Zorginstituut Nederland

Experiences with Managed Entry Arrangements

Examples from NL

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| Van goede zorg verzekerd |

Topics

- What are Managed Entry Arrangements
- Examples from the Netherlands
- Learning and follow-up

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What is a managed entry agreement (MEA)

- A Managed Entry Agreement is 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 effective their use, or limit their budget impact*.
- What types of MEAs#:
  1. Managing budget impacts (caps, volume deals etc)
  2. Managing uncertainty (coverage with evidence development)
  3. Managing utilization to optimize performance (limitation of technology diffusion to appropriately trained practitioners)

*Carlson JJ etal.. Health Policy. 2010;96:179-190.
#Klemp etal. International Journal of Technology Assessment in Health Care, 27:1 (2011), 77–83.

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Focus on Coverage with Evidence and Managed entry (expensive in-hospital drugs)

- 2006-2011: system of coverage with evidence development for expensive medicines in hospitals
- Approximately 5-10 new drugs or indications per year
- Evidence was collected in indication-based patient registries (observational data – comparative effectiveness research)
  - Appropriate use of care in daily practice
  - Cost-effectiveness of real world data

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Process of CER request and guidance provided

- Guidelines on pharmacoeconomics and outcomes research by ZIN, including also VOI as starting point for preparation outcomes research
- Proposals send to ZIN for evaluation
  - Scientific advice
  - Preliminary meeting on dossier contents
  - Submission of official file

Assessment committee
- Maximum budget impact (>2,5M)
- Therapeutic value
- Proposal Outcome Research
- Estimate Cost-effectiveness

→ Conditional reimbursement (outcomes research; 4 years)

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Examples

- oncology:
  - trastuzumab, avastin, rituximab
- rheumatology
  - rituximab, abatacept, tocilizumab
- eye diseases
  - ranibizumab
- (ultra)orphans
  - alglucosidase alfa, galactosidase alfa en beta

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General challenges of CER studies

- VOI was not adequately used as starting point
  - Resulting in too large studies
- Extra tasks for health care professionals
- Small sample sizes
- Lack of consistency in data collection and missing data
- Differences in patient characteristics between treatment groups
- QoL measured per health state not for different treatment groups

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Outcomes of reassessment based on CER results

Infliximab in ulcerative colitis and plaque psoriasis
- Remains reimbursed (*not possible to organize managed entry*)

Ranibizumab in AMD
- Stop reimbursement by 2015 unless…. (*not taken over by Minister!*)

Alfa-glucosidase in Pompe and Alfa-galactosidase in Fabry
- Remove from reimbursement but fund under special conditions (*not taken over by Minister!*)

DIFFICULT TO STOP or LIMIT REIMBURSEMENT!!!!!

Omalizumab in persistent severe allergic asthma
- No cure-no pay deal (2 year try-out)

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Conclusions

- New outcomes based deals should be further explored
- We must try to stay away from previous mistakes. NO MANAGED ENTRY WITHOUT MANAGED EXIT!
- All stakeholders should shoulder a tangible responsibility
- And wear appropriate protection