

# The German MedTech market

Training Webinar:  
Market figures and facts  
January 2026



1. Introduction and National Med Tech Market
2. National Health System
  - National Health Care Market
  - Public and private health care System
3. Market Drivers
  - Reimbursement system
  - Market access
  - reimbursement assessment
  - reimbursement-process and forms
4. Key topics to have to know for reaching the Market
  - AOB
  - Q&A

## 1. Introduction and National Med Tech Market

### 2. National Health System

- National Health Care Market
- Public and private health care System

### 3. Market Drivers

- Reimbursement system
- Market access
- reimbursement assessment
- reimbursement-process and forms

### 4. Key topics to have to know for reaching the Market

- AOB
- Q&A

## The German medtech industry at a glance



**Around 500,000** different **medical devices** on the market in Germany



Over **210,000 jobs**

**450,000 jobs** (total economic employment impact)



**1,510** companies with over 20 employees

**12,000** micro-enterprises

**93% SMEs**



**€41.4 billion** in production

**55 billion** with small businesses



**€19.7 billion** added value



**68%** export ratio



**9%** of turnover is invested  
invested in R&D



# The medtech industry as an economic factor

The industry is characterised by SMEs, is highly innovative and has strong export performance

## 1.

### **Important economic and labour market factor**

- Export quota around 68%
- Turnover in 2023: €41.4 billion (including small businesses, even around €55 billion)
- Over 210,000 employees

## 2.

### **Predominantly small and medium-sized enterprises**

93% of companies have fewer than 250 employees

## 3.

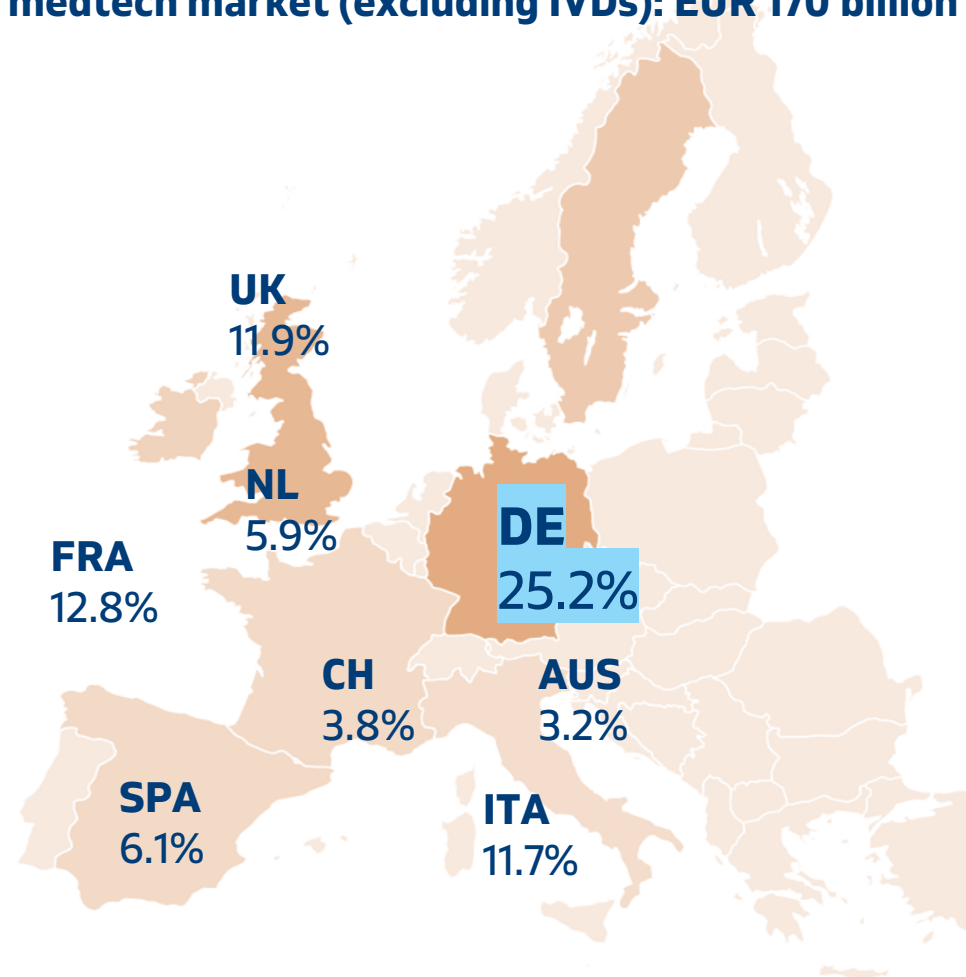
### **Highly innovative – short product cycles**

