

Rethinking Market Access Strategies for Innovative Medical Technologies

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The surge of Innovative Medical Technologies (IMTs): Driving progress in healthcare for rare and complex diseases

The landscape of Innovative Medical Technologies (IMTs) is experiencing a remarkable surge. This growth is fuelled by the technologies' potential to treat and cure rare diseases, offer superior efficacy compared to standard therapies, and address significant unmet medical needs. Orphan legislation further incentivizes the development of these breakthrough technologies.

The broad scope of IMTs: Targeting unmet needs through advanced therapies by focusing on rare diseases and oncology

IMTs encompass a wide range of technologies, primarily focusing on orphan medicinal products (OMPs), advanced therapy medicinal products (ATMPs), and innovative oncology treatments. These therapies are designed to create targeted value, offering advanced, often personalized, solutions to patients with rare or complex conditions.

The high cost of IMTs as a barrier to widespread access: Navigating the challenges of high costs and limited patient populations

IMTs deliver immense clinical benefits but often come at a high cost. Key cost drivers include:

- Small patient populations
- Complex and personalized development
- High production costs
- Limited economies of scale

Consequently, these therapies cannot follow the traditional mass-market approach of common diseases, making widespread access challenging.

Integration of IMTs into Healthcare Systems: The complex challenge of balancing exceptional efficacy, uncertainty, and high upfront costs

IMTs represent a paradigm shift in healthcare, creating significant challenges for healthcare systems, payers, and HTA bodies. Payers struggle with the combination of:

- Clinical uncertainty
- Exceptional clinical benefit
- High upfront costs

For manufacturers, proving long-term value and overcoming uncertainty is complex, especially when long-term clinical data is not yet available at launch.

Evolving role of Health Technology Assessments (HTAs): HTAs as the new gatekeepers of market access

While regulatory approval can be granted based on short-term data, market access increasingly depends on HTAs and payers requiring robust **long-term value demonstration**. Innovative treatment must now secure market access based on both short-term regulatory data and long-term evidence showing incremental value, often encountering resistance due to outdated pricing systems unable to capture the true value of innovation.

Reevaluating market access frameworks for IMTs: Adapting business models for innovative medicines

Traditional market access models designed for conventional pharmaceuticals are **no longer fit for IMTs**. The unique characteristics of these technologies demand a sophisticated, tailored approach to reimbursement and access, distinct from conventional pharmaceuticals. A reevaluation of the framework conditions is necessary to ensure that innovative medicines are introduced effectively into the healthcare system. An adapted access model focusses dominantly on value, not just price.

A shift toward an integrated business model: Value-centric strategies from development to market access

Achieving successful market access demands an **integrated, end-to-end mindset**. Four imperatives stand out:

- Systematically **capturing value** across function, from R&D to pricing and reimbursement
- Framing development from a cost-effectiveness perspective **backward to clinical efficacy**
- Incorporating **management entry agreements** to address data gaps at launch
- **Balancing speed** to reimbursement versus regulatory approval

New capabilities for managing market access: Building cross-functional excellence and early value decisions

Innovative technologies require new capabilities to manage market access effectively. Key recommendations include reshaping teams around current priorities, making early, value-oriented decisions, incorporating payer perspective from the start, and ensuring comprehensive cross-functional involvement. By maximizing value creation and differentiation, companies can better navigate the challenges and seize the new opportunities of the reimbursement process and engage with payers to guide evidence generation.

Shaping constructive stakeholder relationships: Fostering trusted partnerships to achieve market success

The stakeholder landscape has shifted—payers, HTAs, patients, and healthcare providers are more involved in access decisions. Establishing constructive dialogues with external stakeholders is essential for favourable market access outcomes. Recognizing the evolving roles of these stakeholders and building trusted partnership will pave the way for successful access and reimbursement for innovative medical technologies.

- Adopting a Fully Integrated End-to-End Product Development Methodology to Maximize Asset Value, Syneos One, 2020
- Aligning Pharma's Strategy to Payers Priorities, Pharma USA News, 2024
- Comprehensive Market Access in MedTech, QOVIA MedTech, March 2025
- Innovation under Regulatory Uncertainty: Evidence from Medical Technology, PMC PubMed Central, J Public Econ, 2018
- Alternative Payment Models & Access Agreement Highlights, Wim Goettsch, World EPA Congress 2021
- How innovative companies leverage tech to outperform, Article McKinsey, Strategy & Corporate Finance, Dec. 2023
- Simplification for success: Rewiring the biopharma operating model, Article McKinsey, March 2025

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Conclusion

Payers and HTAs as the new power players: A new era of value-based healthcare decisions

The landscape has shifted towards prioritizing the perspective of payers and HTAs as gatekeepers of market access. Innovative technologies must demonstrate not only clinical efficacy but also prove their value for money. Aligning with the evolving expectations of these stakeholders is key to securing market access and ensuring the long-term success of innovative treatments. To remain resilient in this new environment, companies should redesign their operating model to create and sustain value.

Explanations and Literature

This article makes no claim to completeness and is not a scientific treatise. The focus is rather on the entrepreneurial perspective. The most important literature sources used for support are:

- How can health technology assessment be improved to optimize access to medicines? The European Journal of Health Economics, October 2023