Breaking Down the Hurdles to Value-based Arrangements for Pharmaceuticals

Pharmaceutical Summit on Business & Compliance Issues in Managed Markets

June 9, 2016

Washington, DC

Sam Nussbaum, MD

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

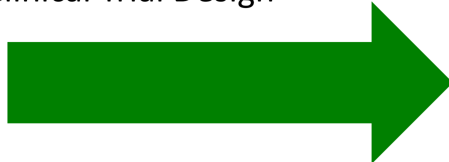
DRIVING FORCES

Breakthrough Science,
“Moon Shot” Initiatives

Personalized Medicine

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;

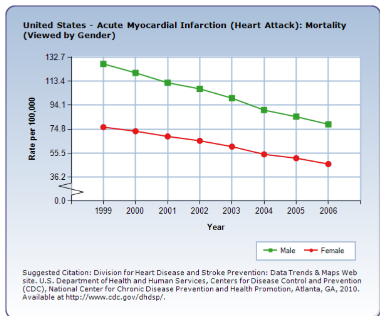
Impact of Consolidation
Health Plans + PBMs

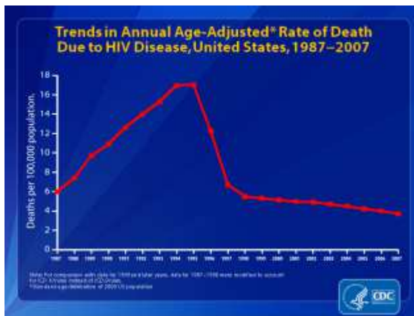
Discovery and Innovation

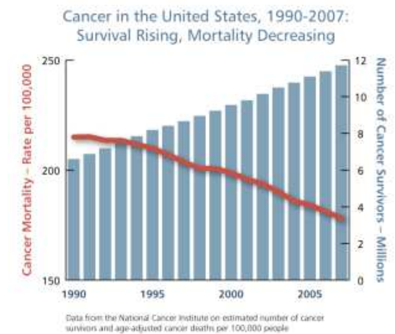
Statins reduce cardiac deaths

Anti-viral drugs transform HIV

Screening and drugs improve cancer survival







Affordability:
Rising Costs are Unsustainable

2002

$9,235

$49,309

2015

$24,671

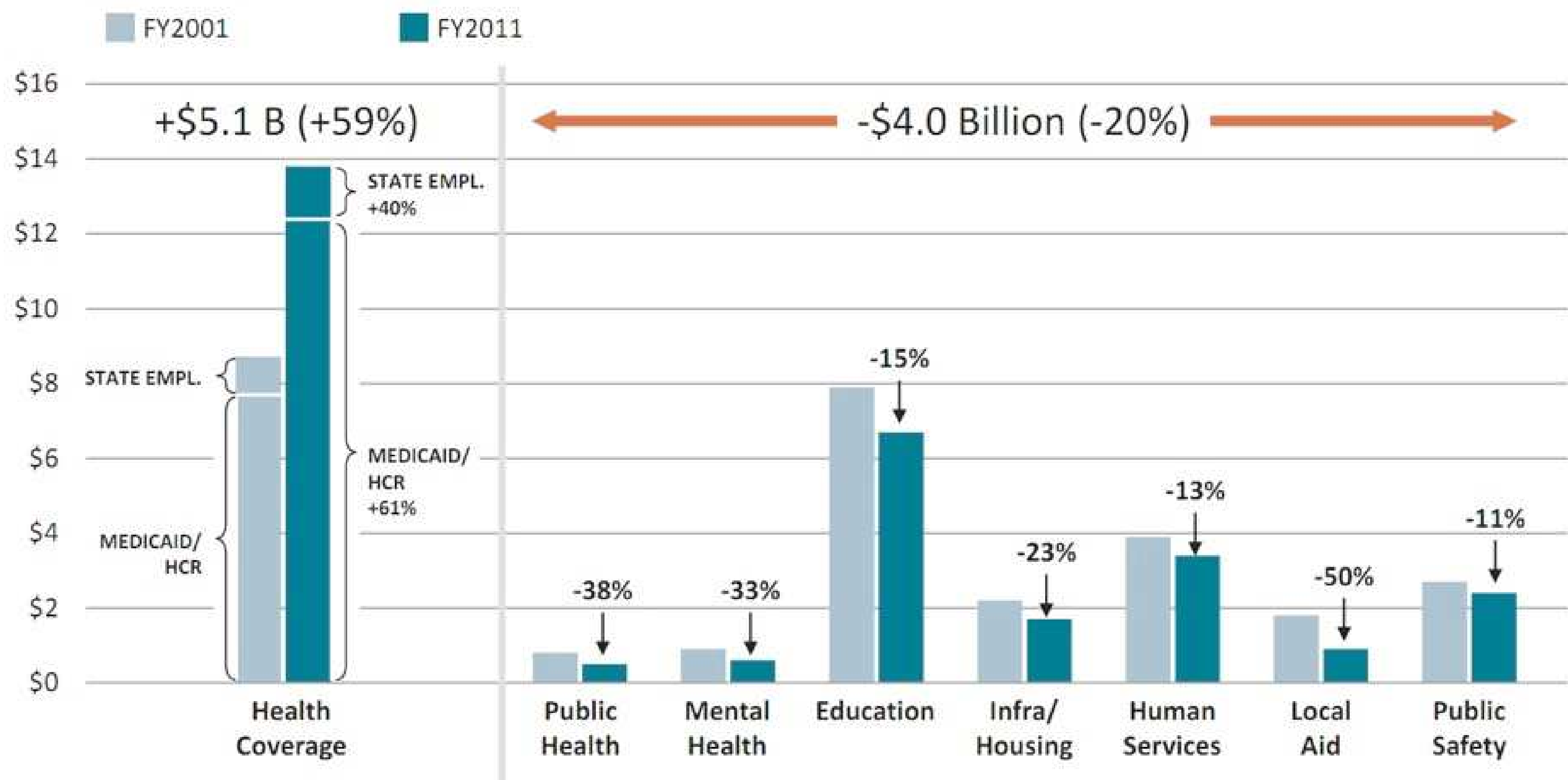
$53,800

Milliman Medical Index (MMI) vs. Average Household Income

THE MORE WE SPEND ON HEALTH CARE, THE LESS WE HAVE FOR OTHER THINGS

FOUNDATION MASSACHUSETTS

STATE BUDGET FY 2001 VS. FY 2011 (BILLIONS OF DOLLARS)



