREE OF DIFFICULTY AND RISK

Source: J Carlson, et al. "Linking payment to health outcomes: A taxonomy and examination of performance-based reimbursement schemes between healthcare health plans and manufacturers." Health Policy. 2010 Aug;96(3):179-90.

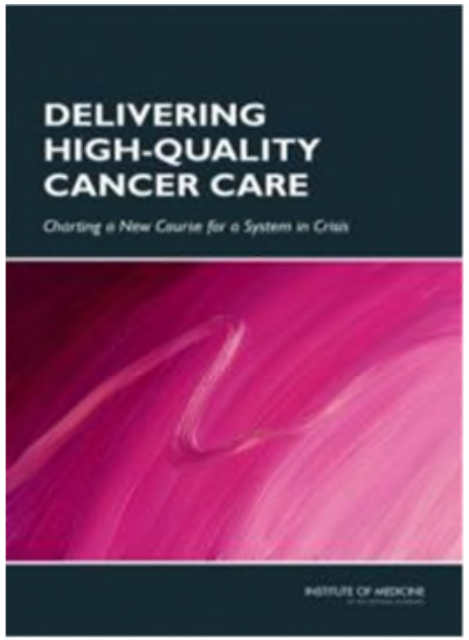
Value-Based Pharmaceutical Contracts
A Challenging Terrain and Evolving Landscape

- What are the clinically relevant and measurable ***metrics or outcomes***?
  - Particularly challenging in oncology and long-tern chronic illnesses, such as multiple sclerosis or rheumatoid arthritis.
  - Personalized Medicine approach: molecular profiles guide therapy which include off-label use
  - Need to measure value appropriately; accommodate patient preferences and reward innovation : QALY, NICE Threshold, DrugAbacus in Oncology, ICER

- Value-based pricing: ***market experience***
  - **Merck and Cigna**: Januvia and Janumet discounts, formulary placements and co-pay, based on A1C values
  - **P&G/Sanofi-Aventis and Health Alliance**: Risedronate, payment for non-spine fractures while on treatment
  - **Novartis**' heart failure drug Entresto and reduction of hospitalization with Cigna and Aetna
  - **Amgen and Harvard Pilgrim Health Care** based on Repatha (PCSK-9) lowering cholesterol to levels seen in clinical trials
  - Consideration of **Medicaid Best Price**

- More frequent in Europe, particularly Sweden, Italy, UK, Netherlands and also Australia

Cancer Care: Charting New Course for a System in Crisis



Institute of Medicine
2013

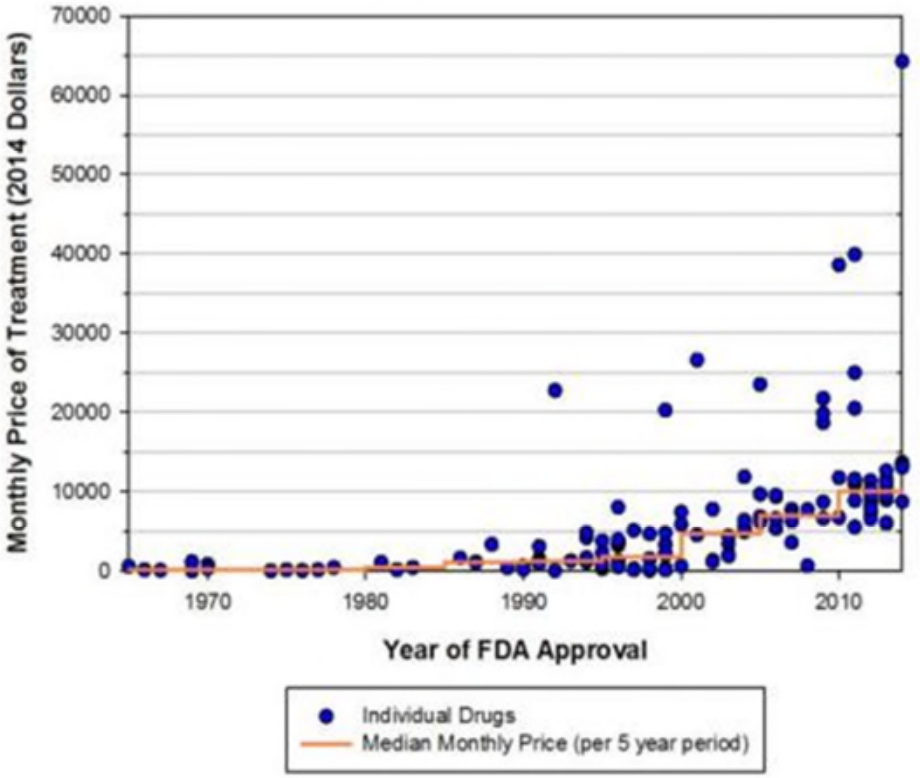
Care often is not patient-centered, many patients do not receive palliative care to manage their symptoms and side effects from treatment, and decisions about care often are not based on the latest scientific evidence.

