

# The Value of Oncology Therapies and Emerging Access Hurdles: Canada and the United States

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# Agenda

Part 1	Background – Global Trends in Healthcare
Part 2	Current and future access challenges – Canada
Part 3	Current and future access challenges – US
Part 5	Strategic Initiatives & Summary

## During this presentation:

We will particularly focus on Canada and the US

- This short overview seeks to conduct an inquiry into recent value paradigm shifts and emerging market access and reimbursement hurdles in oncology in 3 key countries—Germany, Canada, and the US—and identify what can be learned from the evolving landscape for developing access strategies and value propositions
- Canada is one of the historically challenging markets for oncology products to gain access from the public payer, and the US has been undergoing a few noticeable changes following the Affordable Care Act (ACA).

# Global Trends in Healthcare



The word “value” is a ubiquitous term, yet it is often not operationalized in the same way by the manufacturer, the payer and patient, and the society.

$$Value = \frac{Quality \text{ (or Health Outcomes)}}{Price}$$

“Nowadays people know the price of everything and the value of nothing.”

-Oscar Wilde

# Current and Future Access Challenges

Canada

## Cancer has a strong societal and political dimension to it

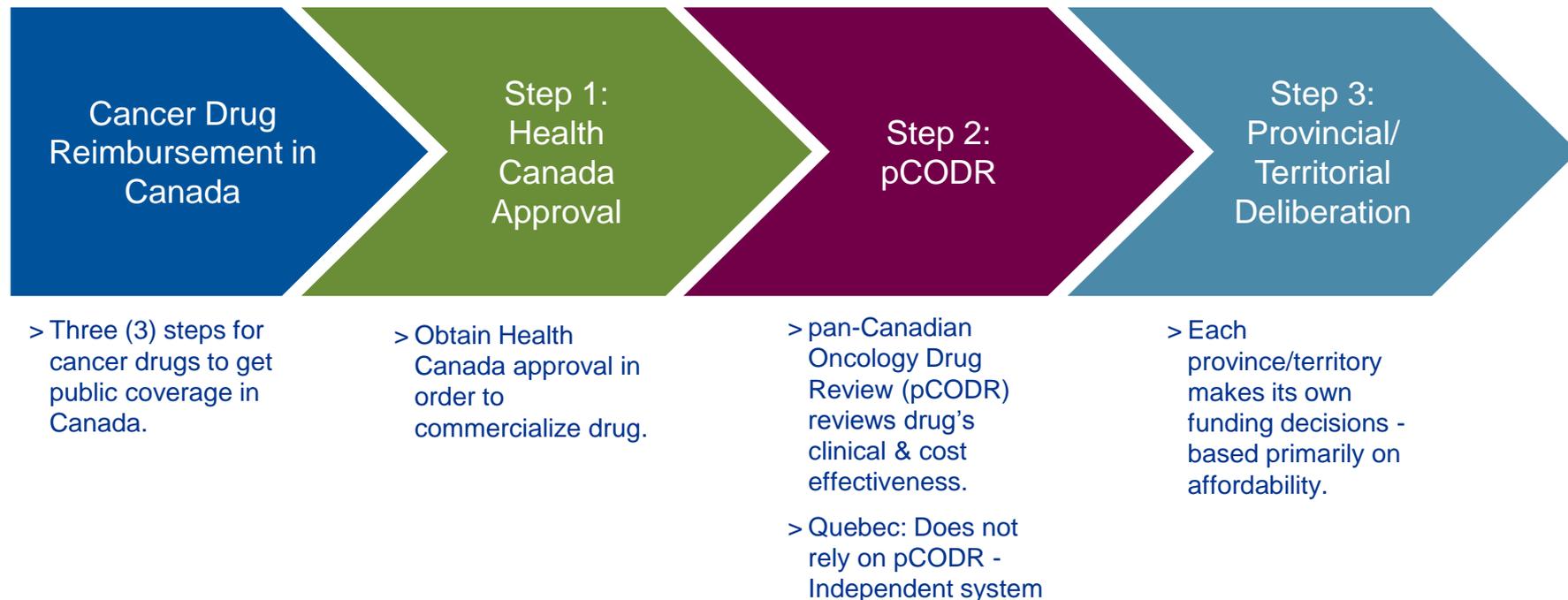


## However, Canada's cancer drug access has been challenging in the International context

Canadian System: Unique	Unfavorable Access to Cancer Drugs	Listing New Cancer Drugs	Reimbursement of Cancer Drugs
<ul style="list-style-type: none"> <li>&gt; Not one single system but rather 13 separate provincial or territorial systems.</li> <li>&gt; As example, Quebec does not rely on pCODR- Independent Process.</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Despite Canada's health care spending being among the highest of all OECD countries, Canadians' access to cancer drugs is unfavorable.</li> <li>&gt; Canada's public drug plans cover on average 57% of the 50 cancer drugs compared to 79% in 31 other OECD countries is 79.9%.</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Canada ranked 13th out of 14 over the past five years when it comes to listing new cancer drugs.</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Canadian reimbursement average for cancer drugs is 48% compared to 83.5% in 31 other OECD countries.</li> </ul>

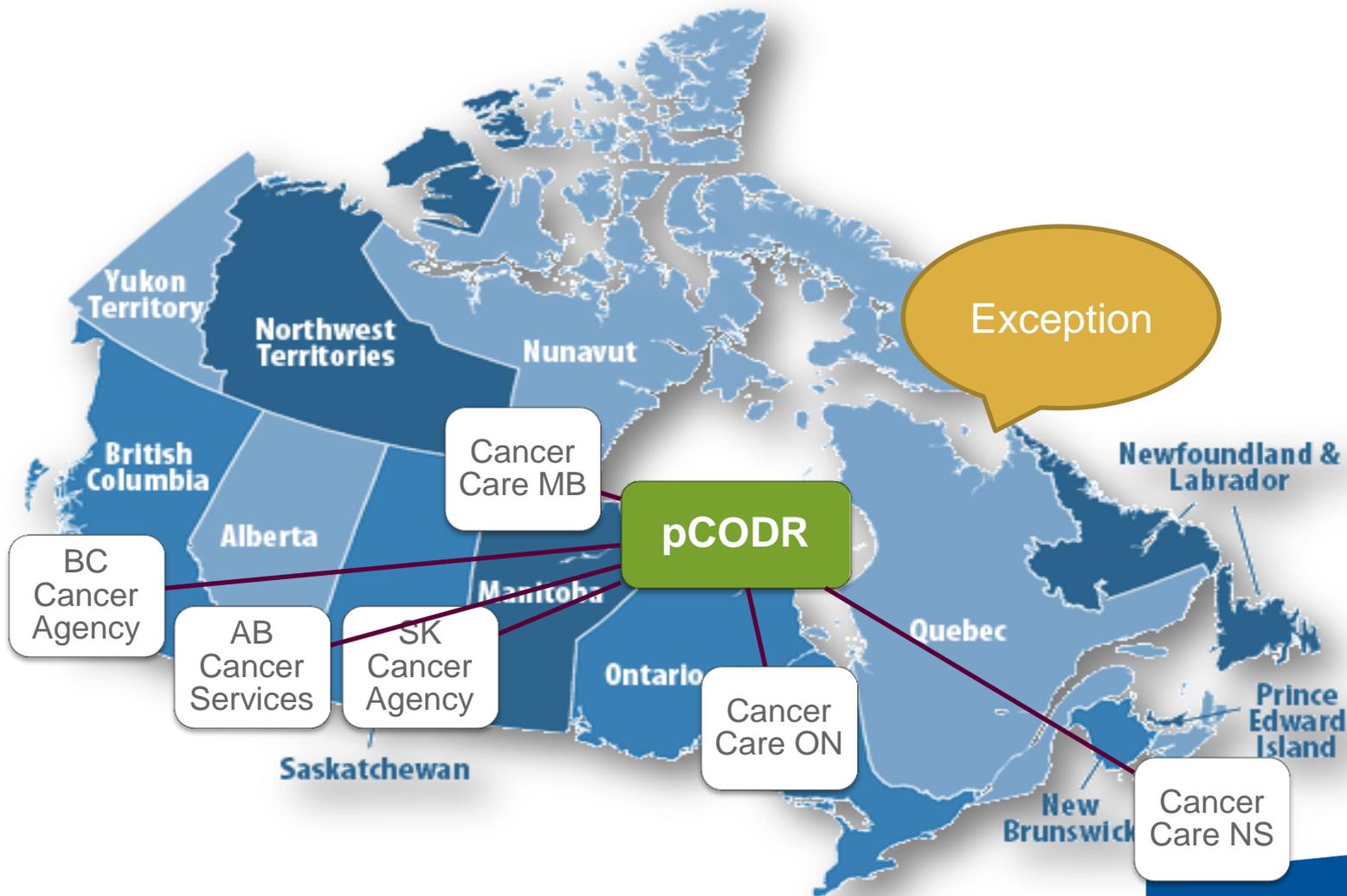
Sources: International variability in the reimbursement of cancer drugs by publically funded drug programs. Medical Oncology, Vol. 19, No. 3 (2012) and The Rx&D International Report on Access to Medicines 2010-2011.