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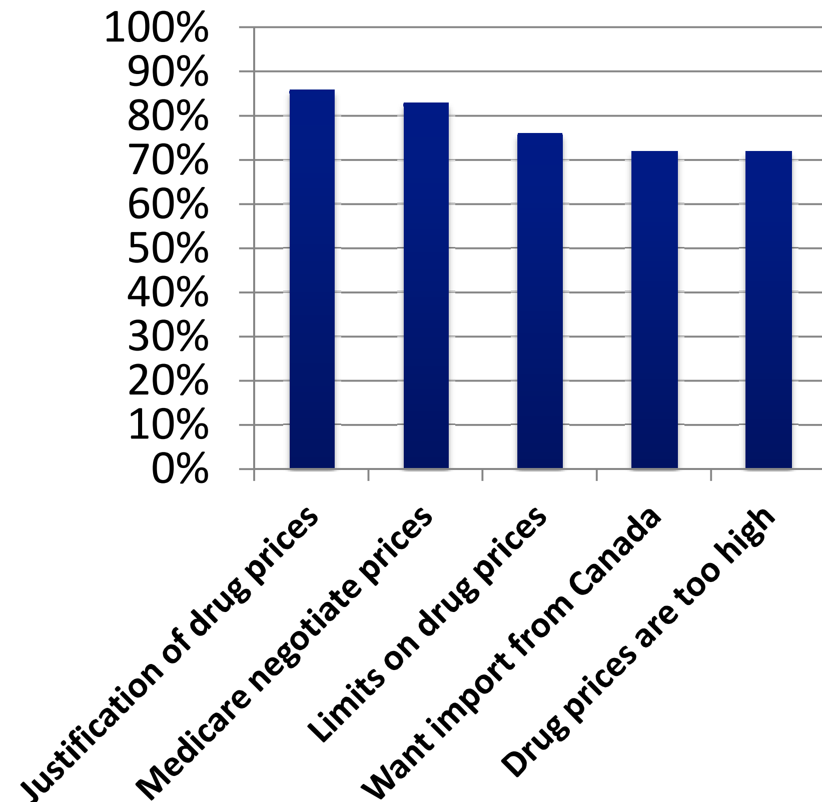
And a view from consumers

- 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"

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 **Current Effective Date:** 11/17/2014
Status: Revised **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
    - Favorable
    - Comparable
    - Insufficient Evidence
    - 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.

Anthem starts with an independent review of the research.

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. Health. Join In.

CER Promotes Value and Innovation

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

Address unsustainable heal 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

SUPERIOR

COMPARABLE

PERSONALIZED

INEFFECTIVE

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.

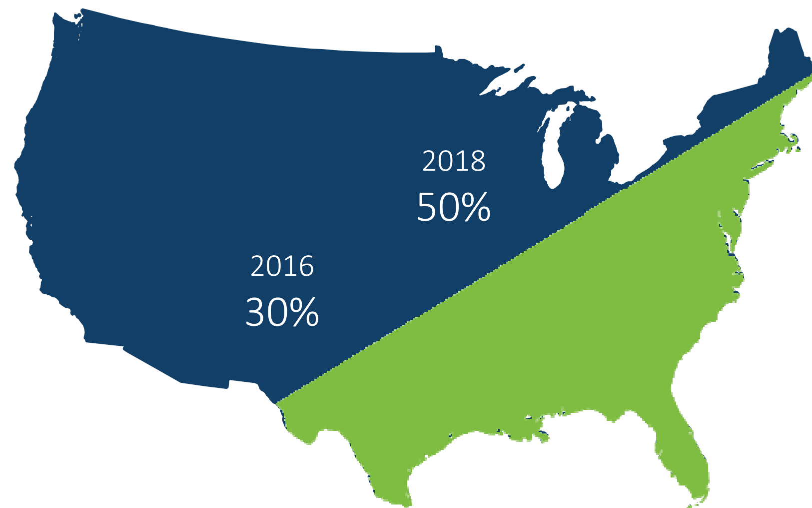
Goals for HHS and LAN

2016
30%
In 2016, at least 30% of U.S. health care payments are linked to quality and value through APMs

2018
50%
In 2018, at least 50% of U.S. health care payments are so linked.

