Indication-Based Pricing – The Good, The Bad, and The Ugly

Susan Abedi, IMS Consulting Group

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Today's Agenda

- What is "indication-specific pricing" ?

- Should we consider indication-specific pricing approaches?
  - The Good
  - The Bad
  - The Ugly

- Where should we go from here?

The cost of care and value debate has evolved over the years, with significant activity in the last year

SOURCE: IMSCG Analysis

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States are getting involved in the pricing debate

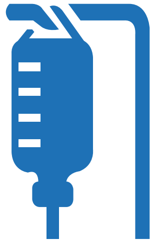
Example: Vermont Price Transparency Law Passed

1. State officials will identify:
   – 15 drugs for which "significant health care dollars" are spent and WAC (list prices) rose by ≥50% over the previous five-year period
   – List prices for 15 medicines that rose 15% or more over a 12-month period

2. Then, the state attorney general will request justification for the price hikes from each manufacturer
   – Manufacturers will provide detailed cost breakdowns and other information that contributed to the price increases

SOURCE: IMSCG Analysis; *Vermont becomes first state to require drug makers to justify price hikes*, STAT, June 2016

Determining the value of specialty drugs is noted as a top challenge for payers



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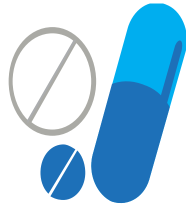

Determining the value of specialty drugs was the **top challenge** faced by 26% of payers

SOURCE: *Specialty Digest, 12th Edition,* EDM Serono (2015)

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Value-based pricing is an umbrella term; today's discussion will focus on indication-specific pricing

Value-Based Pricing

Indication-specific

Price determined by comparing efficacy across indications for a single product

Outcomes-based

Product value and associated price is assessed based on performance across endpoints, level of patient response, and/or performance on specific metrics as demonstrated by clinical trial endpoints or RWE