## The pan-Canadian Oncology Drug Review (pCODR), created in 2011, has reviewed oncology products for their effectiveness and costs



April 2014, pCODR was transferred to CADTH to consolidate policy direction across Canada's drug review programs & to strengthen the pCODR governance structure

# pCODR partners with the provincial Canadian Cancer HTA Agencies



Only 10 molecules have been listed on the positive list out of 33 reviewed since 2012



### pCODR Positive Listing Decisions

DRUG	INDICATION
Giotrif (Afatinib)	Advanced Non Small Cell Lung Cancer
Stivarga (Regorafenib)	Gastrointestinal Stromal Tumours
Trisenox (Arsenic Trioxide)	Acute Promyelocytic Leukemia
Erbitux (Cetuximab)	Metastatic Colorectal Cancer
Erivedge (Vismodegib)	Advanced Basal Cell Carcinoma
Kadcyla (Trastuzumab emtansine)	Metastatic Breast Cancer
Adcetris (Brentuximab vedotin)	systemic Anaplastic Large Cell Lymphoma
Tafinlar (Dabrafenib)	Metastatic Melanoma
Alimta (Pemetrexed)	Advanced Non-Squamous Non Small Cell Lung Cancer
Stivarga CRC (Regorafenib)	Metastatic Colorectal Cancer

# Beyond publicly funded healthcare, the private insurance sector has played an increasingly significant role in Canadian cancer care

>23 Million Lives Covered

## National PBMs

Telus Health (7.6 Million Lives)

Express Scripts (7 Million Lives)

ClaimSecure

## Major Insurers – National Reach

Great West Life  
(4.1 Million Lives)

Sun Life  
(3 Million Lives)

Desjardins

Manulife  
(3.25 Million Lives)

Green Shield

## Major Regional Insurers

Pacific Blue Cross  
(BC)

Alberta Blue Cross

Blue Cross Medavie  
(Atlc)

Desjardins  
(QC – 600K Lives)

SSQ  
(QC – 1 Million Lives)

La Capitale (QC)

# Top 10 Group Health Providers (as of Dec. 31, 2012)

Rank	Company	2012 (Insured Premiums (Millions))	2011 (Insured Premiums (Millions))	% Variance
1	Manulife Financial	\$3,852.6	\$3,222.5	19.6%
2	Great-West Life	\$3,845.8	\$3,612.2	6.5%
3	Sun Life Financial	\$2,912.2	\$2,766.9	5.3%
4	Desjardins Financial Security	\$1,799.8	\$1,663.8	8.2%
5	SSQ Financial Group	\$1,300.4	\$1,162.2	11.9%
6	Industrial Alliance	\$807.3	\$794.0	1.7%
7	Standard Life	\$528.6	\$501.4	5.4%
8	La Capitale Assurance & Gestion du Patrimoine	\$420.8	\$366.8	14.7%
9	Green Shield Canada	\$370.5	\$357.2	3.7%
10	Medavie Blue Cross	\$322.9	\$304.4	6.1%

