Guidance on the Reimbursement of Innovative Medical Devices in Germany

Agency for Health Economic Assessment
and Dissemination

AHEAD supports clients in **obtaining market access and reimbursement in Germany** and in planning, generating and communicating the **product value / 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
- **Product Value / 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

Introduction on the German healthcare system

- The German health insurance system is based on the Bismarck social insurance system. Germany has a population of **≈ 83 million**, **≈90% (73 million)** of whom are covered by one of 110 (Januar 2018) **statutory health insurance funds** (SHIs) and **≈10% by private insurance** (access limited by minimum income level)
- There is only limited competition on products on services between the funds
- **All SHIs provide the same key services** as **defined by the joint federal committee** (Gemeinsamer Bundesausschuss – G-BA)
- **Private insurance** covers **nearly the same services (especially related to pharmaceuticals and inpatient services)** but allows additional benefits (e.g. first class service)
- The framework for health care in Germany is based on central decision making:
  1. Legislation established by the parliament,
  2. **Decrees issued by the Ministry of Health,**
  3. **Directives issued by the G-BA** under supervision of the ministry, and
  4. **Contracts between self-governing organizations** under supervision of the ministry.

For market access and reimbursement of (innovative) medical devices in Germany it plays a key role whether it 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 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 (however reimbursement might be an issue)