SOURCE: IMSCG Analysis

There are many terms for indication specific pricing

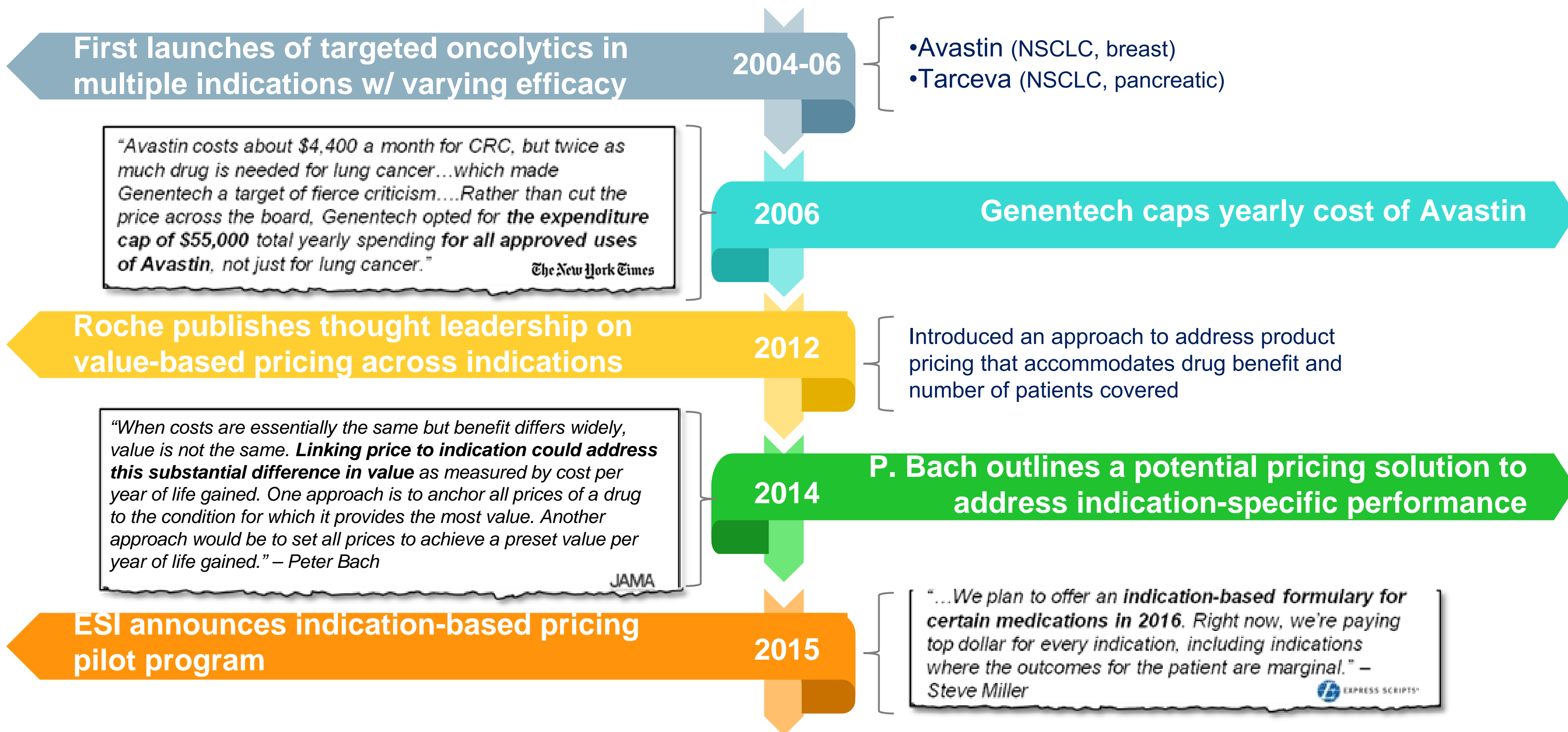
Indication based pricing

Indication based formulary

Indication-specific pricing

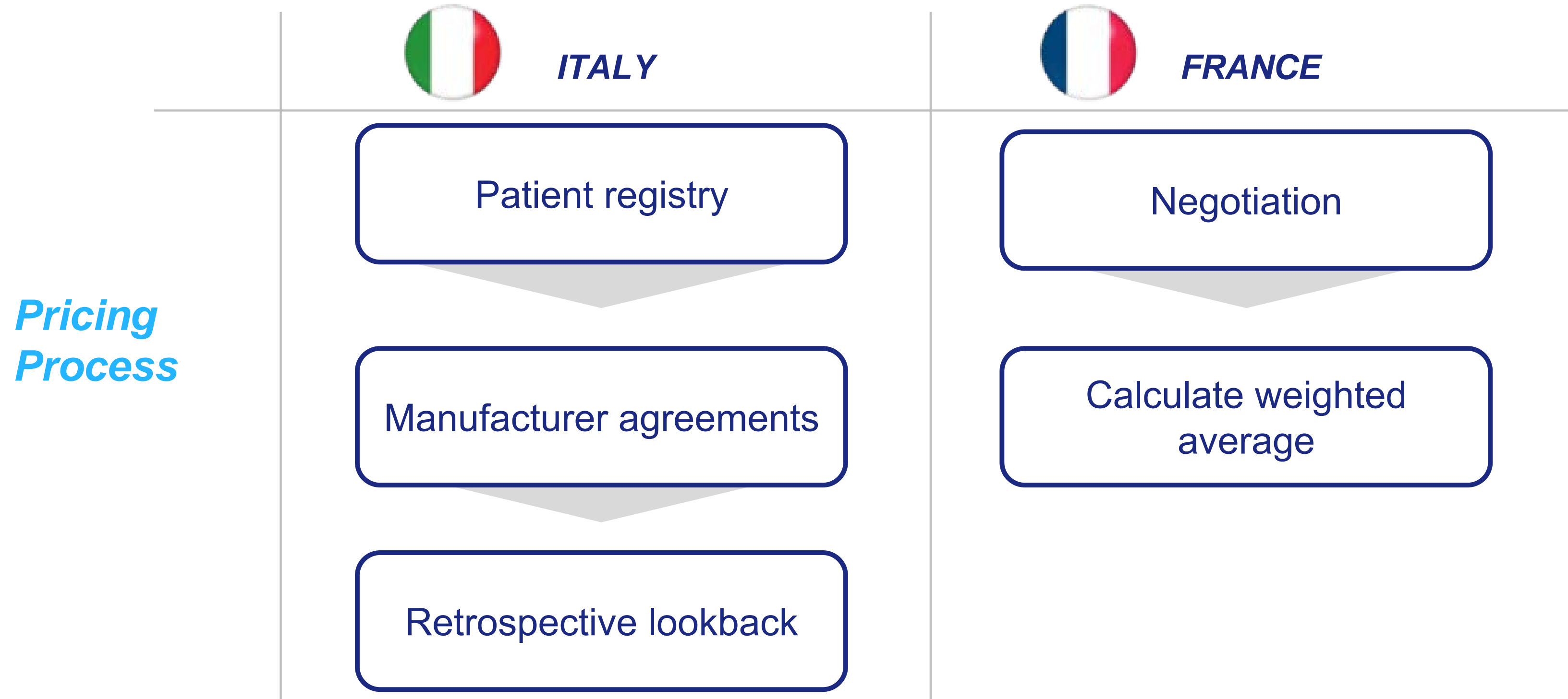
Multi-indication pricing

The concept of indication-specific pricing is not new; it has evolved over time



SOURCE: IMSCG Analysis; National Cancer Institute; *Genentech Caps Cost of Cancer Drug for Some Patients*, NYT 10/12/06; JAMA Oct. 22/29, 2014 Vol. 312 No. 16 Pg 1629-30; *We have to Change How We Pay for Cancer Drugs*, ESI Blog, 6/15/15; *Real World Oncology Evidence and Value-Based Pricing*, Presentation by Gavin Lewis, Roche Strategic Pricing Director

Variations of “indication based pricing” are evolving in certain European markets



SOURCE: IMSCG Analysis; *Value-based Health Assessment in Italy: A Centralised Model*, The Economist (2015)

CMS recently announced plans to test new Medicare Part B prescription drug models -"*Indication-based pricing*" was included

"Value-based Pricing Strategies" Proposed by CMS

Strategies	*Description*
Discounting / eliminating patient cost-sharing	• Decrease or eliminate the cost sharing to improve access and appropriate use of drugs
Feedback on prescribing patterns	• Develop evidence based clinical decision support tools for HCPs that aim to drive appropriate use
