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MArS
Market Access & Pricing Strategy

5-minute guide to:

Medical device reimbursement

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Medical device reimbursement refers to the process by which manufacturers, healthcare providers, and patients obtain financial coverage for medical devices from payers (government, insurers, or health funds).

Crucial for market access and commercial success, an effective reimbursement strategy considers national healthcare policies, clinical benefits, cost-effectiveness, and the product's classification within existing reimbursement systems.

In this 5-minute guide, our Executive Board Member Jörg Dogwiler and esteemed partner Dr Stefan Walzer, CEO of MArS, share an overview of the main reimbursement pathways for the EU & US, and some practical advice for overcoming the challenges.

Medical device reimbursement | EU

The EU does not have a centralised reimbursement system.

Each member state has its own healthcare structure and reimbursement mechanisms. Whether a product is reimbursed depends on national regulations, available evidence, and payer policies.

Main reimbursement pathways | EU

Diagnosis-Related Groups
(DRG System)

Fee-For-Service
(FFS)

Health Insurance Funds &
Private Insurers

Main reimbursement pathways | EU

Diagnosis-Related Groups (DRG System)

- Used in many EU countries for inpatient treatments
- Medical devices are often included in bundled hospital payments
- High-cost or innovative devices may require separate reimbursement (for example, additional payments or special funding schemes)

Main reimbursement pathways | EU

Fee-For-Service (FFS)

- **Common in outpatient settings**
- **Devices can be reimbursed individually if they have a designated reimbursement code**

Main reimbursement pathways | EU

Health Insurance Funds & Private Insurers

- In Germany, France, and the Netherlands, reimbursement may come from public health insurance or private insurers
- Some countries have centralised health funds for specific devices or therapies

Health Technology Assessment (HTA) in the EU

Many EU countries require an HTA evaluation to assess clinical and economic benefits.

HTA agencies (for example, HAS in France, IQWiG in Germany, and NICE in the UK) set high evidence standards for reimbursement decisions.

Market access timeline | EU

Depending on the country, reimbursement decisions can take 6 months to several years.

Fast-track pathways exist for highly innovative or cost-saving products (for example, France's Innovation-Fast-Track).

Medical device reimbursement | US

The US system is more centralised than the EU but has major differences between public and private insurers.

Main reimbursement pathways | US

Medicare & Medicaid

Private insurers

Hospital-based reimbursement

Main reimbursement pathways | US

Medicare & Medicaid

- **Medicare covers individuals aged 65+ and certain patient groups**
- **Medicaid covers low-income patients, with reimbursement policies varying by state**
- **The Centres for Medicare & Medicaid Services (CMS) determine device reimbursement eligibility**

Main reimbursement pathways | US

Private insurers

- Private insurers have the largest market share in the US, with varying reimbursement criteria
- They often follow Medicare's lead but may impose stricter coverage conditions

Main reimbursement pathways | US

Hospital-based reimbursement

- **Inpatient procedures are typically reimbursed through DRG-based payments**
- **Some high-cost devices qualify for separate add-on payments under the CMS New Technology Add-on Payment (NTAP) program**

Coding & reimbursement

Current Procedural Terminology (CPT) codes and Healthcare Common Procedure Coding System (HCPCS) codes are essential for medical device reimbursement.

International Classification of Diseases (ICD) codes are used for diagnosis-related billing.

New products often lack established coding, which can delay reimbursement approval.

FDA approval vs payer decisions

FDA approval does NOT guarantee reimbursement!

Payers require additional clinical and economic evidence beyond regulatory approval.

Real-world evidence (RWE) is becoming increasingly important for demonstrating cost-effectiveness.

Market access timeline | US

If your medical device fits existing reimbursement codes and coverage guidelines are in place, reimbursement can begin soon after FDA approval or clearance.

If your device is novel or innovative (i.e. with no existing codes):

- You may require entirely new billing codes and evidence development to justify coverage
- It typically takes 6 months to 2 years to obtain a new reimbursement code
- Securing coverage from payers can take several years (one study found the median time to Medicare coverage for new devices to be close to 6 years)

Key challenges for stakeholders

Diverse systems & processes	There are over 30 different reimbursement pathways in the EU, and there are major differences between Medicare, Medicaid, and private insurers in the US.
Comprehensive clinical evidence requirements	Payers demand randomised controlled trials (RCTs) and cost-effectiveness analyses, and HTA bodies set strict evaluation criteria.
Slow market access timelines	Reimbursement approvals can take years, making investment planning difficult, and some innovative products require real-world data before reimbursement is granted.
Lack of adequate coding & coverage	Many new devices do not fit into existing reimbursement categories, and without a proper billing code, providers may not receive payment.
Pricing pressure from payers	Health insurers and governments push for lower reimbursement rates, and manufacturers must justify pricing with strong cost-effectiveness arguments.

Practical tips to overcome reimbursement challenges

Engage early with payers & reimbursement experts

Plan your reimbursement strategies from the early development phase.

Generate strong clinical & economic data

Robust evidence is essential for market access and payer acceptance.

Collaborate with HTA Agencies & Key Opinion Leaders

Advocacy from experts can improve payer confidence.

Develop a coding strategy in advance

Ensure your product has a reimbursement pathway with appropriate billing codes.

Understand country-specific differences

Tailor your reimbursement strategies to different healthcare systems.

Use value-based pricing models

Demonstrate how your product reduces healthcare costs or improves outcomes.

Monitor regulatory & policy changes

Stay updated on EU MDR and US CMS reimbursement policies.

Leverage digital tools & automation

Optimise your reimbursement processes with artificial intelligence tools and platforms.

Should you have a medical device reimbursement challenge, our MedTech experts are ready and happy to help. Simply get in touch to start the conversation.

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