Source: Benefits Canada/CIIN 2013 Group Insurance Survey

# Canada's Oncology HTA Environment is Evolving

## Public Payer

### **COST CONTAINMENT ENVIRONMENT- PRICE DRIVEN**

- Pricing will be increasingly based on evidence
- Increased focus on value and health outcomes in real world
- Prioritize HTA for specific provincial needs as requirements and review process is different

## Private Payer

### **Increased Management of Drug Programs**

- Increasingly focused on plan sustainability and concerned with increase in private claims in Oncology
- Looking to HTA to show therapeutic value/incremental benefit
- Interested in indicators that prove reduced absenteeism/presenteeism

## Manufacturer

### **Value AND Customization will be KEY**

- Increasing requirement to prove value through patient outcomes
- Adherence strategies demonstrating positive outcomes a must for optimal therapy
- Be aware that drug review process is not consistent and building timely submission based on value and price supported by positive outcomes will be essential customize to public and private needs

### **Some General Trends:**

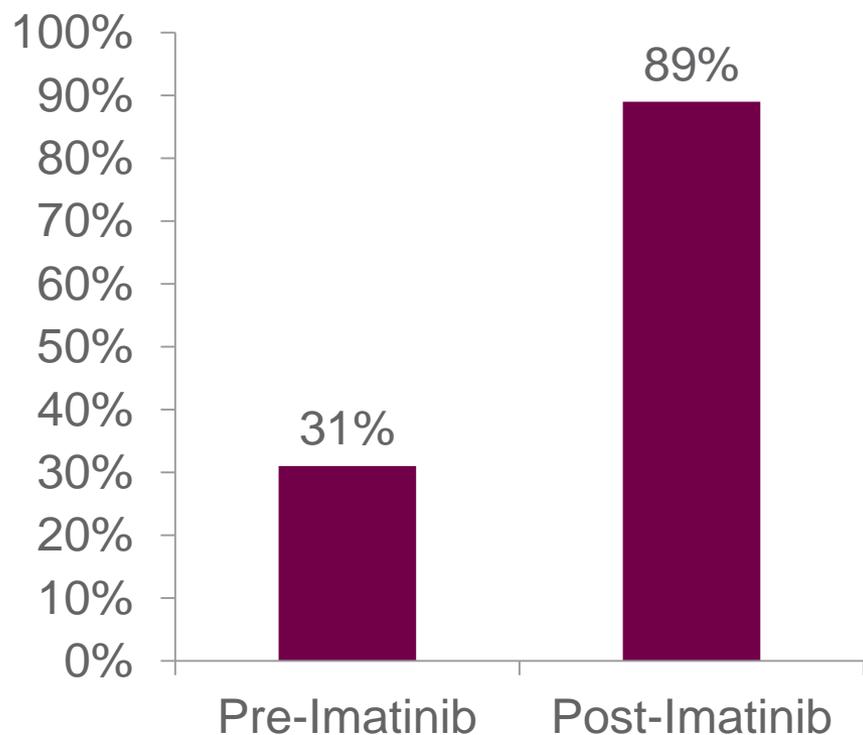
- Customization with provinces required
- Private becoming more of an opportunity for out of hospital therapies