IOM Recommendations to improve the quality of cancer care

- A national quality reporting program with meaningful quality measures
- Improve the affordability of cancer care by leveraging existing efforts to reform payment and eliminate waste
  - Reimbursement aligned to reward affordable, patient-centered high quality care

New Cancer Drugs Are More Expensive … And Producing Less Value

Monthly and Median Cost of Cancer Drugs at the Time of FDA Approval 1965-2014



13 new cancer treatments approved by FDA in 2012

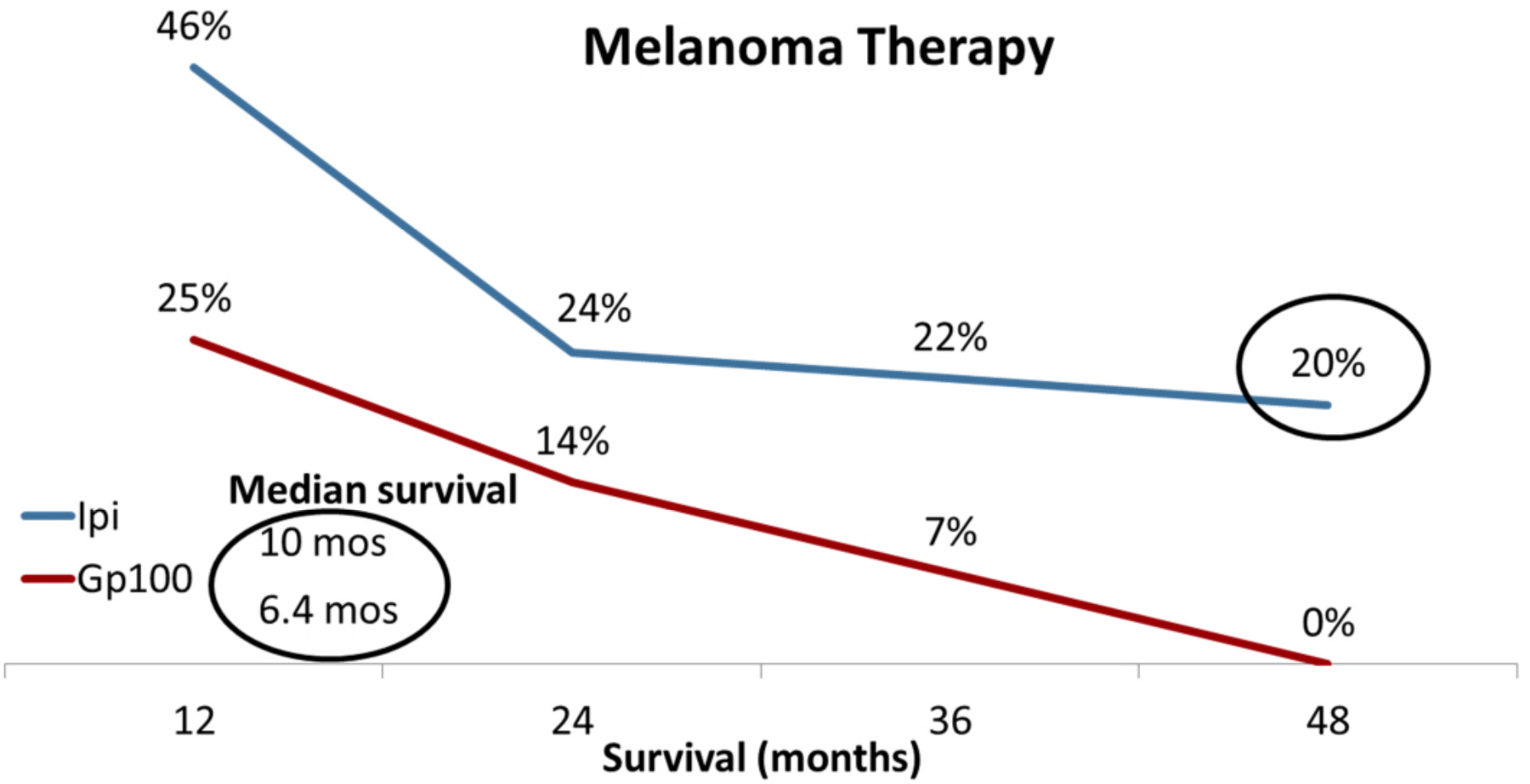
1
Survival extended by 6 months

2
Survival extended by only 4-6 weeks

$5,900
Average cost of treatment per month

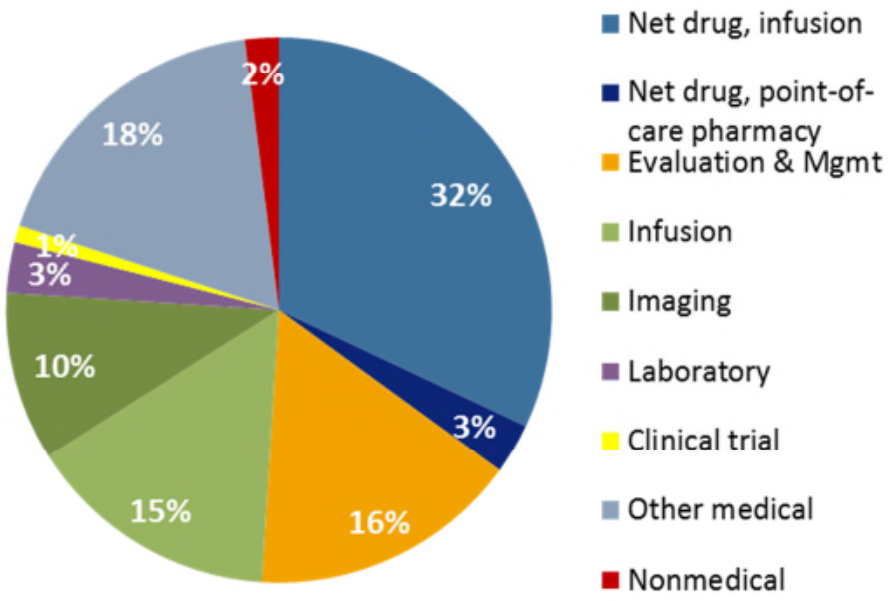
Peter B. Bach, MD, Memorial Sloan-Kettering Cancer Center

Patients Value Therapies That Provide Survival: Study of Ipilimunab Added to GP100 Vaccine



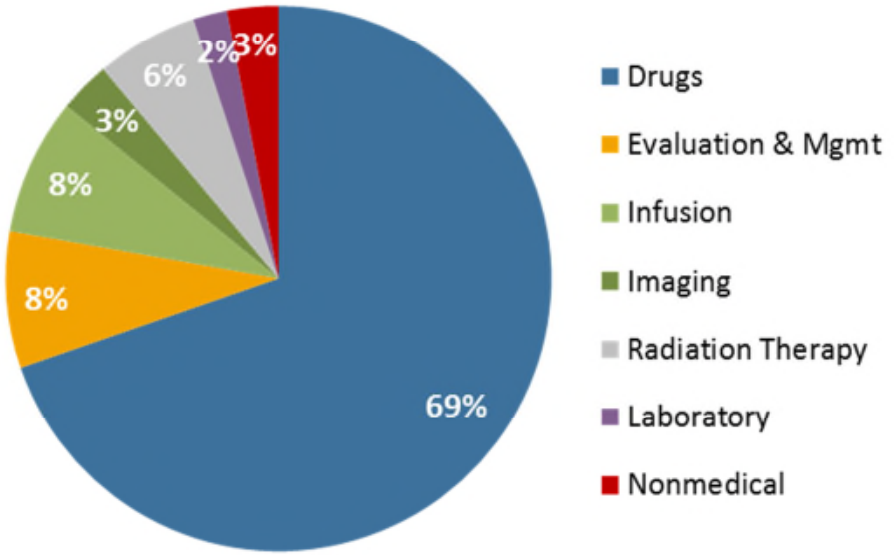
Reimbursement Model: Shift Focus to Cancer Care that is Patient-Centered and Value-Based

