One product, different indications... different prices?

Tom Baker, Terry Tao, Gaelle Marinoni, Daniel Houslay, Ouissam Garbaz, Samir Malhotra

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1. What is indication-specific pricing (ISP) and why is it important?

"Setting different prices for the same product across indications or in distinct patient sub-populations"

- A wave of new and often expensive therapies, including novel combinations, provide different levels of clinical benefit across different indications/patient sub-populations; yet in most countries, a manufacturer can charge only one price
- Indication-specific pricing is one potential solution to this challenge, benefitting the manufacturer, payer and patients

2. In which situations should ISP be considered?

A Varying clinical value across indications

Case Study: Tarceva®

Median survival gain of 3.4 months in NSCLC versus 10 days in pancreatic

Challenge: Assigning a different price for each indication based on clinical value is challenging in the US due to administrative, regulatory, and legal hurdles (e.g. Medicaid Best Price)

Solution: Express Scripts began piloting the Oncology Care Value Program in 2016, using a single, weighted-average price based on estimates of indication usage across their patient population

B Indications with different dosing

Case Study: Zometa®/Reclast®

Zoledronic acid is dosed once per year in osteoporosis and once every 3-4 weeks in the molecule's lead indication, cancer bone metastasis

Challenge: In the US, a single HCPCS code is used to bill for a Part B drug across indications

Solution: Novartis launched Zometa in bone metastasis and later pursued a separate NDA for Reclast in osteoporosis to operationalize differential pricing on a per milligram basis and maximize total revenue for the molecule

C Indications with different population sizes

Case study: Tenapanor

Ardelyx plans to file for FDA approval of tenapanor, first in IBS-C (~11M US patients) in 2018 and later in hyperphosphatemia, a significantly smaller pop. (~0.5M US patients)

Challenge: Launching in a large indication first could limit molecule's pricing potential for follow-on indications

Solution: Developing an indication-specific pricing strategy can help a manufacturer realize pricing potential of any follow-on indications with high unmet need

D Use in combinations with other products

Case study: Revlimid® and Kyprolis®

Revlimid costs $6,500 per cycle but Revlimid and Kyprolis in combination costs a total of $14,300 per cycle in the same indication (relapsed multiple myeloma)

Challenge: Combination of Revlimid and Kyprolis offers incremental PFS of 9 months over Revlimid alone but some payers unwilling to pay the stacked price

Solution: Both manufacturers agreed indication-specific discounts for use of their respective drug when used in combo beyond 12 cycles

3. Are global markets ready for ISP?

- Pricing in some countries already takes into account different levels of clinical benefit by indication via a single, weighted-average price
- However, a single price reflecting overall value across indications dis-incentivizes manufacturers from launching additional indications with lesser clinical benefit

- Feasibility of implementing ISP varies significantly by country but some payers are already moving towards it, leveraging the use of registries, including those developed as part of public-private partnerships (e.g., CODE):
  - Registries provide near real-time information on medicine use (e.g., adoption, utilisation, access by indication) and could be used to inform negotiations between manufacturers and payers (e.g., payment by indication, line of therapy, single vs. combo use)

Feasibility Assessment

LESS FEASIBLE ← → MORE FEASIBLE

US

Historically, legal, regulatory, & administrative hurdles have prevented ISP

Nevertheless, some PBMs are piloting ISP to move towards value-based formularies. CMS now allows indication-based formulary design in Part D, which could lead to ISP or weighted average pricing in Part D plans

DE

There are a number of issues with implementing ISP in Germany due to high levels of data protection and because a weighted-average price is already used

Diagnosis data is collected by payers but is not sufficient for ISP

UK

In England, ISP not being carried out although some indication tracking infrastructure may already exist for onco. drugs through SACT[1] & PAS[2]

In Scotland, ISP is implemented for oncology indications only via Chemocare

ES

ISP moderately feasible; negotiations would take place with regions or private hospital groups

Info gathering is complicated as not all hospitals have the same level of software sophistication to collect data and this is held at the central level

BE

ISP not formally in place but tools exist for indication tracking, e.g., TARDIS[3] platform allows for the tracking of patient data in RA

In addition, e-scripts are to be introduced by 2020, which could support indication tracking for ISP

FR

Govt. moving towards indication-based discounting

Two national databases to soon merge, which will improve data tracking

Currently only expensive hospital drugs are tracked by indication

IT

ISP already being applied to some extent with MEAs

Data collection already by indication, which could facilitate ISP implementation

Uncertainties remain on how to fund creation & maintenance of a new registry

CH

ISP previously implemented

Different rebates by indication for:

- Drugs with multiple indications, e.g. Avastin
- Drugs used in combination, e.g. Revlimid combo with Kyprolis vs. Empliciti

4. What must be considered when implementing ISP?

Step 1 – Evaluate

For inline and pipeline products that could benefit from ISP, evaluate feasibility by country and prioritize those with high potential for implementation

Step 2 – Implement

Manufacturers can propose and help set up ISP in these countries by working with health systems – e.g., data from ODN can help manufacturers negotiate flexible payment agreements

Step 3 – Result

By agreeing on prices that reflect the value of a product by indication, payers no longer risk paying too much for limited value and manufacturers are not dis-incentivized to commercialize all indications that offer incremental value over existing treatments

Sources: IQVIA internal expertise; "Feasibility and attractiveness of indication value-based pricing in key EU countries" Market Access & Policy, March 2016; * Indication-specific pricing of pharmaceuticals in the United States health care system, ICER Report 2015; Ardelyx website www.ardelyx.com/; Office Federal de la santé publique OFDS (Price and rebates in Switzerland), Revlimid and Kyprolis clinical trial: Carfilzomib, Lenalidomide, and Dexamethasone for Relapsed Multiple Myeloma, The New England Journal of Medicine, Jan 2015, NICE website www.nice.org.uk;, [1]Systemic Anti-Cancer Therapy, [2]Patient access schemes allow for a rebate by indication, [3]Tool for Administrative Reimbursement Drug Information Sharing,

Acronyms: ISP: Indication-Specific Pricing, MEA: Managed-Entry Agreement, PAS: Patient-Access Scheme, SACT: Systemic Anti Cancer Therapy Database, DRGs: Diagnosis related groups, PBS: Pharmaceutical Benefits Scheme, CODE: The Collaboration for Oncology Data in Europe, which is supporting creation of the Oncology Data Network (ODN)

International Society for Pharmacoeconomics and Outcomes Research, 21st Annual European Congress, poster presentation