Indication-based pricing	• This proposed test would **vary the payment for a drug based on its clinical effectiveness for different indications**. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time. The goal is to pay for what works for patients.
Reference pricing	• Set a standard payment benchmark for a group of therapeutically similar products
Risk-sharing based on outcomes	• Develop voluntary agreements with drug manufacturers to link outcomes with price adjustments

SOURCE: IMSCG Analysis; CMS proposes to test new Medicare Part B prescription drug models to improve quality of care and deliver better value for Medicare beneficiaries, CMS.gov, March 2016

In the US, Express Scripts is piloting an indication-based approach in Oncology

Scope:

2016 **pilot** program—Oncology Care Value Program—will be limited to a select number of **oral oncology** products within **commercial** lines of business

Approach:

Conduct assessment of value-based price per indication

Calculate a weighted average of prices across indications

Bring analysis to negotiating table

SOURCE: IMSCG Analysis; *Express Scripts' Payer Clients On Board With Indication-Based Pricing, Exec Says*, The Pink Sheet Daily , 9/17/15; *We have to Change How We Pay for Cancer Drugs*, ESI Blog, 6/15/15; *Performance-based pricing for Pharmaceuticals*, Managed Healthcare Executive, 9/30/15; *Express Scripts Aims New Price Model at Cancer, Inflammation*, Bloomberg, *11/16/15*

