DEPARTMENT OF APPLIED HEALTH RESEARCH

UCL

INDICATION BASED PRICING:

ALIGNING INCENTIVES AND VALUE TO IMPROVE PATIENT ACCESS

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The current situation

- Healthcare systems need to balance competing objectives:
  - Prompt access to patients to effective treatments
  - Incentives for the life sciences industry to develop better technologies
  - Sustainability of expenditure on medicines and technologies
- Increased number of products approved in multiple indications
- Growing recognition that the 'fair' price of a medicine should be linked to its value
- Pricing model of 'one price for one drug' in the case of multiple indications may lead to manufacturers sequencing indication launches with the aim to avoid commercial risks rather than address the unmet patient need

SOURCE: White Paper. Indication based Pricing in Oncology: Implications for Changing Treatment Paradigm. 2019. Novartis Oncology

Indication Based Pricing

- IBP means charging different prices for different indications based on the value the drug delivers for each indication leading to greater fairness
- It is third-degree price discrimination where a different price for different consumers for the same products leads to greater market efficiency
- By charging differential prices companies can increase their market, while consumers/patients can benefit from broader access

IBP is an efficient approach to segmenting the market and ensuring all patients who can benefit from innovative medicines do so, but at a fair transparent value-driven price

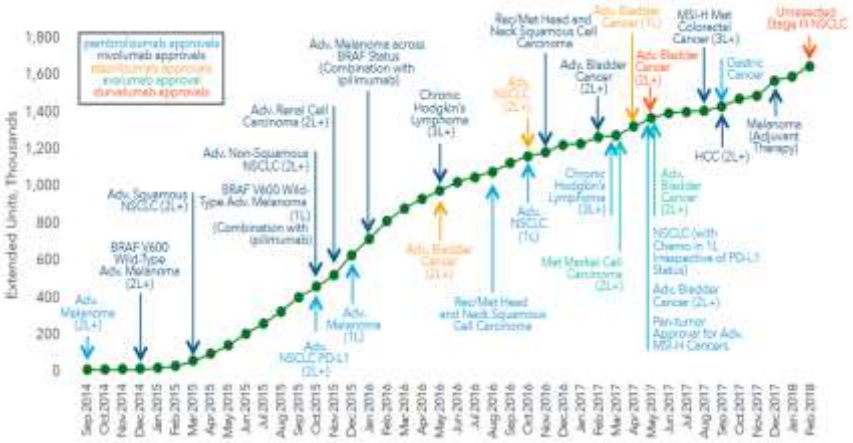
SOURCE: White Paper. Indication based Pricing in Oncology: Implications for Changing Treatment Paradigm. 2019. Novartis Oncology

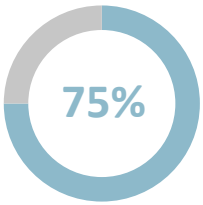
The many forms of IBP

- Vary according to the timing of the pricing/reimbursement decision and therefore the uncertainty involved and who bears the risk
- Outcome based payment (OBP) schemes are ex post, and if different indications deliver different outcomes then OBP schemes are a type of IBP
- Key is that the price of each indication should reflect its incremental value (additional benefit achieved over and above SoC)
- Similarly value-based pricing (VBP) is IBP if indications differ in the value they deliver
- Ex ante (using evidence available at listing) and ex post (RWE or additional trial data post-launch)
- Also referred to a indication-specific pricing (ISP) and multi-indication pricing (MIP)

Extent of the problem

PD-1/PD-L1 inhibitor indications in the US

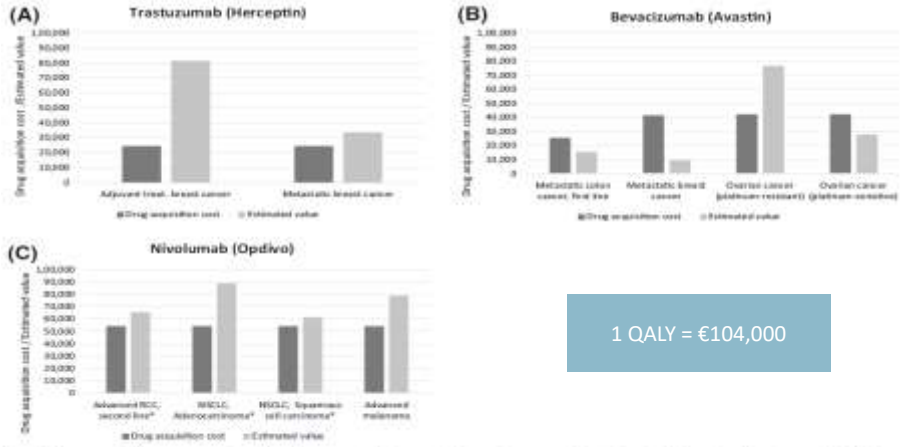




of targeted treatments in oncology are used in multiple indications

SOURCE: U.S. FDA, IQVIA, National Sales Perspectives, Feb 2018; IQVIA Institute, Apr 2018.