These payment reforms are expected to demonstrate better outcomes and lower costs for patients.

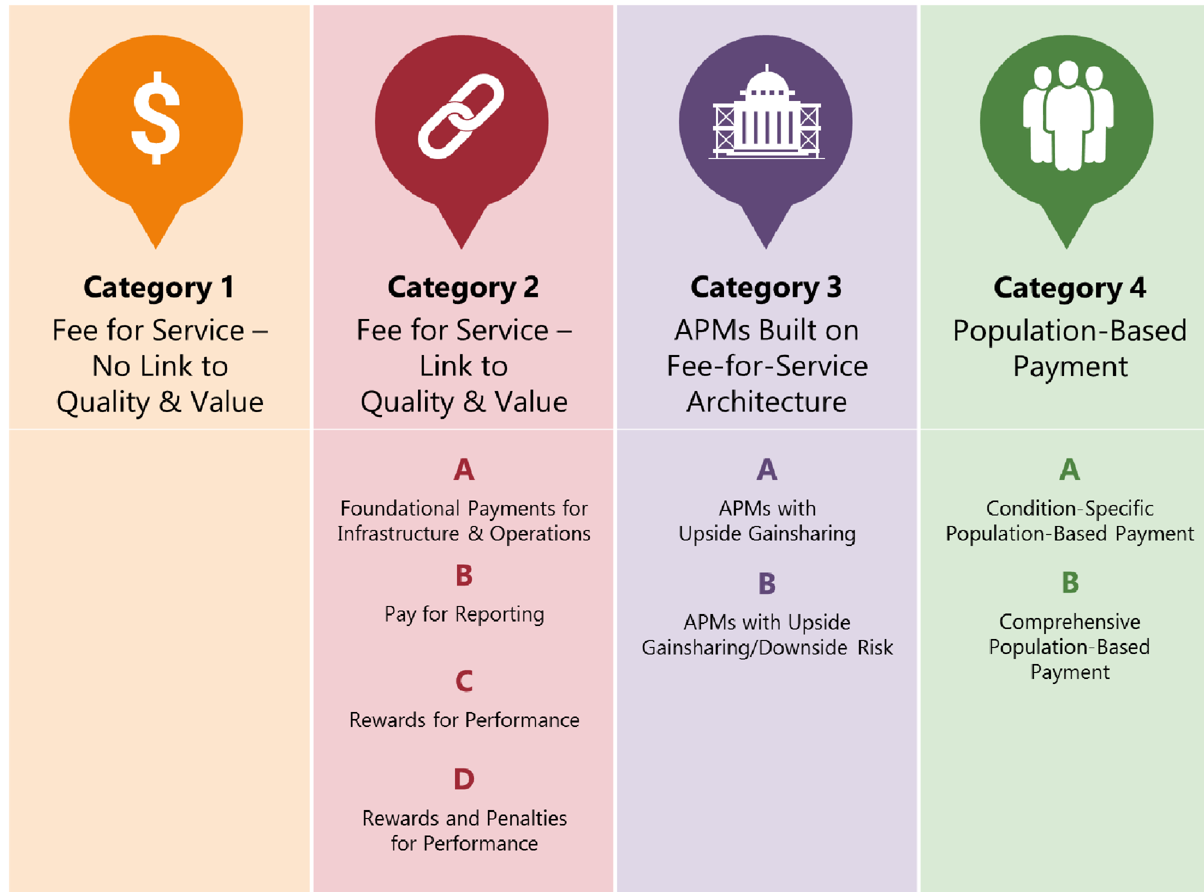
Adoption of
Alternative Payment Models (APMs)