ESI has announced plans to develop an indication-based formulary for inflammation

Objective:

- The **Inflammatory Care Value program** will use an indication based approach to formulary management
- Divide inflammatory diseases into four separate indications to enable drugs with fewer (~1-2) indications to be on an equal playing field with products that are indicated for various inflammatory diseases

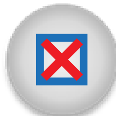
Ideal Outcomes (ESI Perspective) :

- Facilitate more price competition among clinically equivalent drugs
- Control costs
- Ensure patient access to the best drug for their disease

SOURCE: IMSCG Analysis; 3 Solutions Healthcare Payers Need Now, Express Scripts Labs, April 2016

Considerations of Indication-Specific Pricing – The Good

The Good


The Bad

The Ugly

Indication-specific pricing could both facilitate patient access and address payer cost concerns

Payers

- ✓ Provides patient access to innovative medicines
- ✓ Potential for cost-savings and additional price concessions
- ✓ Demonstrates payer innovation

SOURCE: IMSCG Analysis; *Indication-specific Pricing Of Pharmaceuticals In The United States Health Care System*, A Report from the 2015 ICER Membership Policy Summit (March 2016); *Multi-Indication Pricing: Big Hurdles And Actionable Options*, Pink Sheet (May 2016)

Innovative pricing models could also address manufacturer needs

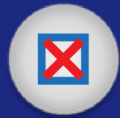
Manufacturers

- ✓ Enables broad patient access to innovative medicines
- ✓ Incentivizes high value secondary indications
- ✓ Demonstrates active willingness to think creatively about drug prices
- ✓ Provides rationale for higher prices for indications with greater clinical value

SOURCE: IMSCG Analysis; *Indication-specific Pricing Of Pharmaceuticals In The United States Health Care System*, A Report from the 2015 ICER Membership Policy Summit (March 2016); *Multi-Indication Pricing: Big Hurdles And Actionable Options*, Pink Sheet (May 2016)

Considerations of Indication-Specific Pricing – The Bad

The Good


The Bad

The Ugly

But, can we do it?

1. Products are not tracked by indication

2. Products are not tiered differentially by indication

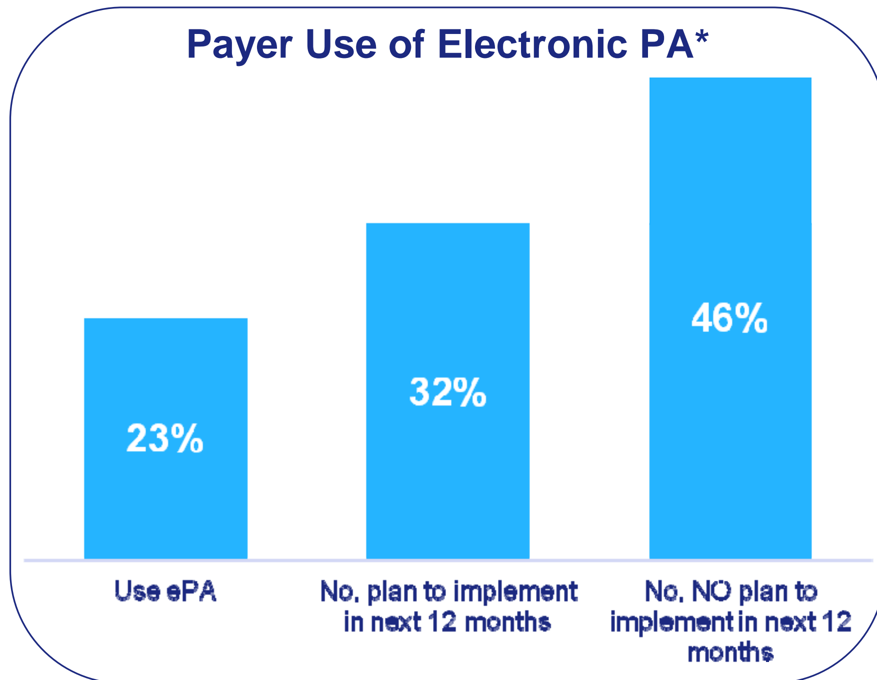
Implementing indication-specific pricing would require infrastructure adjustments to track drug use by indication

