D+B
RECHTSANWÄLTE

Medtech Market Access Germany

The legal perspective

MEDICA

Düsseldorf, November 11th, 2024

Dr. Tobias Volkwein
Specialised Lawyer for Medical Law

Agenda

01

Key **principles**

02

The different legal **pathways**

03

The different legal **requirements**

04

Considerations

05

Current **topics**

D+B
RECHTSANWÄLTE

01

Key **principles**

Key **principles**

D+B RECHTSANWÄLTE

Separate procedure-orientated process:

› Reimbursement of medical devices in the German Social Health Insurance (SHI) is

- separate to the regulatory process of a medical device (CE certification), mainly regulated by the MDR / IVDR
- regulated in an Act called Social Code Book V („*SGB V*“)
- not product-specific, but **procedure-orientated** („**methods**“)
- Providing a special category of „**medical aids**“ (in the outpatient sector)

Reimbursement of methods:

› The system mainly regulates new examination and treatment methods

› It has to be differed between

- Outpatient sector: prohibition with reservation of permission („*Verbot mit Erlaubnisvorbehalt*“)
- Inpatient sector: permit with reservation of prohibition („*Erlaubnis mit Verbotsvorbehalt*“)

D+B
RECHTSANWÄLTE

02

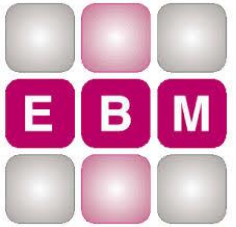
The different legal **pathways**

Reimbursment pathways

D+B RECHTSANWÄLTE

Ambulatory sector (out-patient)

- „prohibition with reservation of permission", Sec. 135 SGB V
- committee for rating office-based doctors' service ("*Bewertungsausschuss*")
- Determination of methods in doctor's fee scale („*Einheitlicher Bewertungsmaßstab*, **EBM**")
- Special case: **medical aids**, Sec. 33, 127 SGB V



Stationary sector (in-patient)

- „permit with reservation of prohibition", Sec. 137c SGB V, Sec. 6 para 2 KHEntgG (Law for payment of services provided by hospitals)
- Determination in DRG / additional fees / new "NUB" fees by InEK (Institute for the Hospital Remuneration System)
- **Special requirements** for high-risk class medical devices according to Sec. 137h SGB V

"testing procedure" (Erprobungsverfahren")

- In cases of an **unproved benefit** of a new examination or treatment method , the Federal Joint Committee (G-BA) can start a testing procedure according to Sec. 137e SGB V
- Applicable in the out-patient sector **and** in the in-patient sector
- Also **manufacturers can request** a testing procedure

D+B
RECHTSANWÄLTE

03

The different legal **requirements**

Ambulatory sector (out-patient) – <u>covered by EBM?</u>

prohibition with reservation of permission

- *New examination and treatment methods* may only be provided at the expense of the health insurance funds
  - **if G-BA has issued recommendations in the EBM** on in particular
    - the recognition of the diagnostic and therapeutic benefit of the new method as well as
    - its medical necessity and cost-effectiveness

- **Parties entitled for a request:**
  - Association of Statutory Health Insurance Physicians,
  - the National Association of Statutory Health Insurance Funds
  - <u>Not</u>: Manufacturers

- But: It is a „**Service“ and no „method**“, no amendment of EBM is necessary
  - Wide understanding of the term „method“: the decisive factor is **how much the respective procedure differs from services according to the EBM** (e.g. technical developments will often be new services and not new methods)
  - Whether it is a new service or a new method can be answered by the evaluation committee in an information procedure in accordance with Section 87 (3e) sentence 4 SGB V that **can be requested also by a manufacturer**

https://www.kbv.de/tools/ebm/

Special case (product-specific remuneration) in out-patient sector: medical aids, Sec. 33, 127 SGB V

D+B RECHTSANWÄLTE

If your product is a medical aid,

1) get onto the Medical Aids Register and
2) sign contract(s) with SHI(s)

then: reimbursement irrespective of EBM!