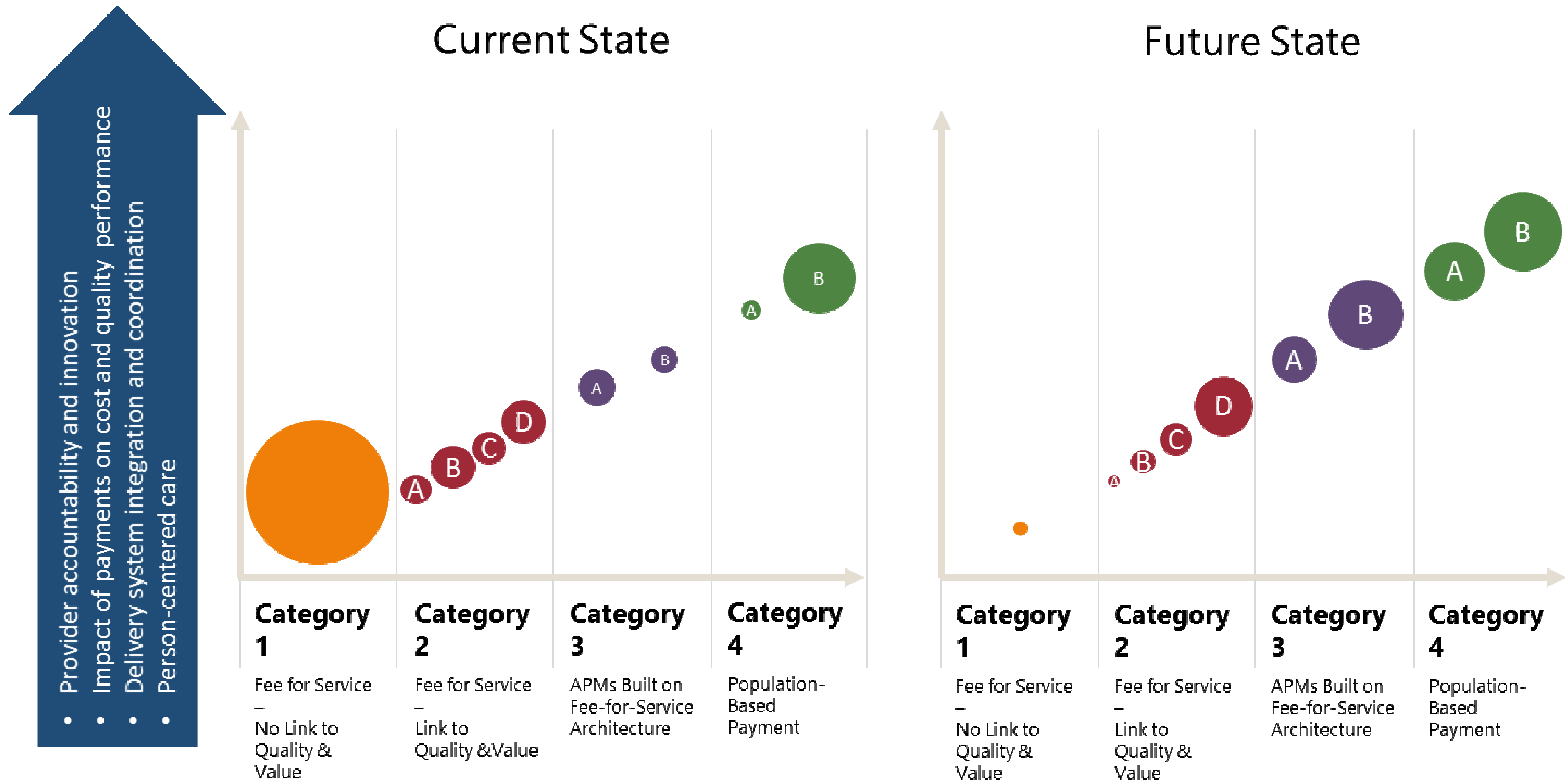
Better Care, Smarter Spending, Healthier People