Oncology Practice Profitability Sources



Towle et al. J Oncol Pract 2014;10:385-406

Oncology Practice Revenue Sources



Barr et al. J Oncol Pract 2011;7: 2s-15s.

Anthem: Clinical Pathways for Cancer Care

- A subset of regimens supported by **evidence** and **clinical guidelines**
- Applicable for **80%-90% of patients** and selected based on:
  1. Clinical benefit (efficacy)
  2. Side effects/toxicities (especially those leading to hospitalizations & impacting quality of life)
  3. Strength of national guideline recommendations
  4. Cost of regimens
- Developed through a **rigorous evidence-based medicine process** involving **external advisors** and **publicly available**
- Publicly available at **www.cancercarequalityprogram.com**

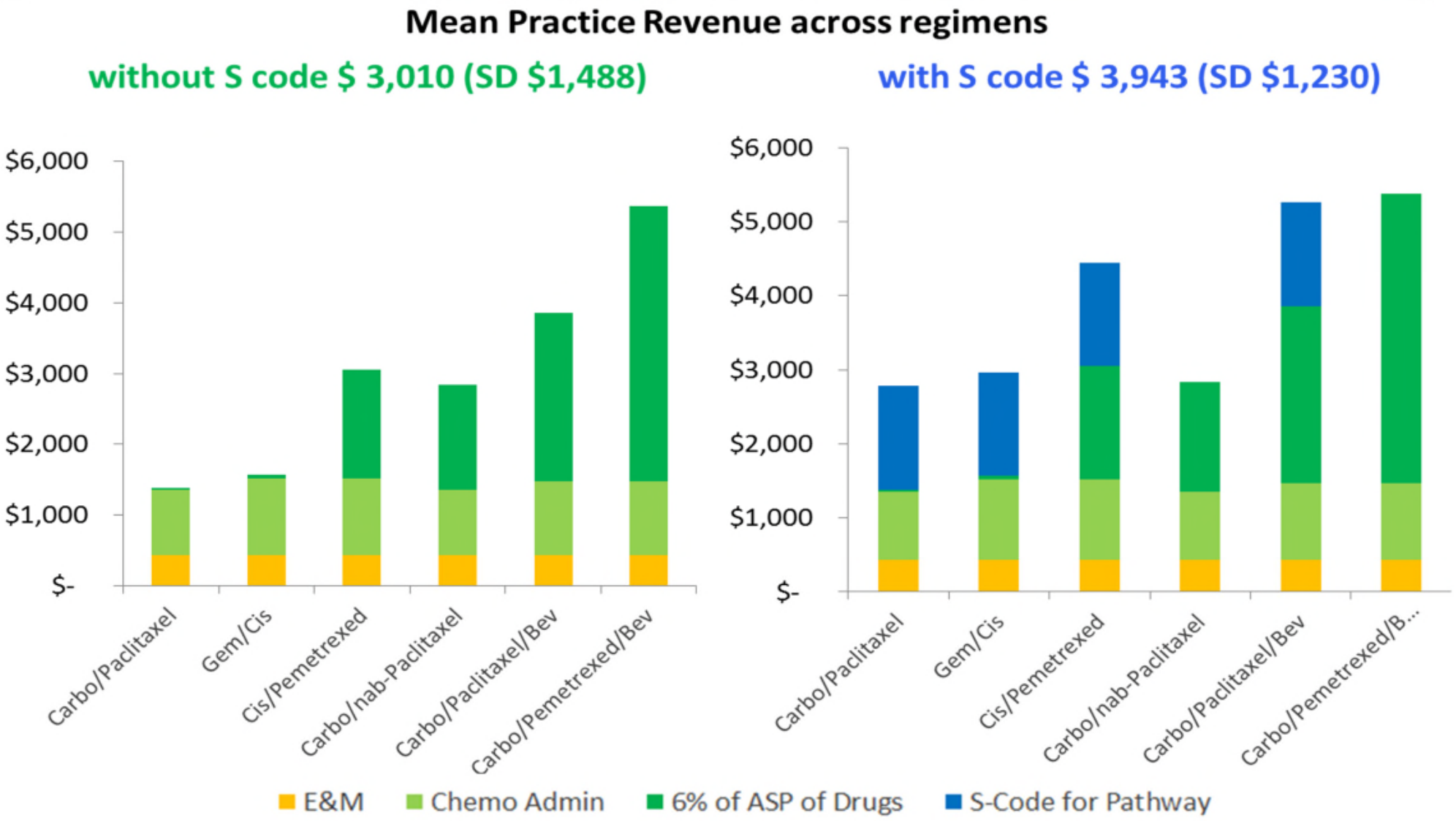
Variations in Outcomes Across First Line Regimens for Non-Small Cell Lung Cancer*