# Current and Future Access Challenges

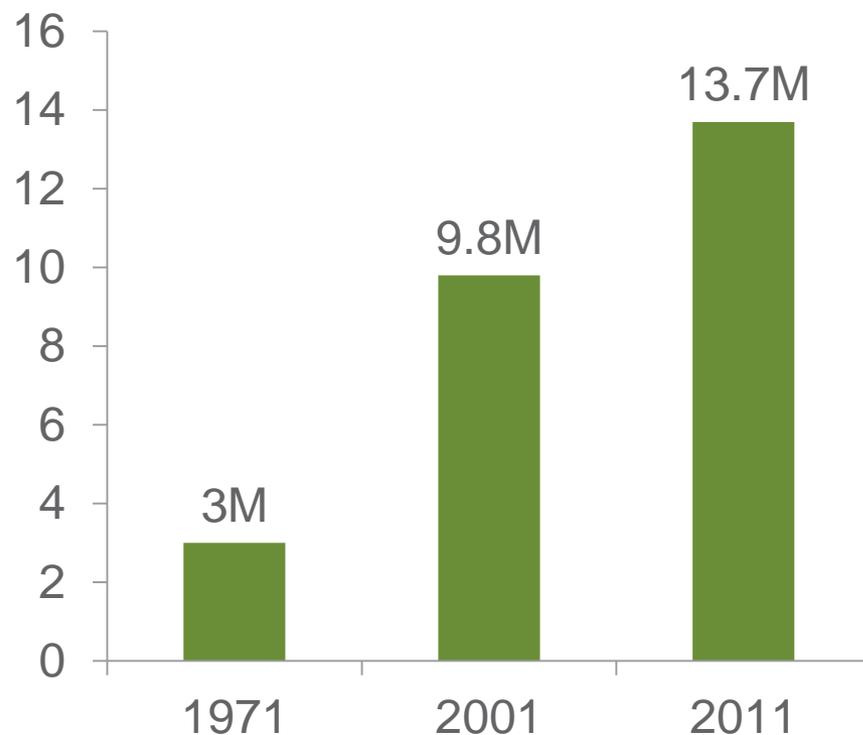
United States

# Innovation has resulted in significant improvement in patient outcomes

## 5 Year Survival Rates in CML



## US Cancer Survivors, Millions



# Dramatic changes in oncology will continue and escalate

## ■ Shift towards Personalized Medicine

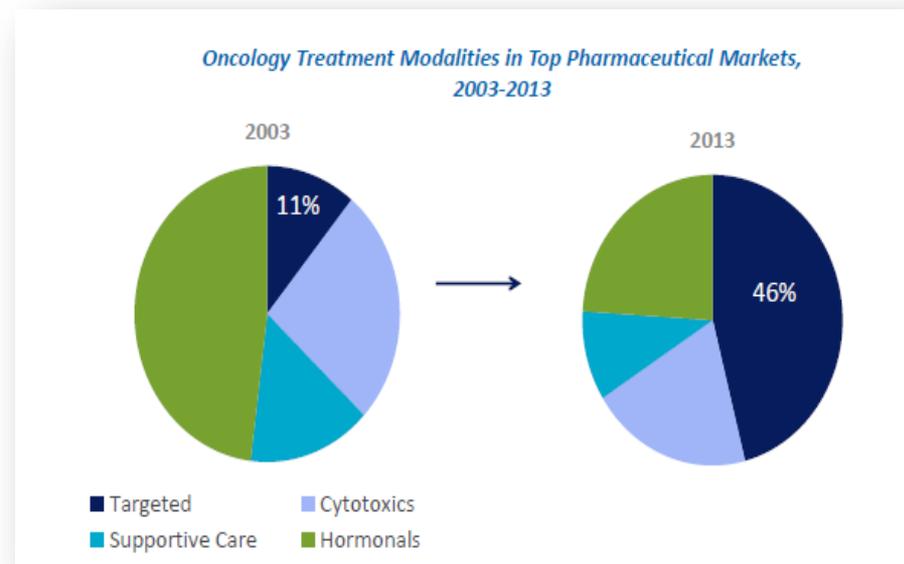
- Increased focused on biomarker-defined sub-populations
- Companion Diagnostics

## ■ Simultaneous shift to Oral Therapy

- ~25% of pipeline oncolytics are oral
- Number of orals on market to double by 2020

## ■ Financial Impacts of Continued Innovation on Healthcare System are Significant

- Potential for additional oncolytics with >\$1B annual sales
- Sales of current products expected to grow >50%



