Three Systems, One Market? A Comparative Analysis of Medical Device Reimbursement in Germany, Austria, and Switzerland

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INTRODUCTION

While European pharmaceutical regulation has been partially harmonized, medical device reimbursement remains nationally fragmented—especially for inpatient technologies. This is highly evident in the DACH region, where Germany, Austria, and Switzerland pursue distinct reimbursement logics with varying levels of transparency, centralization, and reliance on evidence.

This comparative analysis seeks to decode the market access pathways for medical devices across the three countries, providing manufacturers with a strategic framework for regional launches1

METHODOLOGY

A comparative policy review was conducted using:

- Public payer and health system documentation and national reimbursement guidelines, Interviews with local market access experts and hospital procurement leads.

Focus dimensions included:

- Inpatient device inclusion mechanisms
- Role of HTA and clinical evidence
- Transparency and decision timelines
- Local vs. central payer authority

Special attention was paid to:

- Germany: NUB (Neue Untersuchungs- und Behandlungsmethoden) application process
- Austria: LKF-based DRG modifications via internal payer consultation
- Switzerland: Individual BAG (Gesuchsbasierte Abklärung) approvals

RESULTS

Germany uses the NUB (Neue Untersuchungs- und Behandlungsmethoden) pathway for hospital innovations not covered in existing DRGs. Applications are hospital-specific, non-centralized, and evaluated by the Institute for the Hospital Remuneration System (InEK). No formal HTA is required, but evidence of potential benefit and cost implications must be submitted.

Austria integrates devices via LKF catalog adaptations, guided by clinical societies and internal payer assessment. No public HTA body for devices exists; decision-making is opaque, slow, and heavily expert-driven.

Switzerland requires either SL inclusion (for outpatient products) or individual benefit approval by insurers (inpatient). There is no structured HTA for most devices, and reimbursement decisions vary widely across cantons and insurers.

Feature	Germany	Austria	Switzerland
Primary Route (Inpatient)	NUB application (InEK)	LKF catalog adjustments via internal committees	Case-by-case approvals by insurers; DRG assignment indirectly
Process Centralization	Decentralized – each hospital applies separately	Semi-centralized through Dachverband + scientific societies	Highly decentralized – varies by insurer and canton
HTA Involvement	No formal HTA, but clinical plausibility required	No formal HTA; expert-driven assessments	Rare use of HTA; SL evaluations limited to outpatient products
Evidence Requirements	Clinical and budget impact justification required	Non-standardized; varies by committee	Highly variable; often minimal requirements in inpatient setting
Transparency	Moderate – evaluation by InEK; results not always public	Low – opaque decision logic, no public access	Low – decisions rarely published
Reimbursement Timing	Annual NUB cycle (application in Q3; approval for next year)	Unclear timelines; may take >1 year	Variable; insurer decision times unpredictable
Coding Integration	DRG adjustment may follow NUB pilot	LKF updates integrated post-review	DRG and TARMED assignments depend on institutional negotiation

DISCUSSION

The heterogeneity of inpatient device reimbursement across DACH countries poses strategic challenges:

- Germany provides a structured yet decentralized pilot pathway (NUB) that allows hospitals to experiment with new technologies pre-DRG update.
- Austria's device integration relies on closed-door processes with no formal HTA function, making timelines and evidence standards unpredictable.
- Switzerland offers least transparency, especially in inpatient care, with insurer discretion dominating decisions.

Across all systems, manufacturers must proactively provide clinical and economic rationale, even where formal HTA is lacking.

CONCLUSIONS

Device reimbursement in Germany, Austria, and Switzerland is characterized by regulatory fragmentation, variable evidence expectations, and limited transparency.

Manufacturers should consider:

- Tailor launch sequencing to regulatory rhythm and institutional culture,
- Initiate early engagement with hospitals, scientific societies, or insurers,
- Develop robust clinical dossiers with budgetary impact models—even where no formal HTA is required,
- Monitor coding and DRG adaptation cycles.

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