Guidance on the Reimbursement of Medical Devices & Diagnostics in Germany

Bjoern Schwander
Germany Exporter Bootcamp; 28 April 2015
AHEAD supports clients in obtaining market access and reimbursement in Germany and in planning, generating and communicating health economic evidence.

Market Access and Reimbursement: Evaluation and implementation of market access strategies and of reimbursement strategies for medical devices, for diagnostics and for pharmaceuticals in Germany.

- e.g. Market Research, Reimbursement Situation Analysis & Road Map
- e.g. Evidence Summary & German Value Story
- e.g. Reimbursement Applications

Health Economic Evidence: Planning, generation and communication.

The AHEAD philosophy is to provide high-quality, product-specific and client-need-specific consulting & research activities that will be delivered on time.
Agenda: Guidance on the Reimbursement of Medical Devices & Diagnostics in Germany

- Reimbursement pathways (& related key stakeholders) for medical devices and diagnostics in Germany
- Key takeaways for planning a reimbursement strategy
- Clinical and health economic evidence requirements
- Outlook for the future
General Considerations related to the reimbursement of Medical Devices and Diagnostics in Germany

Medical Devices / Diagnostics
- there is no need to differentiate between medical devices and diagnostics (MD/D) as the reimbursement pathways are comparable in Germany.

Innovations / “Me-Too” Products
- for innovations reimbursement is a key issue; whereas “Me-Too” products are usually already reimbursable.

Application Setting: Inpatient / Outpatient
- Inpatient: MD/D applied in hospitalized patients (patient stays at least one night in hospital).
- Outpatient: MD/D applied by outpatient physicians, hospital outpatient centers or by patients (at home).
For market access and reimbursement of (innovative) MDs/Ds in Germany it plays a key role whether a MD/D is applied in the inpatient or in the outpatient setting.

**Inpatient**

All **innovative procedures are permitted** with the reservation of prohibition (‘Verbotsvorbehalt’ SGB V §137c)

Within the hospital (inpatient) new CE marked medical devices can **[currently]** be applied as long as they are not actively prohibited by the joint federal committee

The hospitals are allowed to apply all CE marked innovations

**Outpatient**

All **innovative procedures are prohibited** until they have been officially approved (‘Erlaubnisvorbehalt’ SGBV § 135;1)

Before a new medical device can be applied in the outpatient setting a positive voting from the joint federal committee is required

High evidence requirements in order to gain approval for applying innovations
There are several possible reimbursement pathways for innovative medical devices / diagnostics depending on the application setting:

**Inpatient**
- Adequate OPS/DRG available
  - Already reimbursed
  - OPS/DRG application
  - NUB (ZE) application
  - Application TR (Testing Regulation)

**Outpatient**
- ‘On-top payment required’
  - Additional evidence required
  - Used by patients (catalogue)
  - EBM/ GOÄ /IGeL Application
  - TAS Application
  - Selective Contracts

- Used by physicians (fee schedule)
  - Individual health insurance coverage
The inpatient reimbursement in Germany depends on whether adequate coding (OPS) and adequate coverage (DRG) is available - if not specific applications need to be performed.

**Inpatient Setting**

- Introduction of the DRG grouping system
- Step-wise research approach
- OPS application
- DRG application
- NUB application process
- Key Takeaways

**Diagram: Inpatient**

- Adequate OPS/DRG available
- New OPS/DRG required
- ‘On-top payment required’

1. Already reimbursed
2. OPS/DRG application
3. NUB (ZE) application
For the reimbursement of inpatient services in Germany a DRG based system is used: Specific DRGs are defined by a combination of disease (ICD) and procedure (OPS) coding.