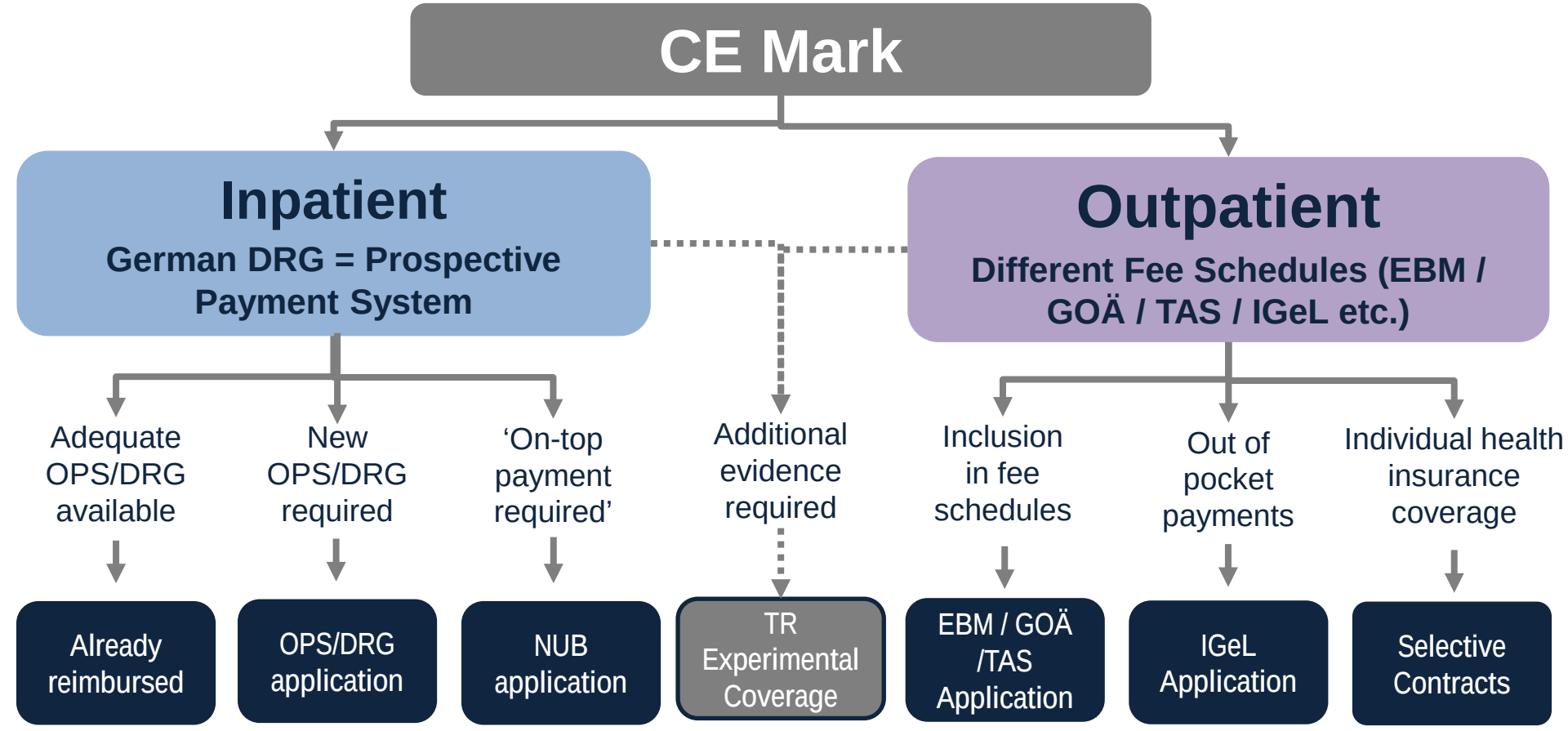
Outpatient

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 specific applications (e.g. joint federal committee or umbrella organization of statutory health insurances) need to be performed

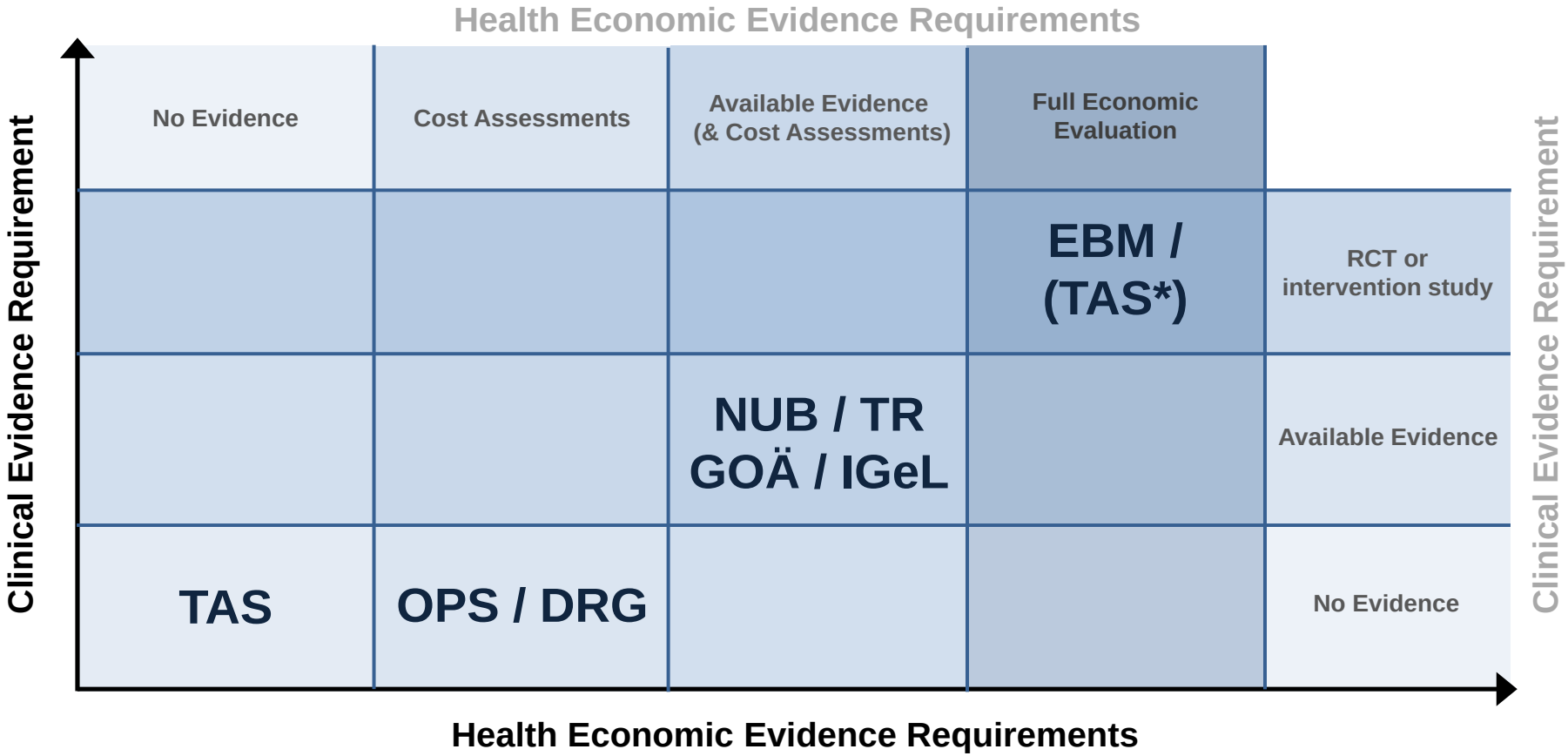
Specific evidence requirements in order to gain approval for applying innovations

