Managed entry agreements: learnings for successful development from a UK perspective

A recent meeting of complex pricing experts from across the EU5 countries (France, Germany, Italy, Spain, and the UK) focused on the variability among countries of payers' and policy-makers' attitudes to managed entry agreements (MEAs), and the practical challenges for implementation capable of satisfying a range of country requirements.

Here we summarize the insights from the UK discussion.

Patient access schemes have been the most common approach to MEA in the UK, with the schemes agreed with NICE and the SMC as part of the HTA submission process.

Recent developments of more complex MEAs include:

- The increasing involvement of NHS England in negotiations, as part of the NICE HTA process; this is seen in the use of more complex approaches to MEAs in the form of commercial access agreements. There have been some notable recent successes, which have been achieved through tough negotiation by both parties.
- The evolution of the Cancer Drugs Fund to incorporate MEAs, to allow access to promising new treatments while further evidence is collected to address clinical uncertainty.

Taken at face value, the following agreements would appear to be successes.

- Ataluren for Duchenne muscular dystrophy – 5 years' managed access including a performance-based component and mechanism to monitor real-world efficacy and provide additional evidence.
- Value-based risk-sharing agreement to provide wider cost-effective access for patients to asfotase alfa for hypophosphatasia, informed by their first-hand experience of the ongoing impact that treatment is having on their health and quality of life.
- For hepatitis C, 'pay per cure' and prioritization of patients with the most severe disease is now being extended to collaboration between NHS England and manufacturers, to identify more people who are living with hepatitis C and need treatment.
- CAR-Ts for diffuse large B-cell lymphoma – although the details of the agreement are not in the public domain, NHS England has already announced commercial access arrangements with both manufacturers, ahead of the final recommendations from NICE.

The examples of recent agreements show that even with very tough environmental challenges and a powerful negotiating body, agreements can be reached. The true success of these for parties will emerge over time.

Key in successfully developing MEAs that work for all parties is:

- An understanding of the key issues for a technology, how these may be addressed by MEAs, and the potential options that would be relevant
- An understanding of the key benefits for patients and how to demonstrate these – for example, capturing quality of life, delayed events, and improved outcomes through coverage with evidence generation
- A recognition of the value of engaging with NHS England, and willingness by manufacturers to enter into negotiations
- Having a mechanism in place for data collection over time with limited impact on NHS stakeholders to collect the data

Perhaps controversially, manufacturers also need to be clear about their negotiation framework and at what point the proposed options are no longer feasible or acceptable.

Follow the link below to view our full presentation, which provides a detailed examination of the opportunities and challenges for manufacturers in implementing MEAs.

Through a review of the learnings on MEAs in the EU5 and case studies of innovative approaches, the presentation provides you with insights for overcoming barriers to acceptance and successful implementation and key principles for manufacturers on what to consider when proposing MEAs.

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