Contracts according to Sec. 127 SGB V

- Para 1: SHI has the obligation to negotiate care agreements with **qualified service providers**
- Para 2: Service providers may join existing agreements with the same conditions agreed with other providers

General requirements for a Qualified Service Provider

- "Prequalification": Sufficient, appropriate and functional
  - production
  - delivery and
  - adaption of Medical Aids
- Certification by **accredited Prequalification Bodies**

Stationary sector (in-patient)

permit with reservation of prohibition

- Sec. 137c para. 1, 3 SGB V:
  - G-BA shall **only at the request of** in particular the GKV-SV review *new examination and treatment methods*
  - **Prior to such request – reimbursement, if method shows the potential of a necessary treatment alternative and their use is in accordance with the rules of medical practice**, i.e. they are medically indicated and necessary.
- But: also **check the hospital remuneration code for covering:**
  - Sec. 6 para. 2 KHEntgG (Law for payment of services provided by hospitals):
    - Hospitals shall agree **NUBs** for the remuneration of *new examination and treatment methods* not appropriately remunerated with the DRGs or additional fees
  - **Before**, **the hospital must obtain information from the InEK by October 31 at the latest** as to whether the new method can be reimbursed appropriately using the DRGs and supplementary fees already agreed

“Testing procedure” (Erprobungsverfahren”) according to Sec. 137e SGB V

D+B RECHTSANWÄLTE

- Applicable to both settings (in-patient as well as out-patient remuneration)
- **Situation**: G-BA comes to the conclusion that a method
  - offers **the potential of a necessary treatment alternative**,
  - but its benefit has **not yet been sufficiently proven**
- Then G-BA must **simultaneously adopt a guideline for testing while suspending its evaluation procedure** in order to gain the necessary knowledge for evaluating the benefit of the method
- **Temporary reimbursement**, Sec. 137e para. 1 s. 2 SGB V
- Also **manufacturers can request** a testing procedure, Sec. 137e para. 7 SGB V

Special requirements for high-risk class medical devices according to Sec. 137h SGB V

D+B RECHTSANWÄLTE

- Situation: hospital requests for remuneration acc. to Sec. 6 para. 2 KHEntgG of a *new examination or treatment* method **largely based on the use of a medical device with a high risk class for the first time**

- Medical devices **with a high risk class:**
  - **assigned to risk class IIb or III** in accordance with Article 51 in conjunction with Annex VIII [MDR] **and**
  - **whose use is particularly invasive in nature**

- Only applicable to methods **with new theoretical-scientific concept**

- **Consequence:** requesting hospital must, in agreement with the manufacturer of the medical device, provide the G-BA **in particular with data on the clinical benefit and complete data on clinical studies conducted with the medical device**.

- On the basis of the information provided, the Federal Joint Committee shall assess **within three months** the benefit of the method using the medical device
  - In case neither the benefit nor the harmfulness or ineffectiveness of the method using the medical device is to be regarded as proven, G-BA **also starts testing procedure acc. to Sec. 137e SGB V**

D+B
RECHTSANWÄLTE

04

Considerations

Considerations

D+B RECHTSANWÄLTE

- In Germany, it makes a big difference whether your procuct is mainly targeting the in-patient or out-patient sector

- In the out-patient sector, check whether **your product can**
  - **either be reimbursed as a medical aid, or**
  - **within an existing method provided in the EBM**

- In the in-patient sector, check whether your product is covered by an existing DRG/additional fee or not
  - If not, you need to cooperate with a hospital to request a NUB
  - Please be careful in case of a medical device **with a high risk class to be able to prove the clinical benefit**

- In unclear cases, the „testing procedure“ applicabe for both sectors can be a good choice, since it **serves for temporary remuneration and can be requested by the manufacturer** itself

D+B
RECHTSANWÄLTE

05

Current **topics**

Current developments in Germany and Europe

D+B RECHTSANWÄLTE

› „Medical Research Act“

- New Act strengthening medical research in Germany adopted end of October 2024
- It also applies to medical devices and provides some measures mainly relating to clinical studies.
- For instance, the law introduces the usage of **standard clauses** in clinical trial agreements (which applicability will of course still last a while).
- Further, new joint guidelines for the assessment of clinical studies to be drafted

› EU HTA Regulation 2021/2282

- Subject to joint clinical assessment are as of 12/01/2025:
  - **Also certain medical devices** classified as class IIb or III MDR
  - **subject to selection** pursuant to Art. 7 para. 4 EU HTA:
    - unmet medical needs;
    - first in class;
    - potential impact on patients, public health or healthcare systems;
    - incorporation of software using artificial intelligence, machine learning technologies or algorithms;
    - significant cross-border dimension;
    - major Union-wide added value.

D+B
RECHTSANWÄLTE

Thank you for your attention and patience!

Kontakt

D+B Rechtsanwälte Partnerschaft mbB

Kurfürstendamm 195
10707 Berlin
+49 30 327 787 0

Kaistraße 2
40221 Düsseldorf
+49 221 41 55 77 70

Theresienstraße 1
80333 München
+49 89 20 500 850 21

Av. de Tervueren 40
B-1040 Brüssel
+32 2 743 09 19

www.db-law.de