There are several possible reimbursement pathways for innovative medical devices depending on whether a medical device is applied in the inpatient or in the outpatient setting



OPS=German Procedure Coding; DRG=Diagnoses Related Groups; NUB=New Diagnosis & Therapy Methods; EBM=Statutory Health Insurance Physician Fee Schedule, GOÄ=Private Health Insurance Physician Fee Schedule; TAS = Therapeutic Appliance Schedule; IGeL=Individual Health Services; TR = Testing Regulation

Clinical and Health Economic Evidence Requirements for the Reimbursement of Innovative Medical Devices in Germany



OPS=German Procedure Coding; DRG=Diagnoses Related Groups; ;MD = Medical Device; NUB=New Diagnosis & Therapy Methods; EBM=Statutory Health Insurance Physician Fee Schedule, GOÄ=Private Health Insurance Physician Fee Schedule; TAS = Therapeutic Appliance Schedule; IGeL=Individual Health Services; (TAS*) = Medical Devices that are applied by the patient at home with therapeutic capacities;

Key Takeaways

- **Usually innovative Medical Devices applied in the German inpatient setting require no specific evidence whereas strong clinical and health economic evidence is required for MDs applied in the German outpatient setting**.
- A special case are first “NUB” applications for methods that are largely based on a high-risk class medical device, and on a new theoretical-scientific concept (SGBV § 137h) – here a G-BA appraisal might be kicked on.

Further Reading

- Busse R, Blümel M. Germany: Health system review. Health Syst Transit. 2014;16(2):1-296, PMID: 25115137 http://www.euro.who.int/__data/assets/pdf_file/0008/255932/HiT-Germany.pdf?ua=1
- NUB Application: https://www.mig.tu-berlin.de/fileadmin/a38331600/2009.lectures/Innsbruck_2009.06.22.ch_EHMA.pdf
- Testing Regulation: Assessments of potential § 137e SGB V: https://www.iqwig.de/en/methods/results/assessments-of-potential.3321.html
- Assessments according to §137h SGB V: https://www.iqwig.de/en/methods/results/assessments-according-to-137h.7606.html

We invite you to benefit from our 18 years of experience in clinical and health economic outcomes research and market access in order **to bring your product AHEAD**

Bjoern Schwander

General Manager

AHEAD GmbH
Waschhausgasse 17
D-79540 Loerrach, Germany
Homepage: www.ahead-net.de

Phone + 49 (0) 7621 583 8125
Fax + 49 (0) 7621 583 8153
Mobile + 49 (0) 1577 194 8125
E-Mail bjoern@ahead-net.de