HCP LAN
Health Care Payment Learning & Action Network

Alternative Payment Models Framework



Learning and Action Network's Goals for Payment Reform



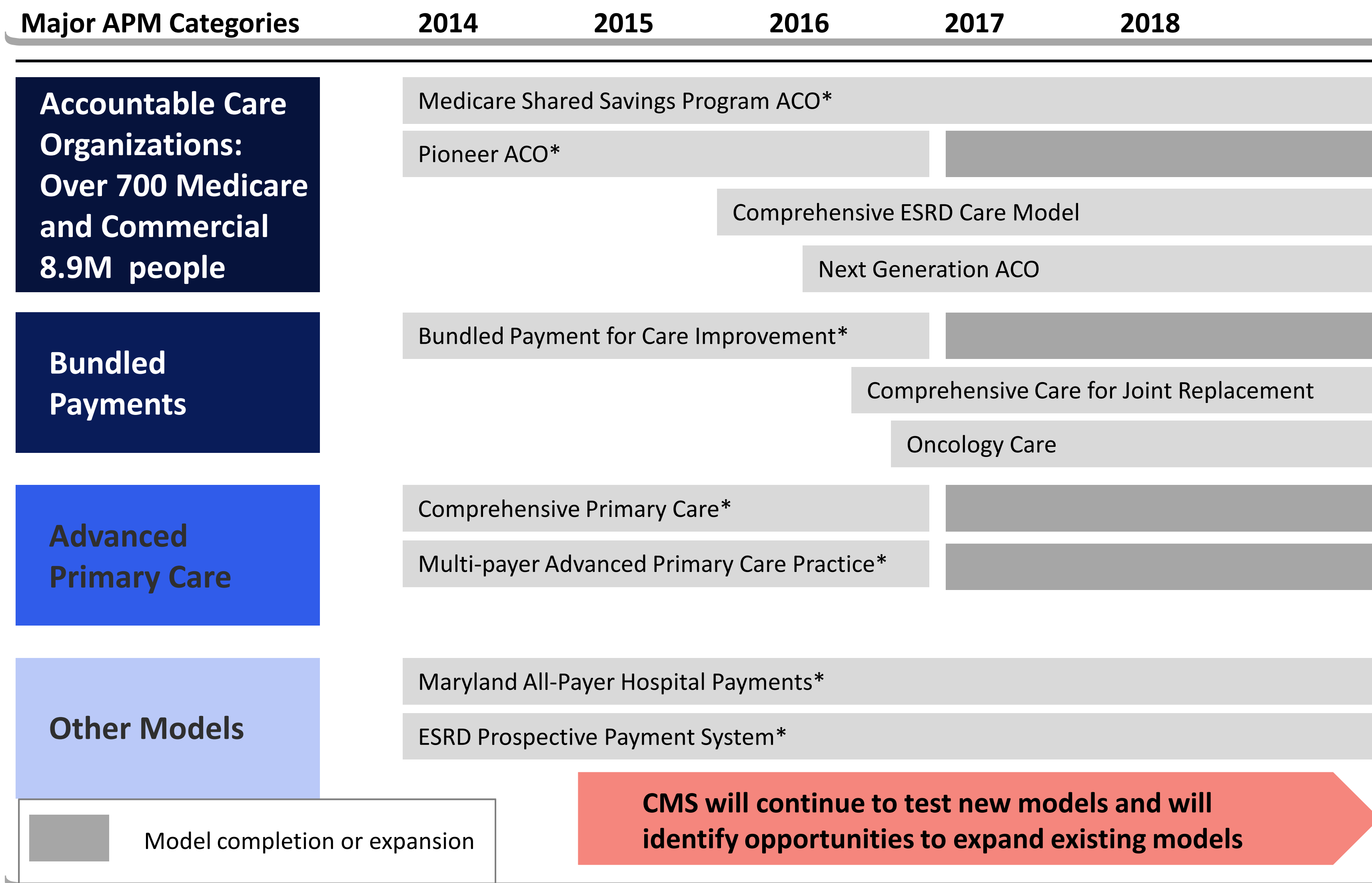
CMS support of health care Delivery System Reform will result in better care, smarter spending, and healthier people

Historical state → **Evolving future state**

Public and Private sectors

Historical state	Evolving future state
Key characteristics	**Key characteristics**
▪ Producer-centered	▪ Patient-centered
▪ Incentives for volume	▪ Incentives for outcomes
▪ Unsustainable	▪ Sustainable
▪ Fragmented Care	▪ Coordinated care
Systems and Policies	**Systems and Policies**
▪ Fee-For-Service Payment Systems	▪ Value-based purchasing
	▪ Accountable Care Organizations
	▪ Episode-based payments
	▪ Medical Homes
	▪ Quality/cost transparency

CMS alternative payment models



* 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

The CMS Innovation Center was created by the Affordable Care Act to develop, test, and implement new payment and delivery models

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

Performance-Based Reimbursement: 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

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.

Beyond the Pill: Barriers to Collaboration

Unclear Goals from Payers and Providers in collaboration with life sciences companies in moving beyond traditional relationships. Historic cultures of distrust amongst stakeholders

Complex Payer and Provider environments; in Europe a single payer system is an easier (although less flexible) landscape for pharmaceutical companies to navigate

Difficulty in measuring program impact and financial reward with more challenging and complex clinical and economic assessments with a significant demand for data collection and monitoring. Longer timeframes are problematic

Regulatory hurdles: Anti-kickback, communication regarding off label use; proactive communication of pharmacoeconomic claims; Medicaid best pricing

Source: NEHI, Tom Hubbard

AMBITION

THE JOURNEY OF A THOUSAND MILES SOMETIMES ENDS VERY, VERY BADLY.

Value-Based Pharmaceutical Contracts
A Challenging Terrain and Evolving Landscape

What are the clinically relevant and measurable metric or outcome?

- 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 pricing
- Misaligned approaches with physician payment for drugs administered by infusion: ASP +6% model encourages more costly therapies; recent CMS drug payment demonstration

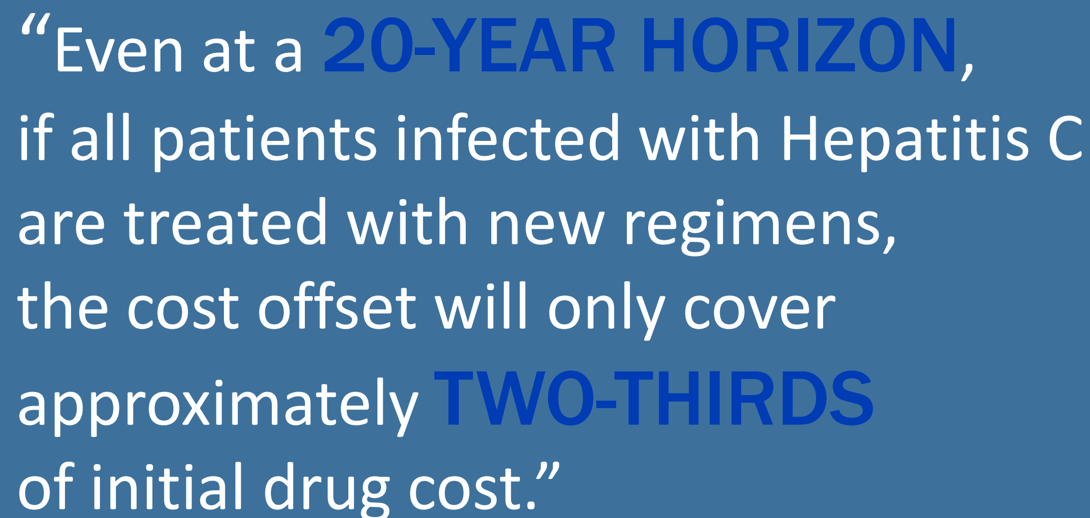
More frequent in Europe, particularly Sweden, Italy, UK, Netherlands and also Australia