- 1/3 of turnover generated by products that are less than 3 years old
- 9% of turnover in R&D

# MedTech market in Europe by revenue in 2024

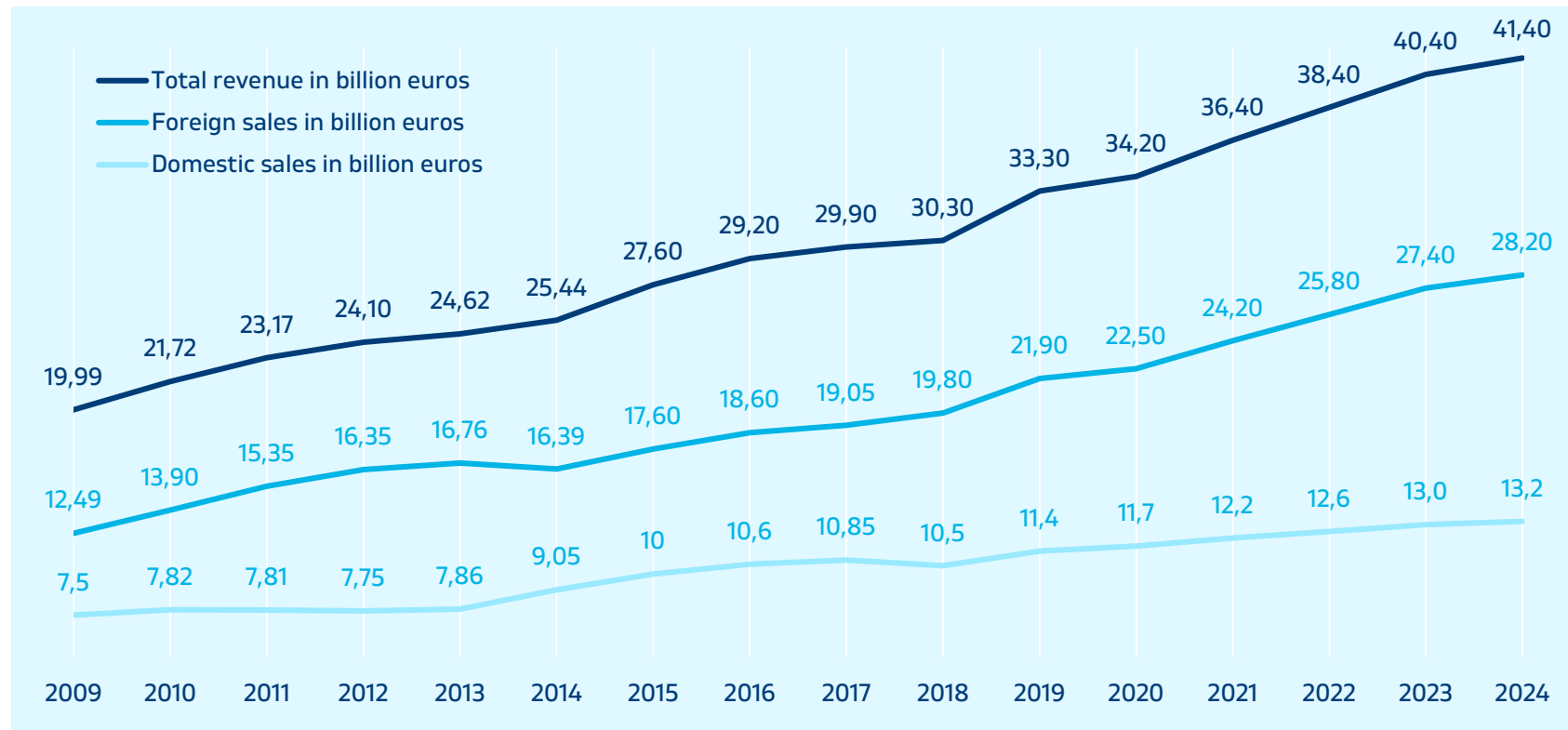
Shares of individual countries in the total European medtech market (excluding IVDs): EUR 170 billion in revenue