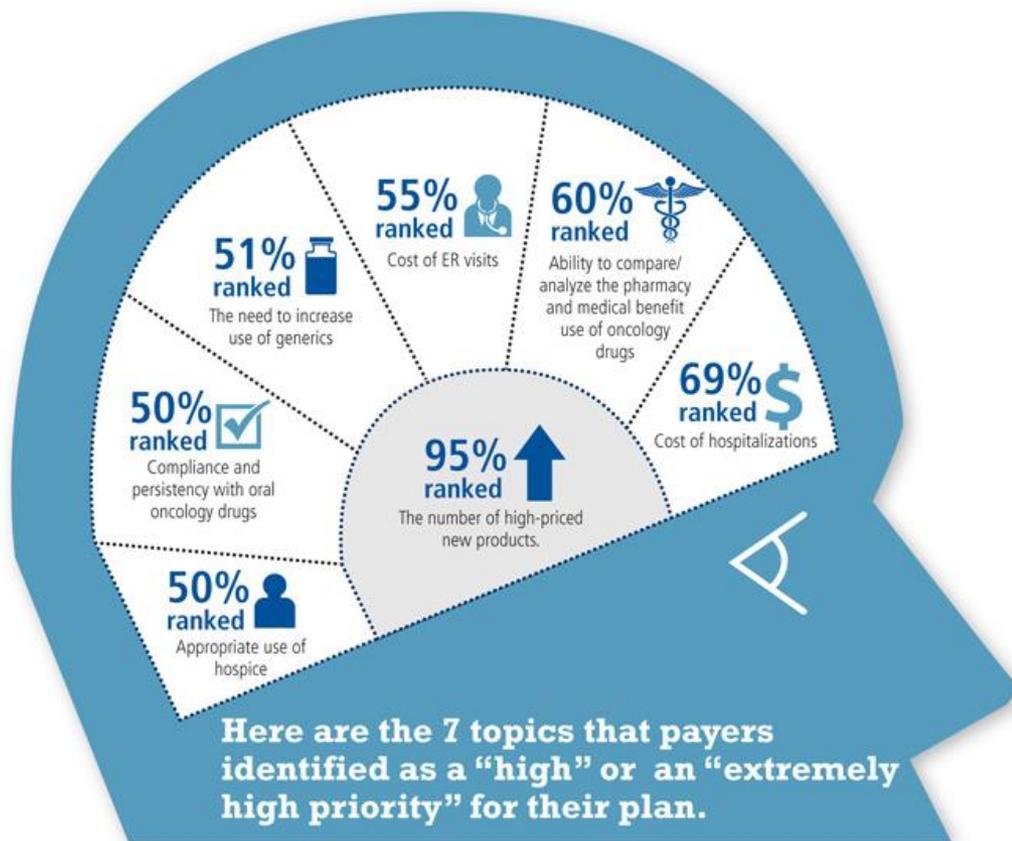
# The US payers are reaching a tipping point where budgetary consideration is inevitable

## High drug prices coming under increased scrutiny

- 95% of surveyed payers ranked high-priced new products as a “high” or an “extremely high” priority<sup>1</sup>
- In 2012, the makers of Zaltrap<sup>®</sup> were forced to lower the price due to negative publicity