ICD-GM Coding

German version of the International Statistical Classification of Diseases and Related Health Problems (ICD)

OPS Coding

German version of the International Classification of Procedures in Medicine (OPS = Operationen- und Prozedurenschlüssel)

Specific G-DRG

German Diagnosis Related Groups that are linked to a specific reimbursement value
Obtaining the inpatient reimbursement strategy is a step-wise approach and in the best case it might be obtained that an adequate DRG reimbursement is already available.
Scenario 2 - after performing an initial coding/coverage research it is obtained that changes in the OPS and/or DRG are required in order to achieve an adequate reimbursement.

**OPS application**

DIMDI (German Institute of Medical Documentation and Information) provides an application form and is the addressee of the OPS application.

**Deadline** for OPS changes in the following year is **end of February** in the current year.

The responsible German Medical Society should be involved.

**DRG application**

InEK (Institute for the Hospital Remuneration System) provides an application form and is the addressee for DRG applications.

**Deadline** for DRG changes in the following year is **end of February** in the current year.

The responsible German Medical Society should be involved.
Scenario 3 - after performing an initial coding/coverage research it is obtained that an ‘on-top payment’ is required in order to achieve adequate reimbursement.

**InEK**

InEK provides an application form and is the addressee for NUB (Neue Untersuchungs- und Behandlungsmethoden) applications.

**Deadline for NUB applications in the following year is end of October in the current year.**

Each hospital needs to submit an own NUB application – the InEK decides whether a ‘on-top payment’ can be negotiated.

**Application Form**

- Form is released in September.
- Submission deadline is end of October.
- Decision is released end of January of the following year and the NUB is then valid.
Key Takeaways: The inpatient reimbursement process is clearly structured and there is (currently) no need to provide detailed evidence during the application process.

- For the application of a new medical device / diagnostic in the inpatient sector only a CE mark is required.

- The reimbursement fee of a new medical device / diagnostic depends on the available coding, grouping & coverage options.

- In a first research step an initial coding / coverage research should be performed in order to identify the best strategy for an (innovative) medical device / diagnostic.

- For each reimbursement pathway there are specific application procedures available – with a clear process & timing structure.

- There is (currently) no need to provide detailed clinical or health economic evidence during the inpatient reimbursement application process.
For the outpatient reimbursement there are different strategies available – the best one would be obtaining inclusion in the official fee schedules / catalogues for outpatient services.

### Outpatient Setting
- Fee schedule inclusion
- Therapeutic appliance schedule inclusion
- Initiation of selective contracts
- Testing Regulation
- Combined strategy proposal
- Key Takeaways

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**Application**

1. **TR (Testing Regulation)**
2. **EBM/ GOÄ Application**
3. **TAS Application**
4. **Selective Contracts**
5. **Individual health insurance coverage**
6. **Used by patients (catalogue)**
7. **Used by physicians (fee schedule)**
8. **Additional evidence required**
Scenario 4 – the fee schedule of the statutory health insurance (EBM) and the private health insurance (GOÄ/IGeL) are valuable reimbursement options for outpatient services

**Fee Schedules**

**EBM inclusion**

- **Gemeinsamer Bundesausschuss**
  - The joint federal committee (G-BA) decides on ambulatory procedures covered by the statutory health insurance
  - An application needs to present the detailed clinical and economic consequences and should be submitted to the G-BA in form of a consultation request (SGB V §137e)
  - A value dossier (rapid HTA) for Germany needs to be submitted to the G-BA

**GoÄ/IGeL inclusion**

- **The German Medical Association (Bundesärztekammer)** is responsible for applications related to the private health insurance fee schedule (GOÄ)
  - An application needs to summarize the available clinical and economic evidence of the procedure
  - The application should be submitted by a medical KOL
Scenario 5 ‘TAS Inclusion’ and scenario 6 ‘Selective Contracts’ represent alternative reimbursement scenarios for outpatient procedures in Germany.

**TAS Inclusion**

The SHI umbrella organization decides on the inclusion of medical devices/aids into the therapeutic appliance schedule (TAS).

- CE marking is the most important precondition for applications for inclusion in the therapeutic appliance schedule.
- In case that an innovative medical device/aid has therapeutic capacities a G-BA consultation is necessary.

