

Strategies to Allow Indication-Based Payment for Biomarkers

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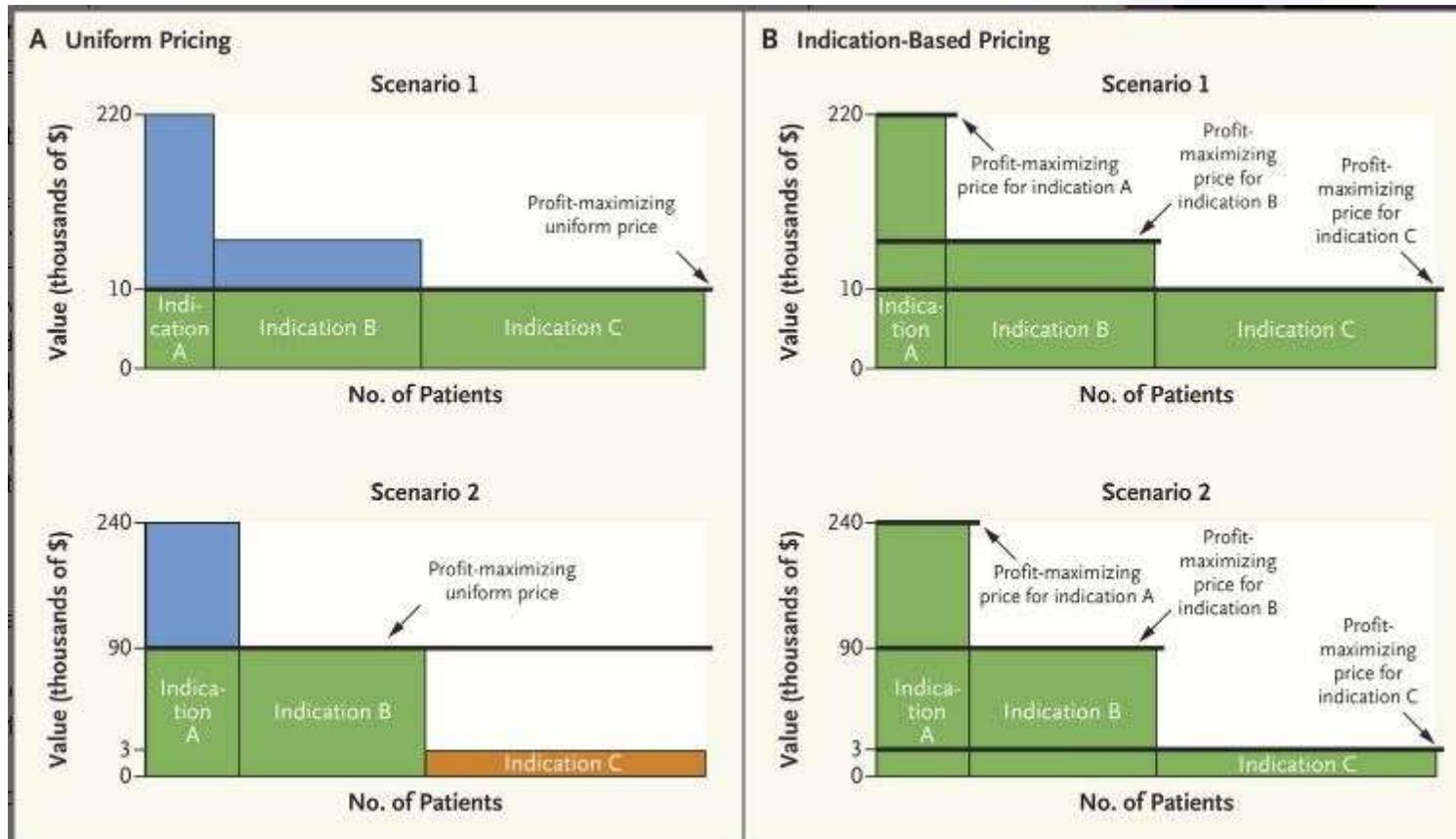
CDDF Workshop on Biomarkers & Personalized Medicines



Indication-Based Pricing

- Is a form of price discrimination: one product but different prices for different patients/indications.
- Example: Keytruda (pembrolizumab) , which is approved for use in PD-L1 biomarker-positive patients irrespective of where the tumor is located
- Aligns drug prices with clinical value (but willingness to pay for a health gain is the same).
- High value yields a high price, low value yields a low price.