- Infrastructure would need to be overhauled to capture, share, and report patient and indication level data
  - Governance models would need to be developed to ensure data is stored and shared appropriately

	Physicians / HCPs	Payers
Change Needed	• Systems to capture indications have not been widely implemented	• Systems would likely need to change the way prices are reviewed and drugs are purchased
Potential Challenge	• Administrative burden may increase	• Reporting requirements necessary to capture the prescription indication may vary – E.g., differences in medical vs. pharmacy benefit or site of care

SOURCE: IMSCG Analysis; *Express Scripts' Payer Clients On Board With Indication-Based Pricing, Exec Says*, The Pink Sheet Daily , 9/17/15; Hebborn, A., *Multi-indication pricing: Do we want it? Can we operationalize it?*, IPSOR, May 2016; I*ndication-specific Pricing Of Pharmaceuticals In The United States Health Care System*, A Report from the 2015 ICER Membership Policy Summit (March 2016)

Today , the majority of Prior Authorizations (PA) are submitted by paper, making tracking by indication a challenge



Of payers who use ePA, it accounts for ***~10%*** of submissions*

*Based on EMD Serono Specialty Medicines Survey Respondents answer to the question: “Does the plan use an ePA for at least 1 specialty drug?”

SOURCE: IMSCG Analysis; *Express Scripts' Payer Clients On Board With Indication-Based Pricing, Exec Says*, The Pink Sheet Daily , 9/17/15; National Adoption Scorecard: Electronic Prior Authorization (ePA), Cover My Meds (2015); *Specialty Digest, 12th Edition,* EDM Serono (2015)

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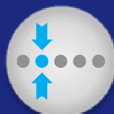
Indication-specific pricing may also have negative implications for patients



Individual Patient Needs

- Could limit drug use to certain populations

Patient Savings

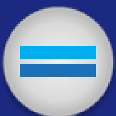
- Savings may not be passed through to patients

SOURCE: IMSCG Analysis; *Express Scripts' Payer Clients On Board With Indication-Based Pricing, Exec Says*, The Pink Sheet Daily , 9/17/15; *Indication-specific Pricing Of Pharmaceuticals In The United States Health Care System*, A Report from the 2015 ICER Membership Policy Summit (March 2016)

If implemented, there are concerns that indication-specific pricing could impact benchmarks

Government Pricing Policies

- Medicaid requires manufacturers to provide rebates that match the “best price” obtained by private market payers
- Other government run programs may be affected (i.e., 340B and Medicare)



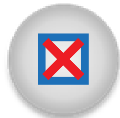
Drug Arbitrage

- Payers/institutions could buy the drug for the lower priced indication and use it for the higher priced indication

SOURCE: IMSCG Analysis; *Express Scripts' Payer Clients On Board With Indication-Based Pricing, Exec Says*, The Pink Sheet Daily , 9/17/15; *Indication-specific Pricing Of Pharmaceuticals In The United States Health Care System*, A Report from the 2015 ICER Membership Policy Summit (March 2016)

Considerations of Indication-Specific Pricing – The Ugly

The Good



The Bad

The Ugly

Should we do it?

DEFINING VALUE

- Who is the arbiter of “value”?
  - How should site of care be factored in?
  - Do we pay more for better services?

