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

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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.

Example Activities

- 2004: Leonard Salz publicly criticizes Erbitux price
- 2009: Pfister’s JCO article
- 2011: ASCO’s 2011 Top Five
- 2012: Kantarjian publishes Blood article
- 2013: Payment reform proposal
  - 2013 Top 5
  - Draft Guidelines on Endpoints
- 2014: ASCO and Industry Meet
- 2015: Peter Bach’s releases DrugAbacus
- 2016: ASCO updates framework
  - ASCO, NCCN, ESMO, ICER develop “value frameworks”
  - ICER reviews MM
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.

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

First launches of targeted oncolytics in multiple indications w/ varying efficacy

“Avastin costs about $4,400 a month for CRC, but twice as much drug is needed for lung cancer….which made Genentech a target of fierce criticism….Rather than cut the price across the board. Genentech opted for the expenditure cap of $55,000 total yearly spending for all approved uses of Avastin, not just for lung cancer.” – The New York Times

2004-06

• Avastin (NSCLC, breast)
• Tarceva (NSCLC, pancreatic)

Genentech caps yearly cost of Avastin

Roche publishes thought leadership on value-based pricing across indications

“When costs are essentially the same but benefit differs widely, value is not the same. Linking price to indication could address this substantial difference in value as measured by cost per year of life gained. One approach is to anchor all prices of a drug to the condition for which it provides the most value. Another approach would be to set all prices to achieve a preset value per year of life gained.” – Peter Bach

2012

Introduced an approach to address product pricing that accommodates drug benefit and number of patients covered

P. Bach outlines a potential pricing solution to address indication-specific performance

“...We plan to offer an indication-based formulary for certain medications in 2016. Right now, we’re paying top dollar for every indication, including indications where the outcomes for the patient are marginal.” – Steve Miller

2014

ESI announces indication-based pricing pilot program

2015

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

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<th>Pricing Process</th>
<th>ITALY</th>
<th>FRANCE</th>
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<td>Patient registry</td>
<td>Negotiation</td>
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<td></td>
<td>Manufacturer agreements</td>
<td>Calculate weighted average</td>
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<td>Retrospective lookback</td>
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CMS recently announced plans to test new Medicare Part B prescription drug models - “Indication-based pricing” was included.

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<th>Strategies</th>
<th>Description</th>
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<td>Discounting / eliminating patient cost-sharing</td>
<td>• Decrease or eliminate the cost sharing to improve access and appropriate use of drugs</td>
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<td>Feedback on prescribing patterns</td>
<td>• Develop evidence based clinical decision support tools for HCPs that aim to drive appropriate use</td>
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<td>Indication-based pricing</td>
<td>• 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.</td>
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<td>Reference pricing</td>
<td>• Set a standard payment benchmark for a group of therapeutically similar products</td>
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<td>Risk-sharing based on outcomes</td>
<td>• Develop voluntary agreements with drug manufacturers to link outcomes with price adjustments</td>
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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
Considerations of Indication-Specific Pricing – The Good
Indication-specific pricing could both facilitate patient access and address payer cost concerns

- 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

- 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

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

Indication-specific pricing may also have negative implications for patients

- Could limit drug use to certain populations

- Savings may not be passed through to patients
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

Considerations of Indication-Specific Pricing – The Ugly

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

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)
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?

- OR -

White and gold?

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