

Conditional Reimbursement

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Summary

- Policy problem
- Possible solutions
- Coverage with evidence development (CED)
- Decision-makers' perspectives
- Practical issues

Policy Problem

- HTA in the product lifecycle
- Need decisions close to launch for maximum impact
- Most appropriate data for HTA not available at launch
- Opportunity costs of “wrong” decision

Policy Solutions

- Clinically driven
- Financially driven
- Evidence-based

Clinical Decision Criteria

- Identify and reimburse treatment for all eligible patients
- Apply stopping rules based on effectiveness of treatment e.g. Xolair for asthma, MS drugs
- Retrospective assessment of effectiveness and repayment for “failures”

Financial Decision Criteria

- Agree potential number of patients
- Negotiate price
- Estimate budget impact from optimum prescribing
- Demand rebate if total expenditure on product exceeds target e.g. French system

Need for Evidence-based Solution

- Retrospective application of clinical or financial criteria assumes the initial uncertainty cannot be reduced
- Definition of “failure” is problematic
- Other external factors can influence total expenditure
- Appropriate use of HTA may clarify the situation

Data Uncertainties - Clinical

- At product launch we may have efficacy data but not true effectiveness
- For devices we may not have any controlled trial data
- The safety data may be only short-term
- Outcome measures may be surrogates for final outcomes
- Trials may not show efficacy against relevant comparators

Data Uncertainties-Economic

- Resource use data from protocol driven studies may not reflect actual routine practice
- Outcomes in Phase III trials may not reflect patient preferences
- Marginal costs will be dependent on utilisation rates
- Trial follow-up periods are too short to capture all future resource use impacts

Coverage with Evidence Development (CED)

- An analysis at launch must be based on modelling and projection with uncertainty
- The data gaps can be filled by post-launch studies which observe use of the technology
- CED is a form of conditional reimbursement which targets specific data needs and establishes criteria for subsequent confirmation of coverage

Decision-makers' Perspectives

- Health service decision-makers
- Manufacturers
- Clinicians
- Patients

Health Service Decision- makers

Advantages

- Managed entry to market
- Meets patient need
- Gives some control over research
- No permanent commitment

Disadvantages

- May spend money on technologies which are shown not to be cost-effective
- Extra burden of appraisal of new evidence
- Difficulty of withdrawing technologies not proven to be cost-effective

Manufacturers

Advantages

- Gain limited adoption of technologies which might otherwise be rejected

Disadvantages

- Delayed diffusion of effective technologies
- Additional burden of evidence generation
- Restriction on pricing

Patients and Clinicians

Advantages

- Earlier access to promising technologies
- Research opportunities

Disadvantages

- Risks of using unproven technologies
- Loss of benefit through using treatments which subsequently prove to be ineffective

Designing a CED System

- Needs goodwill on all sides
- Acceptance of the final decision
- Agreement on funding of additional evidence generation
- Agreement on the analysis of the new data

Selection of Technologies for CED

- Evidence of clinical efficacy but cost-effectiveness equivocal
- Will further data collection reduce the uncertainty?
- Is data from routine practice needed?
- Will CED prevent the use of optimal study designs?
- Can CED produce new evidence within a reasonable time for decision-makers?
- Is the benefit of reduced uncertainty worth the cost of a CED process – value of information?

Practical Issues

- Decision-makers must have robust criteria for approval e.g. cost/QALY threshold
- There should be a time horizon for making the revised decision with further evidence (DFE)
- The expectation is that manufacturers will pay for the new research but this may not be realistic for devices
- In Australia MSAC has a formal system of funding further data collection
- Independent analysis of the data may be preferred
- While an Appeal system on the DFE is desirable a further round of further evidence collection should be avoided.

Conclusions

- Conceptual case is strong
- May be stronger for devices
- Practical problems are not trivial
- Should CED be selective or automatic?
- Better routine data systems in health care organisations would facilitate post-launch data collection