California Technology Assessment Forum: Sovaldi ROI

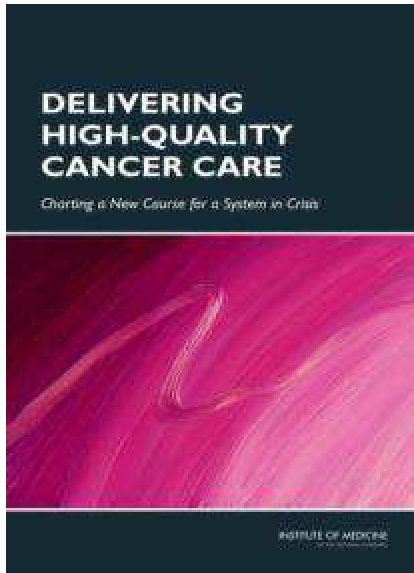
Model of Clinical and Economic Outcomes of Treatment Options for Hepatitis C

$100M-200M

1-year cost per 1,000 patients



Cancer Care: Charting New Course for a System in Crisis



Institute of Medicine
2013

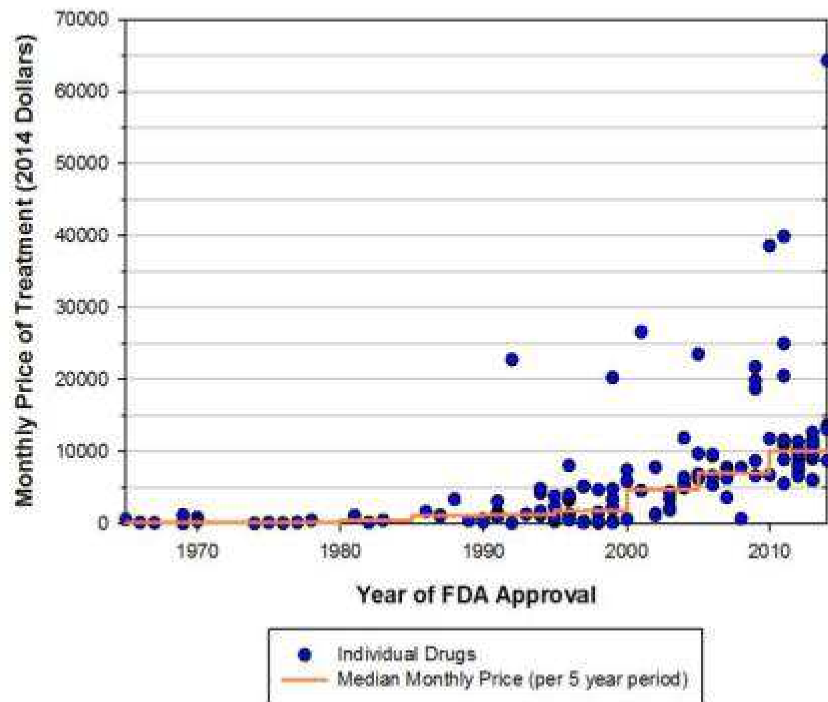
Care often is not patient-centered, many patients do not receive palliative care to manage their symptoms and side effects from treatment, and decisions about care often are not based on the latest scientific evidence.

