Specific Value Assessment Considerations

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Indication Based Pricing
A better way to value drugs?

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What are the economic implications of an alternative model?

What is the need for IBP, and in what format?

- Price should be linked in some way to value
- Increasingly medicines offer patient benefit in multiple different contexts
- A single price for a single drug creates a disconnect between price and value
- We use the term *indication-based pricing (IBP)* to refer to the concept of having different prices when a drug is used in different contexts
What are the arguments for and against: single price model vs IBP

**Bach (2014)**
*IBP would increase transparency and lead to rational prices for drugs, potentially lowering prices for lower value indications*

**Chandra & Garthwaite (2017)**
*IBP would lead to higher prices for patients who benefit the most, higher utilisation for patients who benefit the least, higher overall spending and higher manufacturer profits*

The crucial difference is that starting point: how is the single price set?

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2. Short-term ("static") effects of IBP

**Initial static effects: Critique of the literature**

<table>
<thead>
<tr>
<th>Survival gain (years)</th>
<th>Typical treatment duration (months)</th>
<th>Total treatment cost ($)</th>
<th>Current monthly price ($)</th>
<th>Indicator of current value: Cost per life year gained (approx.)</th>
<th>Monthly price based on indication with most value</th>
<th>Monthly price based on indication with least value</th>
<th>Monthly price based on value of $150,000 per life year gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>First line – low value indication (LOW VALUE)</td>
<td>0.23</td>
<td>4.16</td>
<td>$42,875</td>
<td>$10,319</td>
<td>$190,556</td>
<td>$471</td>
<td>$10,319</td>
</tr>
<tr>
<td>Locally advanced – high value indication (HIGH VALUE)</td>
<td>1.64</td>
<td>1.39</td>
<td>$14,292</td>
<td>$10,319</td>
<td>$8,706</td>
<td>$10,319</td>
<td>$226,075</td>
</tr>
</tbody>
</table>

HNSSC: Squamous cell carcinoma of the head and neck

**What could IBP look like?**

- **Uniform price**
- **High/low value at uniform price**

**Initial static effects: Critique of the literature**

2. Short-term ("static") effects of IBP
The varying impacts of moving to IBP

Uniform pricing scenarios: → IBP scenario (static)

N: Number of patients (N_u under uniform pricing, N_IBP under IBP)
P: Price (P_u under uniform pricing scenarios, P_H [high value] P_M [medium value] P_L [low value] under IBP)
Value: HV: High value; MV: Medium value; LV: Low value

Consumer (payer) surplus → Producer surplus → No patient access

Consumer (payer) surplus
Producer surplus
No patient access

Existing literature fails to take into account three critical factors

1. Level of uniform price assumed under a single price
   - Is it credible to assume profit-maximising uniform price would be equivalent to lowest value indication?
   - More likely profit-maximising uniform price corresponds with higher value indications, with manufacturers choosing to forgo lower value indications altogether to protect profits
   - Where IBP expands access, social welfare is increased

2. The presence of an HTA system to guarantee value
   - If differentiated prices under IBP are set using an acceptable cost-effectiveness threshold, then the spend is a worthwhile and cost-effective way to generate health gains for patients.

3. The dynamic context...
   - Impact on incentives for R&D and role of competition

2. Short-term ("static") effects of IBP
Dynamic context has an impact on R&D and on pricing

- IBP could optimise R&D incentives:
  - Allowing companies to target further indications - by permitting entry into new indication markets without compromising presence in existing indication markets
  - In turn, this will likely drive competition at the indication-level
- Manufacturers are not price-setting monopolists. There can be competing entry during patent-life
- Value-based indication prices (based on setting price at the maximum WTP) should therefore be seen as price ‘ceilings’; competition can drive prices down below these levels.

3. Longer-term (“dynamic”) effects of IBP

The potential impact of competition

<table>
<thead>
<tr>
<th>IBP scenario (static)</th>
<th>IBP scenario (dynamic)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Value ($)</td>
<td>Value ($)</td>
</tr>
<tr>
<td>Number of patients</td>
<td>Number of patients</td>
</tr>
<tr>
<td>P_M (medium value)</td>
<td>P_M (medium value)</td>
</tr>
<tr>
<td>P_L (low value)</td>
<td>P_L (low value)</td>
</tr>
<tr>
<td>P_H (high value)</td>
<td>P_H (high value)</td>
</tr>
</tbody>
</table>

Dynamic price for the medium / low value indications ($P_{Md}/P_{Ld}$)

This leads to transfer of surplus from producer to consumer (payer)
Timelines for PD-1 and PD-L1 inhibitors

Indication timeline for EMA-approved PD-1 and PD-L1 inhibitors

Source: EMA authorisation documentation

*Note that Avelumab is an orphan medicinal product granted conditional approval by the EMA

Abbreviations: Non-Small Cell Lung Cancer (NSCLC); Renal Cell Carcinoma (RCC); Squamous Cell Cancer of the Head and Neck (SCCHN); Urothelial Carcinoma (UC); Merkel Cell Carcinoma (MCC).

Potential impact of competition with IBP PD-1/L1 inhibitors

Using indication information from the previous slide together with evidence from HTA value assessments* we illustrate the potential for competition using the IBP PD-1/L1 inhibitors in three indications.

- Competition at the indication-level can drive down prices below value-based ‘ceilings’
- Transfer of surplus from producer to consumer (payer), thus limiting the impact of IBP on payer budgets.

*Indicative data on gain in quality-adjusted life years (QALYs) and patient numbers obtained from documentation from NICE and the Institute for Clinical and Economic Review.
Can innovative payment models really work?
Practical challenges

• Legal and regulatory hurdles
  - e.g. Medicaid’s best price rule, Off-label use, anti-kickback statute, data privacy issues

• Contractual or financial flow issues
  - Payer who agrees the price with the manufacturer may be reimbursing the provider who in turn pays the wholesaler who pays the manufacturer ...

• Data collection that tracks uses and outcomes by indication
  - Proxies or surrogate measures: e.g. treatment duration?

• Arbitrage (re-selling) must be difficult

• How to attribute value between drugs for combination therapies?

Conclusion

Short term rewards of greater patient access, long term gains of incentivising R&D and competition

• In the short term, IBP can improve overall welfare if patient access increases, but expenditure may rise

• Existing research has neglected longer term impact: optimised incentives for R&D can lead to new treatments options for patients

• Increased price competition at the indication-level drives down prices and delivers better value to the health system
  - The UK NHSE competitive tendering process for Hepatitis C drugs separates tenders by genotype – in effect by indication
  - US health plans and PBMs are currently piloting IBP approaches with the objective to better manage expenditure
Reference list


Thank you for listening

To enquire about additional information and analyses, please contact Amanda Cole (acole@ohe.org) or Adrian Towse (atowse@ohe.org)

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