## Rising costs result in increased patient burden and may compromise care<sup>2</sup>

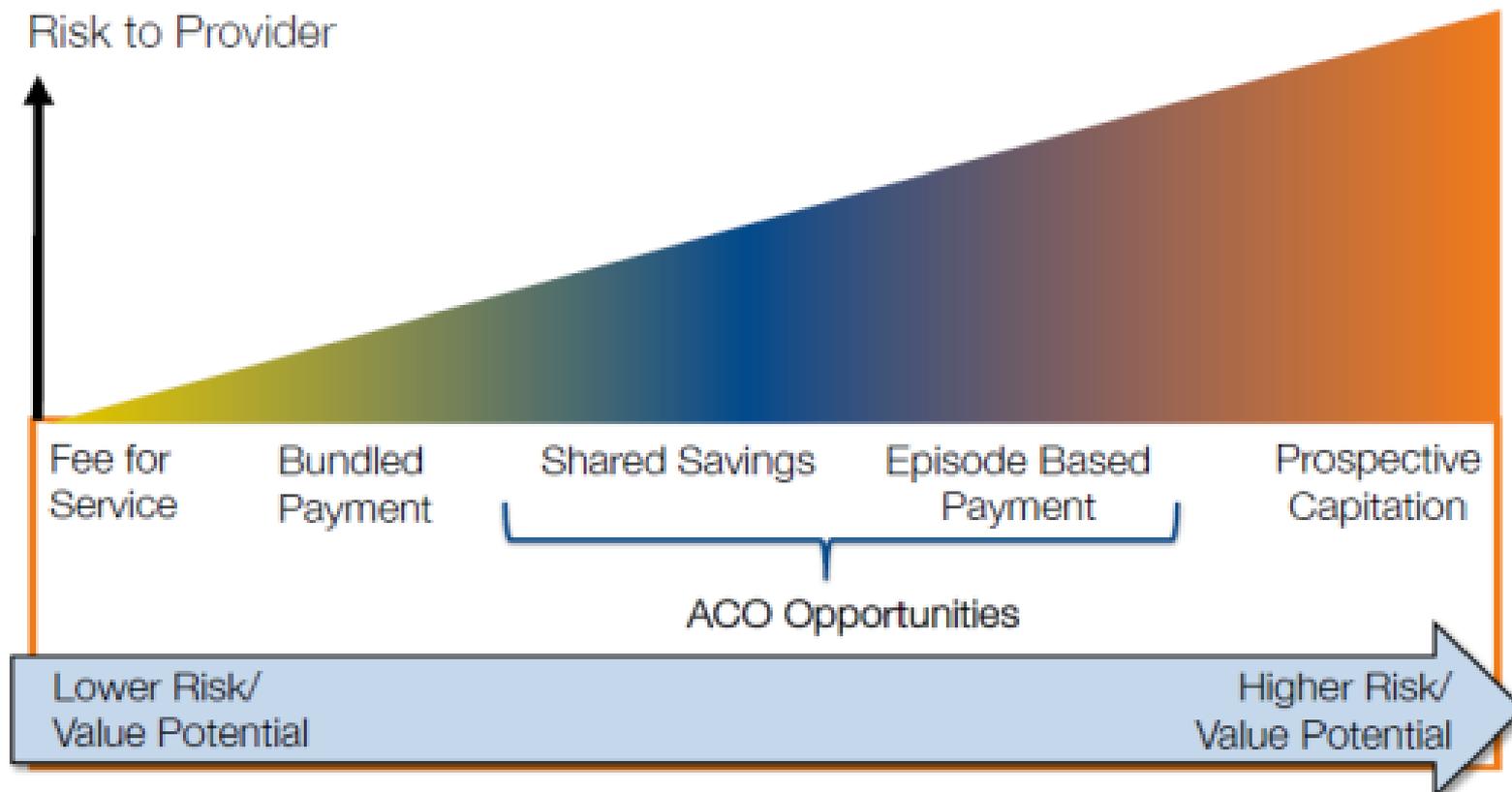
- Patients with higher copayments were 70% more likely to discontinue their cancer therapy and 42% more likely to skip doses



1. 7 Oncology Trends on Payers' Minds. <http://www.xcenda.com/Insights-Library/Payer-Perspectives/7-Oncology-Trends-on-Payers-Minds/>.

2. Dusetzina SB, et al. *J Clin Oncol*. 2014;32(4):306-311. Cited in: <http://www.oncologyurseadvisor.com/out-of-pocket-costs-determine-treatment-adherence-for-cancer-patients/article/330323/>.