Neither payer nor manufacturer win with lack of IBP



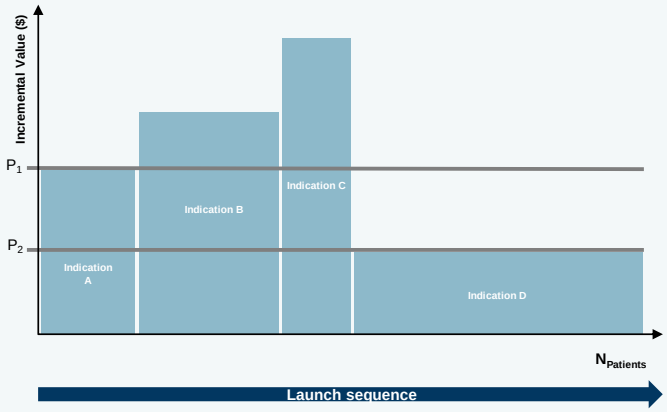
1 QALY = €104,000

Fig. 1 Drug acquisition cost vs. estimated value per month for a typical patient in several indications. *RCC* renal cell carcinoma, *NSCLC* non-small cell lung cancer. *Using a fixed treatment duration of 22.5 months

Source: Multi-indication and Combination Pricing and Reimbursement of Pharmaceuticals: Opportunities for Improved Health Care through Faster Uptake of New Innovations. Persson & Norlin. Applied Health Economics and Health Policy Appl Health Econ Health Policy.

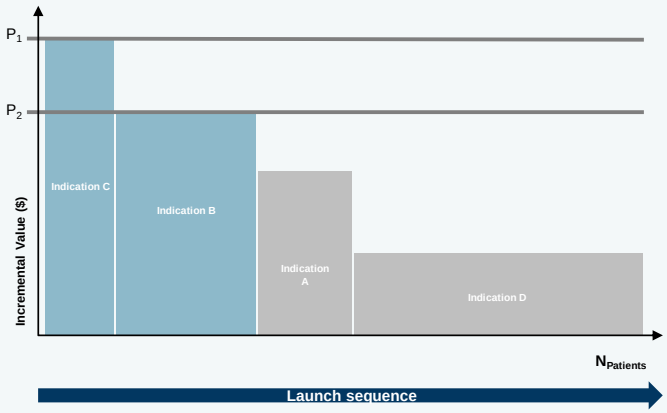
Effect of single (lowest) price on launch sequence

- First drug launched is indication A
- Price is P_1 which reflects it's value
- Launch indication B, price remains P_1 as this is the lowest price
- Similarly for indication C
- **Manufacturer may be reluctant to launch B and C as the price does not reflect the value**, particularly in indication C (as smallest patient population) although this is where the drug has the greatest benefit
- Launching in indication D means the price falls to P_2, this erodes the returns on previous indications



Effect of single (lowest) price on launch sequence

- **If possible manufacturers may change their launch sequence**
- Launching indication C and achieving P_1
- Then launching B with a price reduction to P_2
- The manufacturer may not launch indications A and D because they face further price reductions
- **As a result, many patients with high unmet need are denied (or delayed) access to an efficacious drug**



Market response to the lack of formal IBP

There are a number of ways that manufacturers and payers attempt to assimilate IBP in a single price market

- Different brand names
- Blended price
- Differential discounts
- Withdrawal of indications
- Non launch of indications

SOURCE: White Paper. Indication based Pricing in Oncology: Implications for Changing Treatment Paradigm. 2019. Novartis Oncology

Very few examples exist

France

France applies a benefit rating to new indications and then uses a blended price (where those indications with a high benefit are reference priced across 4 EU countries)

Spain & Sweden

Spain and *Sweden* don't appear to implement IBP, although Spain does have good electronic prescribing system

United States

In the *US*, CVS Health and Express Scripts have launched IBP initiatives for cancer drugs but generally IBP presents itself as different brand names, using weighted pricing and indication-specific risk sharing arrangements

Medicaid's best price rule (any large discount offered on an indication to one payer must be extended to Medicaid for all indications – best price for each drug not each indication) creates a challenge in the US market

Belgium

In *Belgium* indication extensions are usually followed by volume discounts

United Kingdom

The *UK* arguably has VBP with its explicit threshold, but IBP is most commonly seen in discounts or rebates via managed access agreements or patient access schemes

Germany

In *Germany* a weighted or blended price is used where the HTA of each new indication triggers new price negotiations (although exactly how is unknown) which are then applied to all indications

Italy the 'posterchild' for IBP

IBP is implemented in Italy via market entry agreements (MEA)

Payment by results schemes or OBP schemes make up the majority of MEA schemes (62.6%)

Key to the wide implementation of IBP in Italy is the use of online registries whereby for each indication or line of treatment the AIFA track patient eligibility, supply, dispensing and follow-up

Healthcare professionals collect patient-level data on health outcomes into this registry which subsequently support decisions regarding conditional reimbursement schemes and specifically whether the outcome achieved is what was expected

AIFA own the registries and it is AIFA that verifies the quality of the data, as well as verifying that the use has been appropriate according to the MEA

The complexity due to the high number of registries and the heterogeneity of the mechanisms through which regions/companies/pharmacies/hospitals are refunded add both confusion and burden

Would are the benefits and risks?