Indication-Based Pricing



■ Consumer surplus (willingness to pay minus actual price)

■ Profit



Indication-Based Pricing

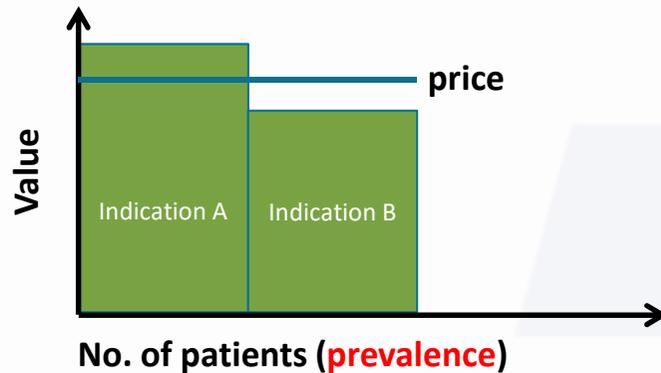
- Increases revenues for manufacturers and avoids a price decline associated with indication expansion (unless there were high prices in low-value indications before).
- Sends positive signals for R&D investment.
- Improves access to treatment (enables payers to have a low price for a low-value indication).

How Is IBP Operationalized at Present?

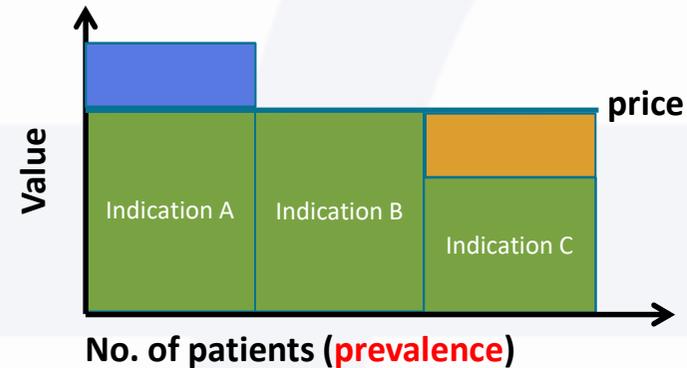
- *Different brand names according to the indication* – for the same product ⇒ confusion, e.g., with multiple lines of treatment
- *One brand with separate discounts per indication* – based on treatment failure in the various indications, by tracking actual outcomes on a per-patient basis (Italy)
- *One brand with single weighted-average price* – weighting implicit prices in different indications by the estimated population size (France and Germany)

