



Outcome-based agreements in Europe: Opportunities, challenges and future directions

Executive summary

Managed Entry Agreements (MEAs) are innovative reimbursement mechanisms designed to facilitate access to high-cost or high-uncertainty therapies while managing financial and clinical risks. Among these, Outcomes-Based Agreements (OBAs) specifically tie payment to the achievement of predefined clinical outcomes. In Europe, MEAs—including OBAs—are increasingly being adopted to address rising healthcare costs, uncertainty around real-world effectiveness and the need for sustainable access to advanced therapies. This paper explores the current landscape, key enablers, challenges and future directions for MEAs in Europe, drawing on recent literature and policy developments.^{1,2,4}

1. Introduction

The emergence of high-cost therapies, particularly in oncology, rare diseases and neurology, along with an aging population characterized by multiple comorbidities, has prompted European healthcare systems to explore alternative reimbursement strategies. MEAs offer a promising solution by aligning payment with the value delivered to patients, whether through financial mechanisms or performance-based models. These agreements are designed to mitigate payer risks and confirm that healthcare spending translates into meaningful health outcomes.²

MEAs are particularly relevant in the context of precision medicine and advanced therapy medicinal products (ATMPs), where clinical trial data may not fully reflect real-world effectiveness. By incorporating real-world evidence and conditional reimbursement, MEAs—including OBAs—aim to reduce uncertainty and facilitate access to innovative treatments.¹

2. Definition and types of MEAs

MEAs can be categorized in several types:

- **Financial-based agreements:** These include discounts, price-volume agreements or budget caps that are not directly tied to patient outcomes but aim to manage financial exposure^{1,2}
- **Health outcome-based schemes:** These usually take one of two forms: (1) coverage with evidence development, in which reimbursement is contingent on the initiation of postlaunch evidence generation and (2) performance-linked schemes, in which reimbursement of the covered products is associated with measures of clinical outcomes in real practice settings^{2,5,6}

The choice of model depends on the therapy, disease area, data availability and country (payer preferences). Performance-based models are more complex but offer greater alignment with value-based healthcare principles.²

3. Current landscape in Europe

Several European countries are implementing OBAs in the HTA processes:



Italy

Pay-for-Performance (P4P)
Coverage with Evidence Development (CED)
Extensive use via AIFA registries,
>50 OBAs implemented



France

CED, Financial-based MEAs
OBAs used under ATU schemes and for orphan drugs



Denmark

OBAs in selected cases
HTA body open to OBAs for ultra-rare conditions



Belgium

OBAs and financial MEAs
KCE supports structured MEA processes



Germany

Limited CED
AMNOG limits broader use; etranacogene dezaparvovec is covered under first national OBA*



Netherlands

OBAs for ATMPs
HTA body exploring OBAs; registry challenges noted



Scotland

OBAs via Scottish Medicines Consortium (SMC)
Used for rare diseases and high-cost therapies



England

Individual OBAs, CED
Used via NICE and Cancer Drugs Fund; conditional reimbursement



Spain

Pay-for-Performance (P4P)
Regional variation; oncology and ATMPs targeted



Sweden

Pilot OBAs
HTA body support conditional reimbursement with RWD



Poland

OBAs in selected cases, Financial based agreements
HTA body open to OBAs for rare and severe conditions

* https://www.gkv-spitzenverband.de/media/dokumente/krankenversicherung_1/arzneimittel/amnog_praxisbesonderheiten/23045pb20250401.pdf

These examples highlight the diversity of approaches across Europe and the importance of national context in shaping OBA implementation.

4. Key enablers

Successful implementation of OBAs depends on several factors:

- **Robust real-world data infrastructure:** Accurate and timely data collection is essential for outcome measurement. Countries with integrated health records and registries are better positioned to implement OBAs^{7,8,9}
- **Clear outcome definitions:** Outcomes must be clinically meaningful, measurable and agreed upon by stakeholders. Ambiguity can undermine the credibility of the agreement^{7,8}
- **Stakeholder collaboration:** Effective OBAs require coordination between payers, manufacturers, providers and sometimes patients. Trust and transparency are critical^{8,9}
- **Legal and regulatory frameworks:** Supportive policies for data sharing, conditional reimbursement and privacy compliance (e.g., GDPR) are necessary for operationalizing OBAs^{7,8,9}

5. Challenges

Despite their potential, OBAs face several challenges:

- **Data collection and quality:** Fragmented systems and lack of interoperability can hinder outcome tracking. Manual data entry increases administrative burden and risk of error^{7,8,9}
- **Administrative complexity:** OBAs require ongoing monitoring, reporting and evaluation, which can strain resources, especially in smaller healthcare systems^{7,8}
- **Outcome selection:** Identifying outcomes that are both clinically relevant and feasible to measure within a reasonable period is often difficult^{7,8,9}
- **Transparency vs. confidentiality:** While public accountability is important, commercial sensitivity may limit disclosure of agreement terms and results⁸

These challenges underscore the need for capacity building and policy support to scale OBAs effectively.

6. Policy and regulatory considerations

The European Commission and the European Medicines Agency (EMA) have expressed support for innovative access models for medicines by initiating initiatives supporting early and progressive evidence development plans and issuing guidelines.^{10,11,12,13} EMA's initiatives on real-world evidence and adaptive pathways align with the principles of OBAs.³

National HTA and payer bodies are increasingly open to conditional reimbursement schemes, especially for therapies with high uncertainty or high budget impact.^{14,15}

7. Future directions

OBAs are expected to expand beyond oncology and rare diseases into covering broad spectrum of advanced therapy medicinal products (ATMPs) for chronic prevalent conditions such as diabetes, cardiovascular disease and neurodegenerative disorders.¹

8. Conclusion

Outcomes-Based Agreements represent a strategic shift toward value-based healthcare in Europe. By linking reimbursement to patient outcomes, OBAs can offer a pathway to financially sustainable access, reduced uncertainty and improved accountability in pharmaceutical reimbursement.

While challenges remain, the growing experience and infrastructure across European markets suggest a promising future for broader adoption. Continued investment in data systems, stakeholder engagement and policy innovation will be key for unlocking the full potential of OBAs.^{1,2}



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