	Potential Benefits	Potential Risks
Payers	– Offers new mechanism to facilitate patient access to medications within a model that seeks to balance payer needs for affordability and manufacturer needs for sustainability – Aligns with value-based drug pricing and benefit designs – Offers potential to save the system money and facilitate patient access to medications – Allows more appropriate pricing for lower value follow-on indications – Highlights competitive advantage in innovative thinking about value-based pricing mechanisms	– Administrative burden of implementation may be greater than anticipated – Required infrastructure to track indication specific use – Could have minimal impact on overall affordability or even increase costs – Could be difficult to explain to patients and stakeholders and may raise concerns if not tied to lower out of pocket costs for patients
Manufacturers	– Provides incentive to develop indications for small populations while protecting existing price in high-value indications – Aids decision-making regarding pipeline prioritization – Supports rationale for higher prices for secondary indications that provide greater clinical benefits – Demonstrates commitment to changes that will impact the sustainability of health care and decrease overall health system costs	– May support efforts to link drug prices to a standard of clinical value that constrains pricing power – Potential conflict with other pricing policies in including Medicaid Best Price and average sales price (ASP) – Potential risk for arbitrage by purchasers of the drug, i.e. where payers purchase the lower priced indication for use in a higher value indication population – Reduces potential return for development of "lower value" secondary indications

SOURCE: Pearson, S., Dreitlein, B. and Henshall, C., 2016. Indication-Specific Pricing of Pharmaceuticals in the United States Health Care System. *ICER*.

Enablers

HARD

Concept
Gain endorsement from key stakeholders (especially academia and HTA) on the concept of IBP

Data Access and infrastructure
Demonstrate the ability to efficiently collect relevant data compliant with all data privacy and IT compliance regulations

Reimbursement Mechanisms
Advance the way that systems review prices and purchase medicines

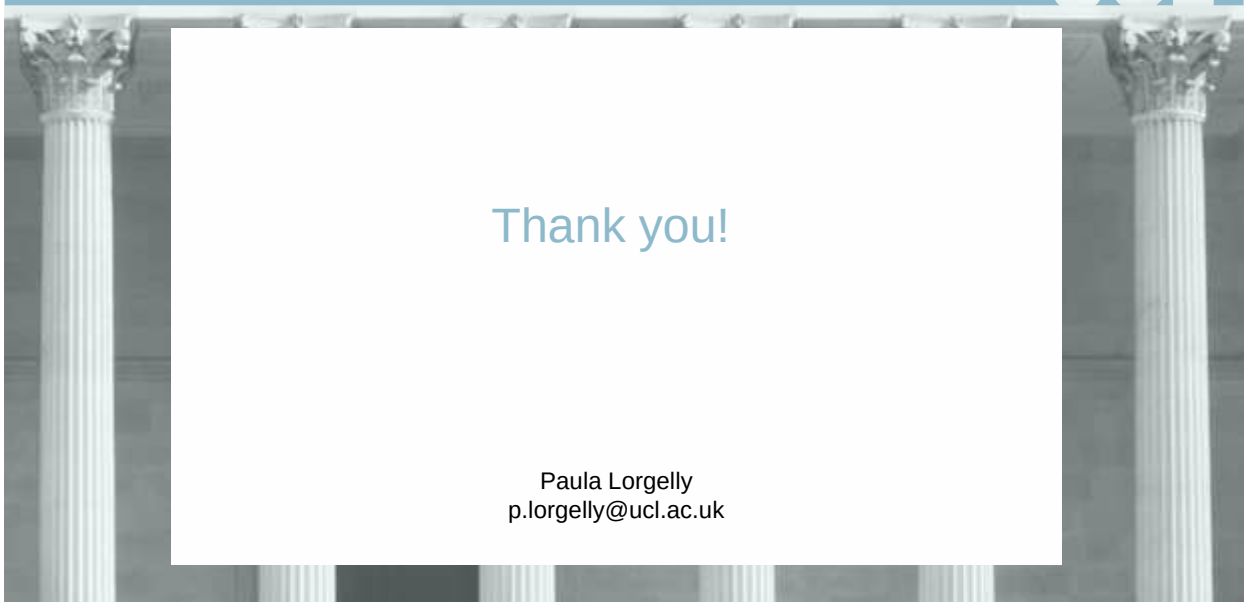
Contracts
Design and implement contractual arrangements and implementation workflows

SOFT

Trust
Trusted relationship between payers and manufacturers to ensure risks and benefits are shared fairly

Openness
General openness from manufacturers to enter into IBP; and helping with the effort to design and administer such agreements

Capabilities
Internal capabilities and processes required capabilities to implement and track agreements by both payer and pharma



Thank you!

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