Single Weighted-Average Price vs. Conventional IBP

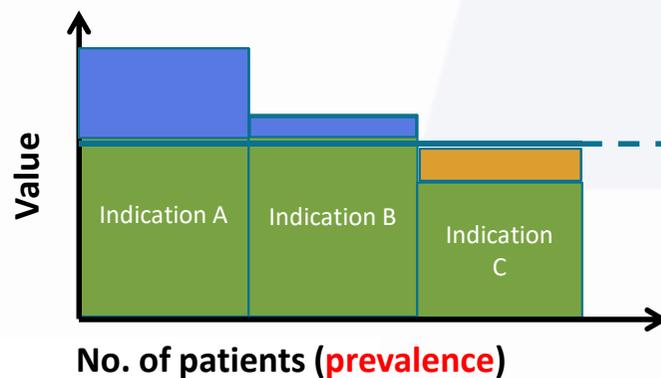
A: Two indications



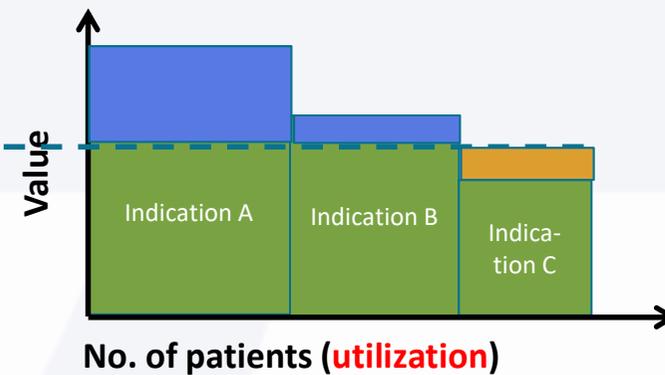
B: Three indications



C: Three indications (price-volume negotiation)



D: Three indications (utilization data)



Source: Author's own illustration

- Change data protection regulation: indications for drug use need to be reported on prescription label or communicated to a pharmacist
- *Leveraging existing data collection by payers* – requires an information system/registry that tracks
 - patient characteristics (age, gender)
 - diagnostic criteria including disease stage (ICD-10 code), molecular profile (biomarkers), and other clinical data
 - prior lines of therapy (ATC code, drug code)
 - concomitant medications (ATC code, drug code): value may differ within an indication when a drug is given as a monotherapy or used in different combination regimes

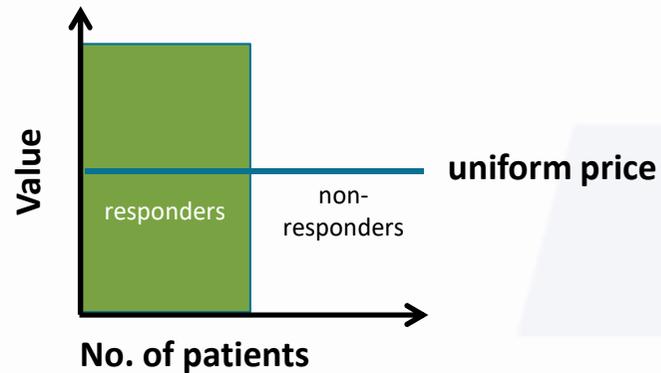
Anatomical Therapeutic Chemical (ATC) Classification System



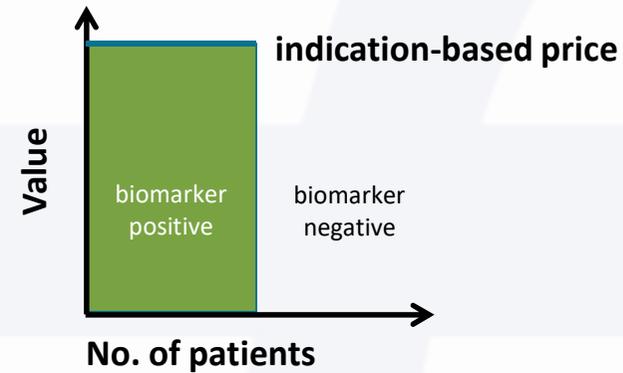
- Data collection/monitoring problems:
 - Costs of information system (who pays?)
 - Costs of incentives to overcome resistance by physicians for additional data entry
 - ICD data can be misclassified
 - Need to obtain informed patient consent that information on their condition (e.g., indication, molecular profile, therapy) would be used in the billing process and data are anonymized
 - Time delay between data collection and reimbursement

Does Precision Medicine Lead to Savings under Value-Based Pricing?

A: Two subgroups reimbursed



B: One subgroup reimbursed



The Broader Picture

- IBP tends to increase revenues of manufacturers.
- IBP does not address the more fundamental question of how to set the cost-effectiveness threshold.
- Reduction in profitability reduces rate of innovation, albeit evidence on negative impact on initial “inventive activities” such as patent applications is absent.
- Excessive innovation results when multiple firms enter into a race to produce an innovation.