Treatment Regimen	Estimated Survival (months)	Grade 3-4 Adverse Events	Any serious AE (Hospitalization)	Deaths on Rx (Deaths due to Rx)	Cost (4 cycles)
Carbo/Paclitaxel	**13.0 (NR)**	N/V risk: Moderate* FN + infection:1% Neuropathy: 11% Debilitating fatigue: 6%	53% (**)	<1% (<1%)	**$452**
Gem/Cis	**10.4 (9.6-11.2)**	N/V risk: High FN + infection:4% Neuropathy: ND Debilitating fatigue: 5%	35% (**)	7% (1%)	**$886**
Cis/Pemetrexed	**11.8 (10.4-13.2)**	N/V risk: High FN + infection:1% Neuropathy: ND Debilitating fatigue: 7%	37% (**)	7% (1%)	**$25,619**
Carbo/nab-Paclitaxel	**13.1 (NR)**	N/V risk: Moderate FN + infection:1% Neuropathy: 3% Debilitating fatigue: 4%	** (**)	<1% (<1%)	**$24,740**
Carbo/Paclitaxel/Bev	**13.4 (11.9-14.9)**	N/V risk: Moderate FN + infection:4% Neuropathy: 4% Debilitating fatigue: 5% Bleeding 4%	75% (19%)	5% (4%)	**$39,770**
Carbo/Pemetrexed/Bev	**12.6 (11.3- 14.0)**	N/V risk: Moderate FN + infection:2% Neuropathy:0% Debilitating fatigue:11%	** (20%)	** (2%)	**$64,988**

* Non-squamous histology; first line platinum based chemotherapy indicated when no EGFR or ALK mutation present ** Not reported

Socinski JCO 2012; Sandler NEJM 2006:355; Scagliotti JCO 2008:26; Reck Annals of Oncology 2010; Patel 2012

Anthem: Impact of Enhanced Reimbursement for Pathways



Sentinel Initiative: A Model for Collaboration

PCORnet NIH Distributed Research Network

- Congressionally mandated (2007 FDAAA), FDA funded active surveillance system
  - Lead Harvard Pilgrim Health Care, in collaboration with over 30 data and scientific partners nationwide, including large health plans and academic institutions

- Distributed database held by 18 data partners in a standardized format
  - 193 million members *
  - 351 million patient years of observation time
  - 39 million members currently accruing data
  - 4.8 billion prescriptions
  - 5.5 billion unique encounters

*Double counting exists for individuals who change health plans

4 FDA drug safety communications - Tri-valent inactivated flu vaccine and febrile seizures (no increased risk) - Rotarix and intussusception (label change) - Dabigatran and bleeding (no increased risk) - Olmesartan and sprue-like enteropathy (label change)	**70** peer-reviewed articles **48** methods reports/white papers **Thousands** of unique queries and comparisons contributing to over 140 formal assessments

Considerations for the Path Forward

Bundled pricing for treatment of patient with a specific illness

Value-based purchasing of drugs determined by clinical outcomes

Real world evidence development on outcomes following FDA approval

Economic models to determine approaches to drug pricing

Policy/regulatory opportunities to promote transparency (timing of pricing, labeling indications and dialogue with payers in advance of approval)

Questions?

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Thank you.