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

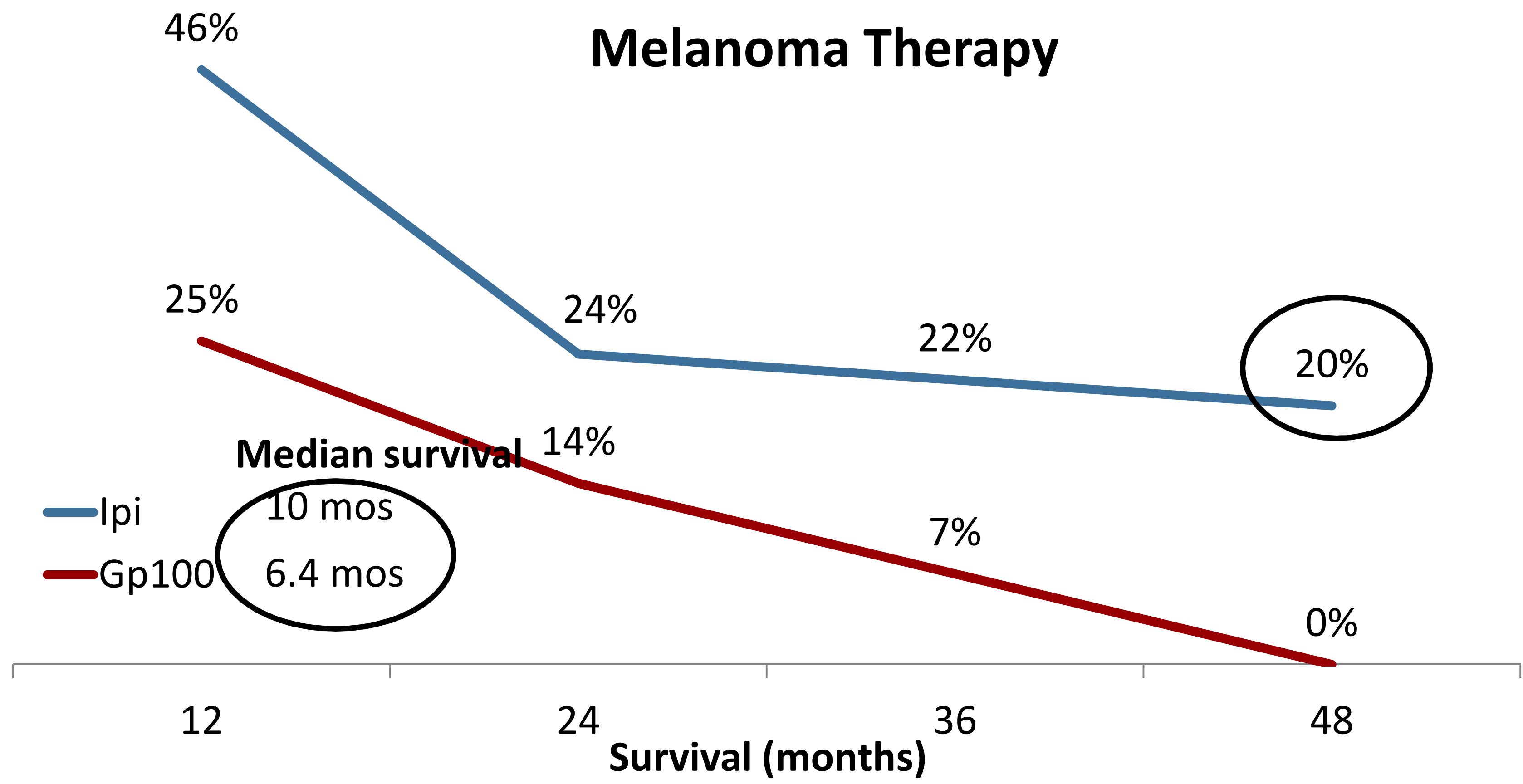
Survival extended by only 4-6 weeks

$5,900

Average cost of treatment per month

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

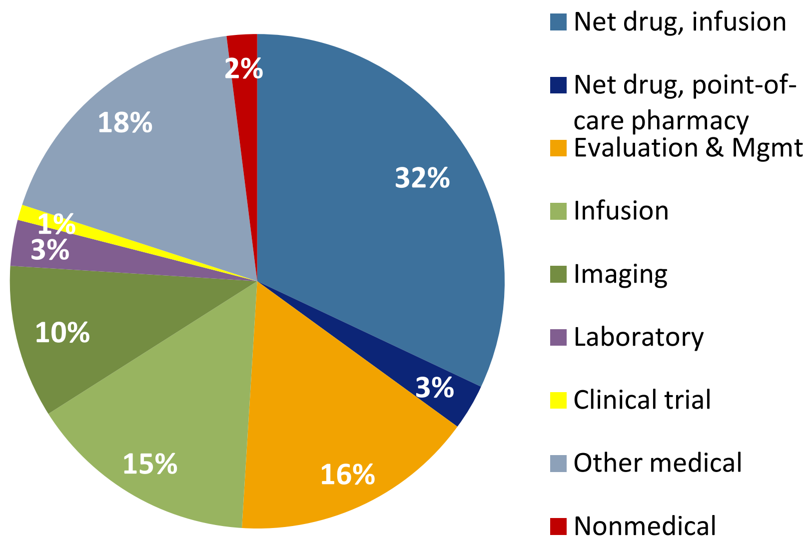
Patients Value Therapies That Provide Survival: Study of Ipilimunab added to GP100 Vaccine



Source: Hodi et al, *NEJM,* 2010.