- How should products be judged within an indication?
  - How can real world data be incorporated?
  - Should off-label use be incorporated into value metrics?

- Should they be compared to other available products in that indication (i.e. Tarceva vs. other pancreatic drugs) rather than vs. Tarceva in NSCLC?

- How should differences in dosing and dosing schedules be reflected in a price?

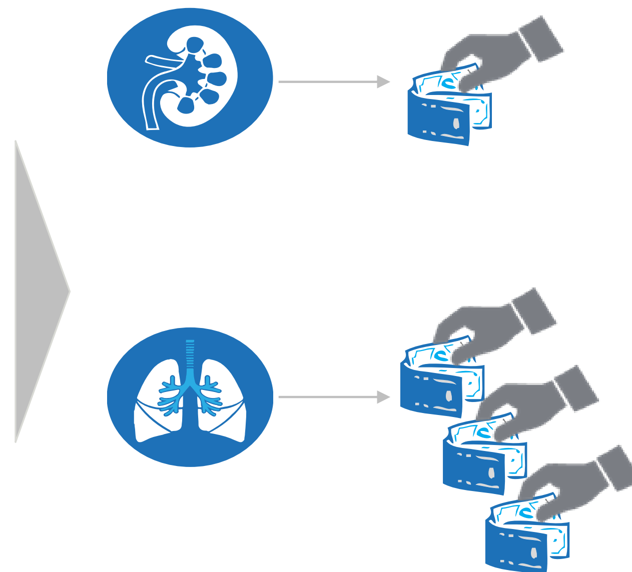
SOURCE: IMSCG Analysis

Does it benefit patients?

IMPACT ON PATIENTS

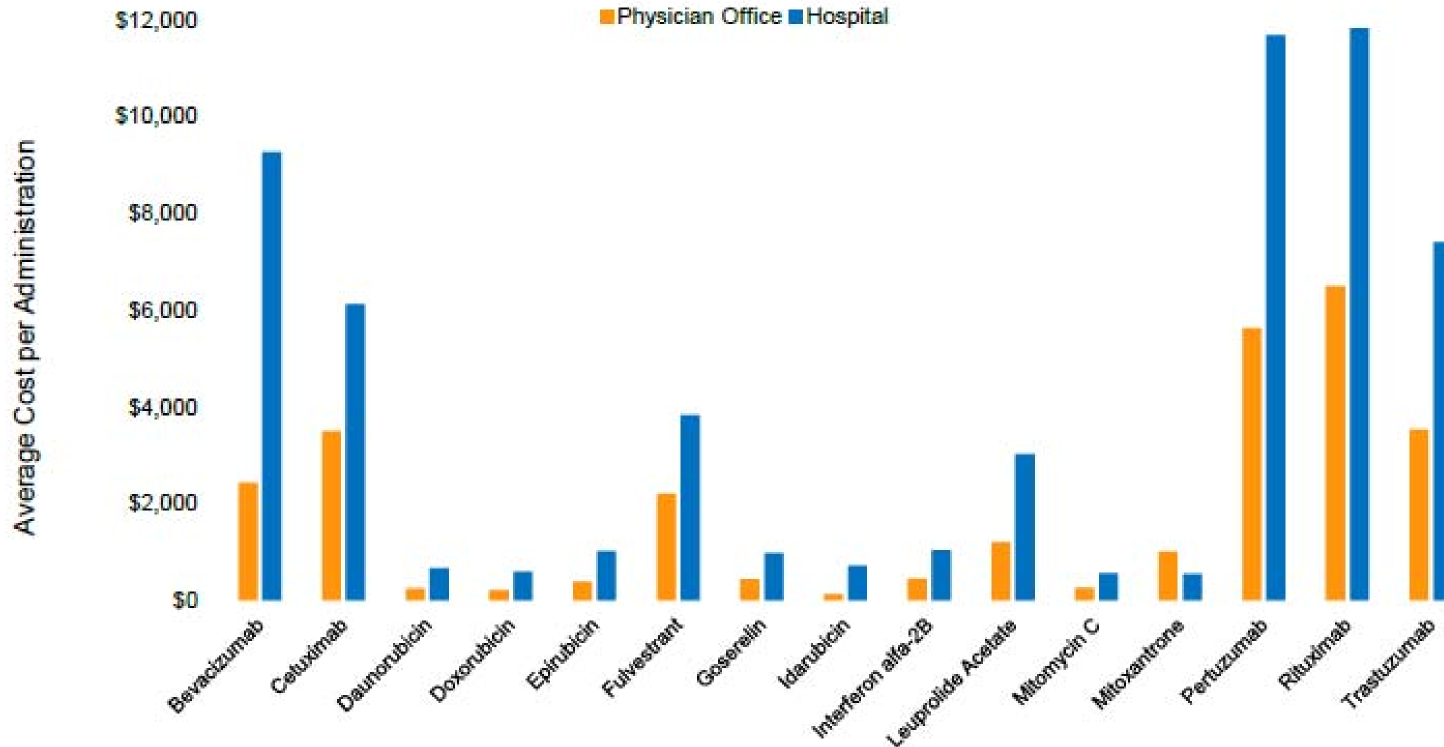
- Should one patient pay more for the higher "value" indication ? Or should they pay less, if we think of the Premara Value-Based Benefit Design approach ?

