MANAGED ENTRY SCHEMES FOR MEDICAL DEVICES: GREAT OPPORTUNITY OR A MAJOR CHALLENGE?

A RESEARCHER PERSPECTIVE

Aleksandra Torbica, PhD

Agenda

• Managed Entry Agreements: What?

• Why Relevant For Medical Devices?

• Major Challenges

• A Way Forward
Managed Entry Agreements: What?

“arrangements between a manufacturer and payer/provider that enables coverage or reimbursement of a health technology subject to specific conditions. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies or to manage the adoption of technologies in order to maximize their effective use or limit their budget impact.” (Klemp et al, IJTAHC 2011)

There is no universal consensus on the labelling and terminology and several taxonomies of MEAs have been proposed in the literature. There is general agreement on two clusters:

— Outcome based agreements (Performance based schemes-PBS)
— Non-outcome based agreements (Finance based schemes)

PBS: why relevant for medical devices?

• As of today, premarket evidence requirements for medical devices are less demanding
• In addition, collecting robust clinical evidence (e.g RCTs) may be unethical or unfeasible
• Thus, evidence base for estimating clinical and economic impact of medical devices is often less extensive and lower in quantity/quality
• Consequently, access to new technologies may be delayed because of the absence of scientifically sound evidence needed to respond to the expectations of policy makers deciding on reimbursement
• The distinctive characteristics of medical devices such (i.e. rapid incremental innovation, learning effects and upfront irrecoverable costs) all present additional challenge for the timing of reimbursement decisions
PBS: why relevant for medical devices?

Perceived Benefits of PBS

1. Strengthen evidence bases on the benefits and costs of new medical devices
2. Enable payers to participate in the research process.
3. Allow hospitals and clinicians to monitor more closely procedures being performed and manage costs until benefit is substantiated.
4. Encourage industry to generate the data needed to support the value claims of their innovations.
5. Allow earlier access for patients to potentially valuable medical devices than they might otherwise be granted.

A methodological framework for optimising the use of these schemes for medical devices was developed as part of the FP7 MedtecHTA Project (Rothery et al., Characterising Uncertainty in the Assessment of Medical Devices and Determining Future Research Needs, Health Economics 2017).

Figure 2: An illustration of coverage decisions at different points on the learning curve
Challenges

**Objectives:** To investigate how policymakers and the general public in the Netherlands value removing a previously reimbursed treatment from the basic benefits package relative to not including a new treatment.

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Average scenario</th>
<th>Least-preferred (CV)</th>
<th>Most-preferred (CV)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of patient</td>
<td>40</td>
<td>90</td>
<td>15</td>
</tr>
<tr>
<td>Quality of life before treatment</td>
<td>10</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Health gain from treatment</td>
<td>10</td>
<td>5</td>
<td>10</td>
</tr>
<tr>
<td>Include new treatment</td>
<td>New &gt; existing</td>
<td>New &gt; existing</td>
<td>New &gt; existing</td>
</tr>
<tr>
<td>KBP</td>
<td>50,000</td>
<td>100,000</td>
<td>150,000</td>
</tr>
<tr>
<td>Budget impact</td>
<td>10 million</td>
<td>15 million</td>
<td>20 million</td>
</tr>
<tr>
<td>Probability that the cost per QALY will double</td>
<td>15%</td>
<td>25%</td>
<td>30%</td>
</tr>
<tr>
<td>Changes in predicted probability (CV)</td>
<td>+4.1%</td>
<td>+6.8%</td>
<td>+12.3%</td>
</tr>
<tr>
<td>Changes in predicted probability (policymakers)</td>
<td>+0.1%</td>
<td>+0.7%</td>
<td>+4.7%</td>
</tr>
<tr>
<td>CV of LSE (CV)</td>
<td>7.21</td>
<td>6.14</td>
<td>7.63</td>
</tr>
<tr>
<td>CV of policymakers (CV)</td>
<td>7.69</td>
<td>6.60</td>
<td>7.87</td>
</tr>
</tbody>
</table>

CV, compensating variation; QALY, quality-adjusted life-year; KBP, incremental cost-effectiveness ratio; LSE, life expectancy.
A way forward

1. Establishing a clear framework for applying PBS (e.g. deciding when they are appropriate, for what medical devices)
2. Identifying and applying appropriate research methods (e.g. RCTs, observational studies)
3. Involving all the relevant parties (e.g. manufacturers, health providers, professional groups)
4. Funding and conducting the research
5. Determining appropriate coverage arrangements based on the research findings and implementing them!