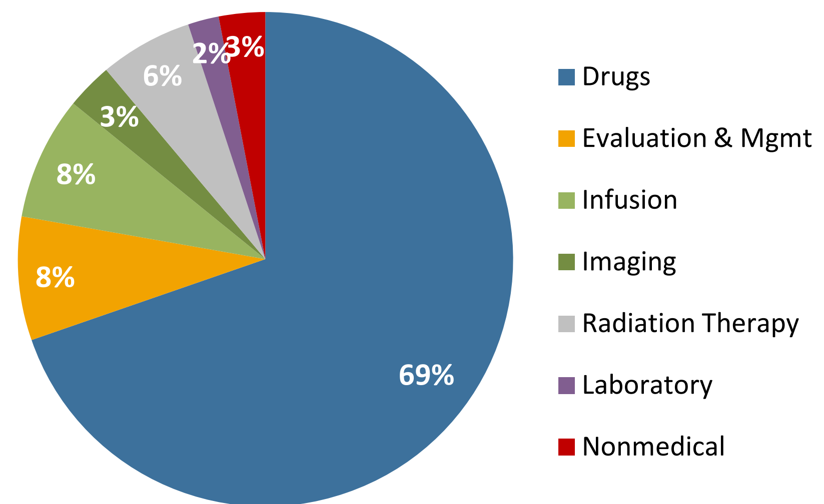
Reimbursement model: shift focus to cancer care that is patient-centered and value based

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**

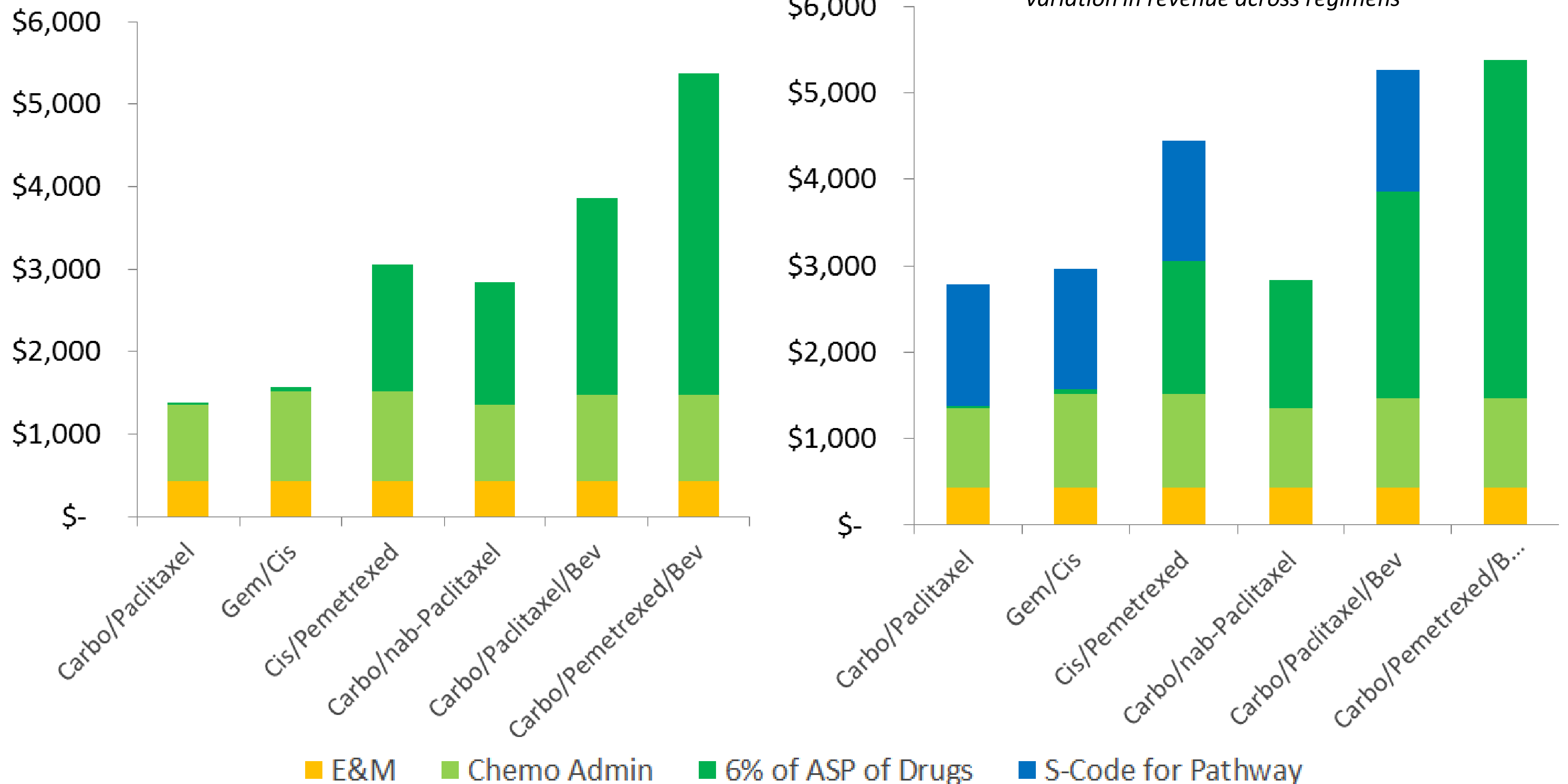
Variation in outcomes across first line regimens for non-small cell lung cancer*

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

- 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, 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

- **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

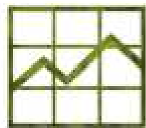
*Double counting exists for individuals who change health plans

Considerations for the Path Forward

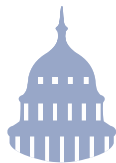
Bundled pricing for treatment of patient with a specific illness

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)