# New payment models transfer financial risk to providers and patients



**This shift will likely put increased emphasis on providing additional evidence of value to providers as well as payers**

# Accountable care models are changing the landscape of oncology care

- Accountable care organizations (ACOs) aim to coordinate care and provide financial incentives for efficient patient management<sup>1</sup>
- Several innovators are adapting the ACO model to oncology care
  - Miami-Dade Accountable Oncology Program (Florida Blue)
  - Moffitt Cancer Center in Tampa (Florida Blue)
  - Texas Oncology (Aetna)
- Potential savings are derived from<sup>2</sup>:
  - Chemo pathway adherence (1%–3%)
  - Avoidance of hospital and ER visits (4%–7%)
  - Diagnostics (0.2%–0.5%)
  - End-of-life planning (0.9%–1.9%)

## Miami-Dade Accountable Oncology Program<sup>3</sup>

- Built in May 2012 via a collaboration among Florida Blue, Baptist Health South Florida, and Advanced Medical Specialists
- Providers are paid fee-for-service along with a **shared savings** agreement
- The ACO is on target to meet and exceed its goals of decreasing readmissions, reducing ER visits, increasing medication adherence, and **improving quality of care**

1. Mehr SR. Applying Accountable Care to Oncology: Developing an Oncology ACO. *AJMC*.com. May 2013. <http://www.ajmc.com>.

2. Barkley R. The Forum for Re-engineering the Cancer Care Delivery Process and for Harnessing the Cancer Spend. October 2013. <http://www.ccbgroup.com/aco1013.pdf>.

3. Edlin M. Oncology ACOs offer innovation for high-cost populations. *Managed Healthcare Executive*. <http://managedhealthcareexecutive.modernmedicine.com/managed-healthcare-executive/news/oncology-acos-offer-innovation-high-cost-populations?contextCategoryId=21>.

# Patient-centered medical home (PCMH) models aim to coordinate care, improve quality, and streamline costs

## Several groups are pioneering oncology PCMH models

- Priority Health Oncology Medical Home (Michigan, Ohio)
- Innovative Oncology Business Solutions Community Oncology Medical Home CMMI Grant (7 community oncology practices nationwide)
- Wilshire Oncology Medical Group with WellPoint-Anthem BC Medical Oncology Home (California)



Emphasizes measuring and benchmarking outcomes in cancer care



Aligns reimbursement with the quality and value of care delivered by oncologists & allied healthcare providers

# The ACA has accelerated the drive toward evidence-based treatment through a number of avenues

## Key CMS Programs



- The Center for Medicare and Medicaid Innovation (CMMI)
- Medicare Shared Savings Program (MSSP)
- Federally Qualified Health Center (FQHC) Advanced Primary Care Practice Demonstration
- Bundled Payments for Care Improvement Initiative

## New Audiences for Evidence of Value



- CMS will become even more of a bellwether payer due to the ACA's strengthening of its quality programs
- Health exchange plans may restrict formularies to high-value drugs
- ACOs will likely approve/reject drugs based on evidence of value

## New Types of Required Evidence



- The Patient Centered Outcomes Research Institute (PCORI) was created to foster patient-centric comparative effectiveness research
- Comparative effectiveness research will drive interest, attention on comparisons of innovative therapies to existing treatment options

*“Today’s Medicare policies fail to adequately reimburse cancer care provided in the community setting while incentivizing care provided in settings that are more expensive.”*

– Dr. Thompson, Community Oncology Alliance (COA) President

Manufacturers will need to address the needs of multiple stakeholders, produce evidence tailored to specific circumstances

## ACOs represent new stakeholders for manufacturers to consider for communicating evidence of value

- Most major commercial payers are planning, or have developed, ACOs
- CMS incentives likely will result in increased focus on comparative data, selection of cost-effective therapies

## Payers are incorporating health-technology assessments (HTA) in pharmaceutical evaluation

- Payers of all sizes use third-party HTA organizations (eg, ECRI Institute, Hayes, ICER, MTPPI)
  - Small, medium, and regional payers rely more on third-party HTA organizations, due to insufficient internal resources
- Many national payers have developed internal HTA capabilities (eg, Aetna's Clinical Policy Unit, BCBSA Technology Evaluation Center, Kaiser Permanente's Interregional New Technologies Committee)

## Within Biologics Market, the threat / promise of biosimilars is no longer in the distant future

- With multiple biologics losing exclusivity in coming years, need for comparative data

# Strategic Imperatives & Summary

Questions?



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