Industry-Payer Agreements: payer perspectives

Chris Henshall

Chair, HTAi Policy Forum
Associate Professor, Brunel University
Honorary Fellow, University of York

Overview

- Payer perspectives
- HTAi Policy Forum
- Policy Forum discussion of Managed Entry Agreements
- Policy Forum discussion of Coverage with Evidence Development
- Some thoughts

Payer perspectives

- Payers are seeking to:
  - Ensure their systems respond to the needs of the patients and the populations they serve
  - Respond to increasing expectations and demands from patients and populations, articulated/fuelled by patient groups and advocates, politicians and the media
  - Manage budgets and, in many systems, maximise value from expenditure
- Payers therefore want:
  - To provide rapid access to new treatments, provided they deliver useful benefits, are affordable and (in many systems) are cost-effective (ie the benefits for patients treated justify the opportunity costs for others in a system with a fixed budget)
- But – there may be uncertainty at launch about
  - Real world outcomes, effectiveness and cost-effectiveness
  - Real world use and hence budget impact (and cost-effectiveness)

It is in this context that interest is growing in Managed Entry Agreements

HTAi

Health Technology Assessment International

- International professional society for those doing and/or using HTA
- Charity registered in Alberta; Secretariat hosted in Institute for Health Economics in Edmonton
- Institutional and individual members from industry, government, health care coverage, reimbursement and HTA bodies, health economics consultancies, universities and research institutes
- Annual Scientific Meeting, journal (International Journal of Technology assessment in Health Care), Interest Sub-Groups, other member services, Strategic Programme (currently focusing on partnerships, emerging regions and HTA/Regulation interface)

HTAi Policy Forum

- “Neutral” place for senior figures from public and private sector organisations with strategic interests in HTA to meet and discuss its development and use in decision making in health systems and industry
- Topics reflect areas of shared interest for industry and payer/reimbursement bodies
  - Coverage with Evidence Development: an analysis fo policy and conceptual issues (2007)
  - Harmonization of evidence requirements in HTA for reimbursement decision-making (2008)
  - HTA to optimize health technology utilization: using implementation initiatives and monitoring processes (2009)
  - Managed Entry Agreements (2010)
  - HTA and Regulation (2011)

Managed Entry Agreements (1)

Forum definition of Managed Entry Agreement*

> "an arrangement between a manufacturer and payer/provider that enables access to (coverage/reimbursement of) a health technology subject to specified 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, M et al (in press) What principles should govern the use of managed entry agreements? International Journal of Technology Assessment in Health Care

Managed Entry Agreements (2)

- Main uses of MAEs (in my words!)
  - When there is material uncertainty on key outcomes
    - CED to promote development of evidence that can then be reviewed in later “regular” coverage decision
  - When key outcome are sufficiently clear but there are uncertainties around use in practice which present risks to the payer/system on vfm or budget impact:
    - Limiting to relevant patient groups by severity or co-morbidities (often also used in “regular” coverage decisions)
    - Limiting to those responding to initial treatment
    - Linking payment to achievement of specified health outcomes
    - Limiting max use per patient and/or for the population
  - When a reduction in the effective price is needed to ensure vfm
- Mechanisms may include free product, capped total expenditure for payer, refunds etc

Managed Entry Agreements (3)

Examples used in Forum paper

- Finasteride (Proscar) - 1994 agreement between Saskatchewan and Merk: Merk to pay for surgery for patients taking drug for at least 12 months
- Renibizumab (Lucentis) - 2008 agreements between various payers and Novartis: Novartis to pay for treatment over defined levels
- Stents – agreements between J&J and hospitals in Canada: J&J provided training to physicians and refunded cost of stents in unsuccessful procedures

For further examples and discussion see eg:

- Carlson JJ et al Health Policy (in press)
- special edition of Pharmacoeconomics (2010: 28(2))

Managed Entry Agreements (4)

Key principles emerging from Forum discussion

- Early engagement of all stakeholders
- Clarity on what has been agreed and who will do what
- Independent collection and analysis of relevant data
- Clarity on duration of agreement and review arrangements
- Extent of use, feasibility and effectiveness (in meeting objectives) is unknown – focus on cases where expected added value justifies effort and where data collected will address material uncertainties in decision parameters

Coverage with Evidence Development

Additional points from 2007 Forum discussion on CED:

- Limit to cases where there is uncertainty about (cost)effectiveness that is material to a decision on ongoing adoption and/or reimbursement
- And where research to resolve the uncertainty is feasible
  - appropriate study design; duration; cost; patient/clinician buy-in
- Clear agreement on responsibilities for
  - Treatment costs; research costs; data collection and analysis
- Clear agreement on stopping rules and arrangements for review of data and coverage

Interesting to note that both manufacturers and payers have concerns about the effect that the availability of the CED route may have on the other's behaviour

Some personal thoughts on MAEs

- "Regular" decisions on coverage/reimbursement often place restrictions or conditions on use (eg disease severity) – MAEs building on this
- Lots of MEAs but limited information available publicly on their content or even existence
- Many address multiple objectives, often reflecting policy and political issues as well as technical challenges
- Many are more than simple price reductions, but many would not be necessary if manufacturers could reduce list prices more easily
- MAEs can protect a payer against the risk of inefficient use of the budget and hence allow coverage where it would not otherwise be possible
- If based on valid and transparent analysis of data on outcomes and costs, MAE can help to promote (early) access to innovative technologies, good clinical practice and value for money in a health care system
- But they take time and effort to negotiate and implement/monitor, so they need to be focused on areas where they really do add value
- CED can be helpful for specific technologies, but it's expensive and difficult to implement and needs to applied appropriately – it is not a general substitute for the early collection of effectiveness data
- That said, manufacturers, regulators and payers need to (continue to) discuss how best to generate the data that is needed on safety, efficacy, effectiveness and impact over the lifecycle of a technology to manage its development, approval and use in health care systems

Further details

- chenshall@htai.org