- Will patients feel they are being unfairly targeted for having a tumor type with more efficacious treatments available?



SOURCE: IMSCG Analysis

Where to do it? Today, costs vary for the same drug by setting



SOURCE: IMSCG Oncology Trend Report 2016

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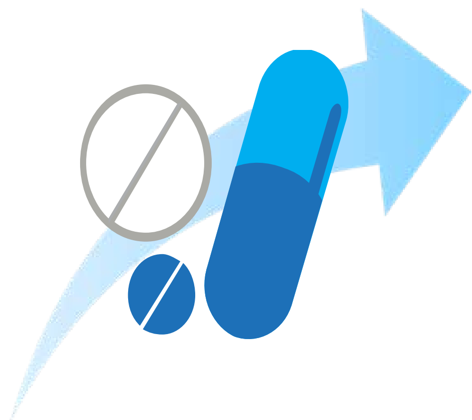
There is more to value than price



Examples

- Technology
  - Biogen used FitBit fitness trackers for MS patients to monitor treatment outcomes
- Patient services
  - Provide patient support via education, training, advocacy and financial support
  - J&J and IBM developed a patient engagement app that helped reduce hospital readmissions
- Infrastructure
  - Integrated systems that support data analytics and clinical decision making (e.g., via ePA or lab testing)

SOURCE: IMSCG Analysis; *Think different? Pharma turns to tech partnerships for beyond-the-pill moves*, FiercePharma, December 2015; *How Pharma Can Offer More than Pills*, Harvard Business Review, July 2015; *Specialty Digest, 12th Edition,* EDM Serono (2015); *The new Healthcare model: Beyond the pill, the premium and the patient*, CIO, September 2015

Where should we go from here?

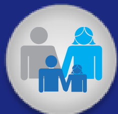
Preparing For The Future

Manufacturers

- What investments should be made to support decision making?
- How can manufacturers prepare for these agreements from a data perspective?

Payers

- How should conflicting value assessments be resolved?
- How can real-world evidence be incorporated in real time after a value-based prices has been assigned to a product?



Patients

- Does such a system allow for individual patient characteristics to be factored into value assessments?

#thepill – what color is the pill ?

#thepill – what color is the pill ?

White and gold?

- OR -

Blue and black?

Now if value was the pill- how do payers and pharma engage?

Blue and black?

White and gold?

QUESTIONS?

Please contact me for more information

Susan Abedi
Senior Principal,
IMS Consulting Group

sabedi@imscg.com
+646-266-0747