MEA REIMBURSEMENT FRAMEWORK

MANAGED ENTRY AGREEMENTS (MEAS)

For many innovative health technologies, traditional reimbursement mechanisms are no longer fit for purpose. MEAs provide a mechanism to **balance risks and gains**, regarding **costs of innovative therapies**, **long-term evidence**, **real-world effectiveness**, **budget impact** and **faster patient access to innovation**.

The 3 Stages of ASCERTAIN's MEA Framework

STAGE 1: IDENTIFY AND CHARACTERIZE UNCERTAINTY

Decision makers first assess the nature and magnitude of uncertainty associated with a technology to identify which uncertainties drive reimbursement risk. Uncertainty means that there may not be strong enough evidence to predict how a medicine will perform in the real-world (e.g. on benefits, risks, and value). Key uncertainty domains:

- **Financial uncertainty**
- **Clinical or performance-related uncertainty**
- **Population uncertainty**
- **Implementation uncertainty**

STAGE 2: PRELIMINARY ASSESSMENT OF MEAS

There are 2 main types of MEAs:

Finance-Based MEAs

Advantages

- ✓ Simpler administration
- ✓ Immediate budget control
- ✓ Predictable implementation

Limitations

- ⚠ Do not reduce clinical uncertainty

Outcome-Based MEAs

Advantages

- ✓ Link reimbursement to value delivered
- ✓ Generate real-world evidence
- ✓ Reduce uncertainty over time

Limitations

- ⚠ Data-intensive
- ⚠ Higher administrative burden
- ⚠ Require robust monitoring mechanisms

ⓘ **Important:** The optimal agreement should match the specific uncertainty being managed. Financial uncertainty generally is best addressed by finance-based arrangements, while clinical uncertainty is better addressed through outcomes-based approaches.

STAGE 3: MONITORING AND REASSESSMENT

MEAs need to be monitored and reviewed periodically to see if extensions of the initial agreements are still necessary.

Possible outcomes:

- ✓ Continue reimbursement
- ✓ Modify agreement terms
- ✓ Renegotiate price
- ✓ Expand access
- ✗ Withdraw reimbursement

Critical success factor: data infrastructure

- Patient registries
- Real-world data systems
- Outcome tracking capabilities
- Governance and reporting mechanisms

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MEA REIMBURSEMENT FRAMEWORK

Innovative health technologies, including precision medicine, advanced diagnostics, and cell and gene therapies, offer the potential for substantial health gains but come with significant uncertainty regarding clinical effectiveness, long-term outcomes, eligible patient populations, and financial sustainability. Healthcare decision makers thus find themselves in difficulty when deciding for which of these new technologies to pay (reimburse) from national budgets. This is the case not only because of the challenges these technologies bring but also because traditional reimbursement mechanisms are no longer fit for purpose.

Managed Entry Agreements (MEAs) provide a mechanism to balance risks and gains, regarding costs of innovative therapies, long-term evidence, real-world effectiveness, budget impact and faster patient access to innovation.

The ASCERTAIN project proposes a new structured framework for evaluating and implementing MEAs, which allow healthcare systems to provide patient access while managing financial and clinical risk.

THE ASCERTAIN MEA FRAMEWORK HAS 3 STAGES:

Stage 1: Identify and Characterize Uncertainty

Decision makers first assess the nature and magnitude of uncertainty associated with a technology to identify which uncertainties drive reimbursement risk.

Key uncertainty domains

- Financial uncertainty (e.g. price, treatment duration, budget impact)
- Clinical or performance-related uncertainty (e.g. real world effectiveness, treatment response, safety, long-term effectiveness)
- Population uncertainty (e.g. eligible population, patient selection)
- Implementation uncertainty (e.g. outcome measurement, feasibility in routine practice)

To remember:

Not all technologies require an MEA. Agreements should only be considered when uncertainty directly affects reimbursement decisions.

Stage 2: Preliminary Assessment of MEAs

Potential agreements are evaluated before implementation to determine their expected impact. There are 2 main types of MEAs: finance-based and outcome-based

a. Finance-Based MEAs

Examples:

- Discounts and rebates (Manufacturer agrees to offer confidential discounts or pay back percent rebates per individual doses.)
- Expenditure caps (The agreement establishes an absolute ceiling on the total amount a payer will spend on a specific drug over a given period)

- Price-volume agreements (The unit price of the medicine is tied directly to the total volume or quantity purchased by the healthcare system. As the volume increases, the price per unit scales down.)

Advantages

- Simpler administration
- Immediate budget control
- Predictable implementation

Limitation

- Do not reduce clinical uncertainty
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b. Outcome-Based MEAs

Examples:

- Pay-for-performance (Reimbursement or full payment is conditional on an individual patient achieving a pre-specified clinical response within a set timeframe.)
- Coverage with Evidence Development (Reimbursement is granted provisionally on the condition that real-world evidence is systematically gathered over time. If this data confirms the drug's cost-effectiveness then final reimbursement is granted.)
- Conditional treatment continuation (Reimbursement is granted for early doses of a therapy, but further doses are funded only if certain clinical milestones, such as biomarker levels, are met.)

Advantages

- Link reimbursement to value delivered
- Generate real-world evidence
- Reduce uncertainty over time

Limitations

- Data-intensive
- Higher administrative burden
- Require robust monitoring mechanisms

To remember:

The optimal agreement should match the specific uncertainty being managed. Financial uncertainty generally is best addressed by finance-based arrangements, while clinical uncertainty is better addressed through outcomes-based approaches. Complex situations can be addressed through combined financial and outcomes-based agreements.

Stage 3: Monitoring and Reassessment

MEAs need to be monitored and reviewed periodically to see if extensions of the initial agreements are still necessary.

Key activities include:

- Collection of real-world evidence
- Performance monitoring
- Updating economic models
- Periodic reassessment of reimbursement arrangements

Possible outcomes:

- Continue reimbursement
- Modify agreement terms
- Renegotiate price
- Expand access
- Withdraw reimbursement

To remember:

MEA implementation should be viewed as a dynamic process rather than a one-time contracting exercise. Continuous learning and various stakeholder engagement are essential to maximizing value and reducing uncertainty.

KEY POINTS TO DRIVE CHOICE OF MEA:

1. Uncertainty Should Drive Agreement Selection

There is no universally preferred MEA model. Selection should be determined by the dominant source of uncertainty (e.g. clinical, financial) associated with the technology.

2. Simpler Agreements Often Deliver Greater Practical Value

While outcomes-based agreements are theoretically attractive, implementation complexity frequently limits effectiveness. Simpler finance-based arrangements may provide greater net value when uncertainty is primarily financial rather than clinical.

3. Data Infrastructure Is a Critical Success Factor

Successful outcomes-based agreements require:

- Patient registries
- Real-world data systems
- Outcome tracking capabilities
- Governance and reporting mechanisms

Without these foundations, measurement and accountability become difficult.

4. Reassessment Must Be Built into the Process

Reimbursement decisions should evolve as new evidence emerges. Agreements should include predefined review milestones and decision criteria.

BOTTOM LINE

The ASCERTAIN framework provides a practical methodology for selecting, evaluating, and managing MEAs for innovative health technologies. Its central message is that reimbursement decisions should be driven by the specific uncertainties associated with a technology, supported by structured economic evaluation, and continuously refined through real-world evidence generation. For healthcare decision-makers, the framework offers a transparent pathway to balance patient access, affordability, and value in an increasingly complex healthcare environment.

For more information on ASCERTAIN please visit: https://www.access2meds.eu/