**Selective Contracts**

From 1st January 2012 on the statutory health insurances are allowed to reimburse innovative outpatient procedures (SGB V § 11(6)).

- Precondition is that a procedure has not been excluded from reimbursement by the joint federal committee (see EBM inclusion).
- A strong clinical and economic argumentation is required in order to convince individual health insurance funds.
Scenario 7 – a new strategy to obtain (in- or outpatient) reimbursement for innovative medical devices in Germany is the application for a ‘Testing Regulation’

**TR application**

The joint federal committee (G-BA) decides on whether a medical device is suitable for the ‘Testing Regulation’ program.

An TR application needs to point out the potential of a new method (strong innovative potential and a high unmet need); the manufacturer needs to carry a specific part of the clinical research costs.

Medical device manufacturers are allowed to apply for such an experimental coverage by using the specific forms provided by the G-BA.

**Application Form**
Especially for medical devices applied in the outpatient sector, the ‘testing regulation’ program provides an additional valuable reimbursement access strategy.

Submission of a Rapid HTA Report to the G-BA

Consultation Request according to SGB V § 137e

Is the available evidence regarded as adequate?

- **YES** → G-BA application
  - **EBM / TAS Inclusion**
  - **Testing Regulation Application**
  - **Consider IGeL Inclusion / Selective Contracting**

- **NO** → Strong innovative potential & unmet medical need?
  - **YES**
  - **NEGATIVE**
Key takeaways: The outpatient reimbursement process is quite diverse and requires to provide specific clinical and health economic evidence during the application process.

- For the application of a new MD/D in the outpatient sector a positive reimbursement decision is mandatory.
- The consultation request allows manufactures (the first time) to apply for reimbursement directly at the G-BA (usually applications were only possible by G-BA members).
- The first strategy should be to apply for inclusion in the EBM (SHI) and GOÄ (private health insurance) or the TAS (SHI medical aids) fee schedules.
- The ‘Testing Regulation’, the ‘IGeL inclusion’ (out-of-pocket payment) and the ‘Selective Contracting’ (coverage by single/local health insurances) should be seen as fallback strategies.
- It is mandatory to provide detailed clinical and health economic evidence during the application process.
There are several opportunities to obtain reimbursement for an innovative medical device in Germany but there are great differences in the evidence requirements.
Currently MDs&Ds used in the inpatient setting require no detailed evidence whereas strong clinical & health economic evidence is required for MDs&Ds used in the outpatient setting.

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<th>Clinical Evidence Requirement</th>
<th>Health Economic Evidence Requirements</th>
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<td>No Evidence</td>
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<td>All available Evidence (incl. CA)</td>
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<td>Full Economic Evaluation</td>
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<td>EBM / TAS*</td>
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TAS* = Medical Devices that are applied by the patient at home with therapeutic capacities.
Outlook for the future

- New SHI supply fortification law (SHI-Versorgungsstärkungsgesetz) expected to be adopted in July 2015.

- According to this law (even inpatient) MD / D of the risk classes IIb and III need to be assessed by the G-BA; it is not yet known how the process will look like.

- Hence for such MD / D the NUB process will be accompanied by a G-BA assessment.

- In case that this regulation would be aligned with the process for pharmaceuticals this would mean that a detailed clinical and health economic evidence reporting might be required; even if they are applied in the inpatient setting.
In the future the reimbursement process for class IIb and class III MDs&Ds applied in the inpatient setting will require detailed clinical & health economic evidence.

TAS* = Medical Devices that are applied by the patient at home with therapeutic capacities

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**Legend**

- NUB: National Uniform Code
- EBM: Evidence-Based Medicine
- TAS*: Medical Devices that are applied by the patient at home with therapeutic capacities

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We invite you to benefit from our more than 14 years of experience in clinical and health economic outcomes research and market access in order to bring your product AHEAD.

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