- Total revenue (excluding IVDs): EUR 170 billion
- Second largest market after the USA
- 37,000 companies
- 90 per cent SMEs
- Over 930,000 employees
  - *Comparison with pharmaceuticals: 900,000*



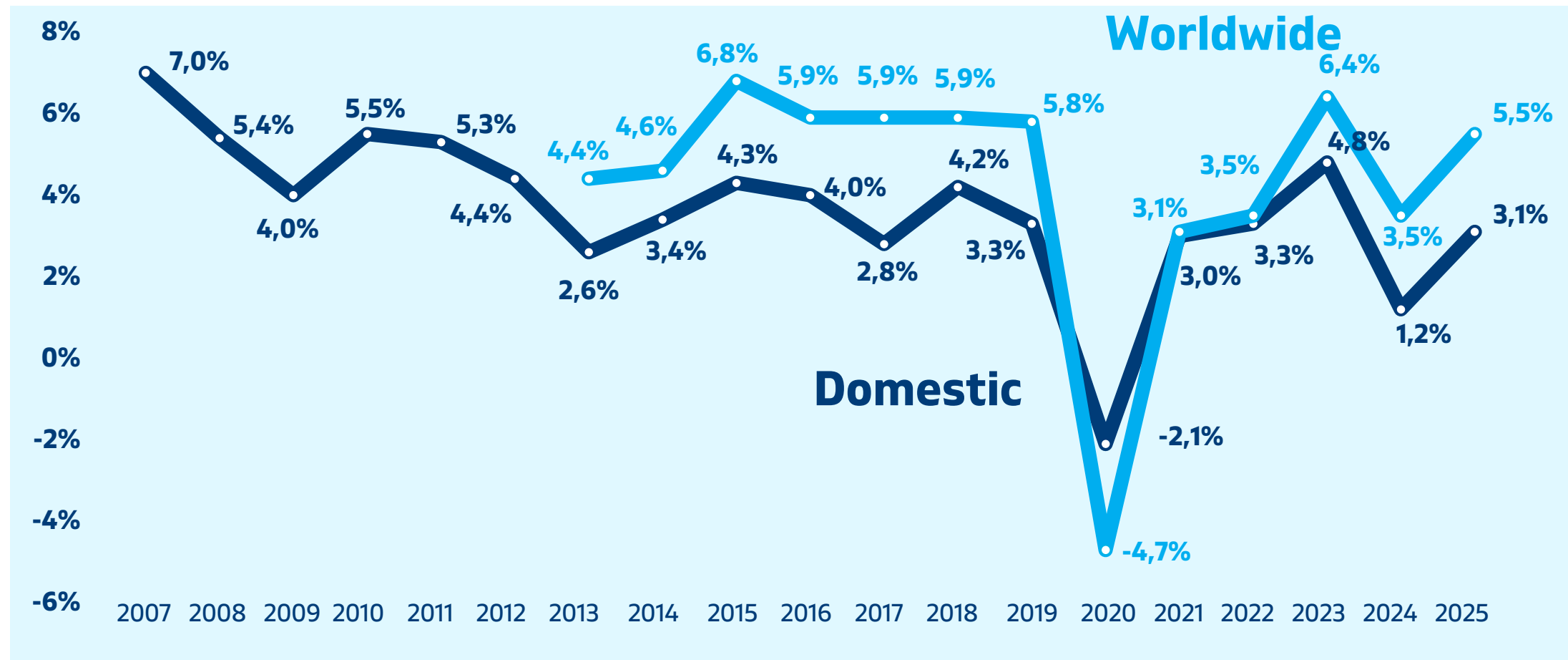


# Sales in the medical technology industry in Germany 2009–2024



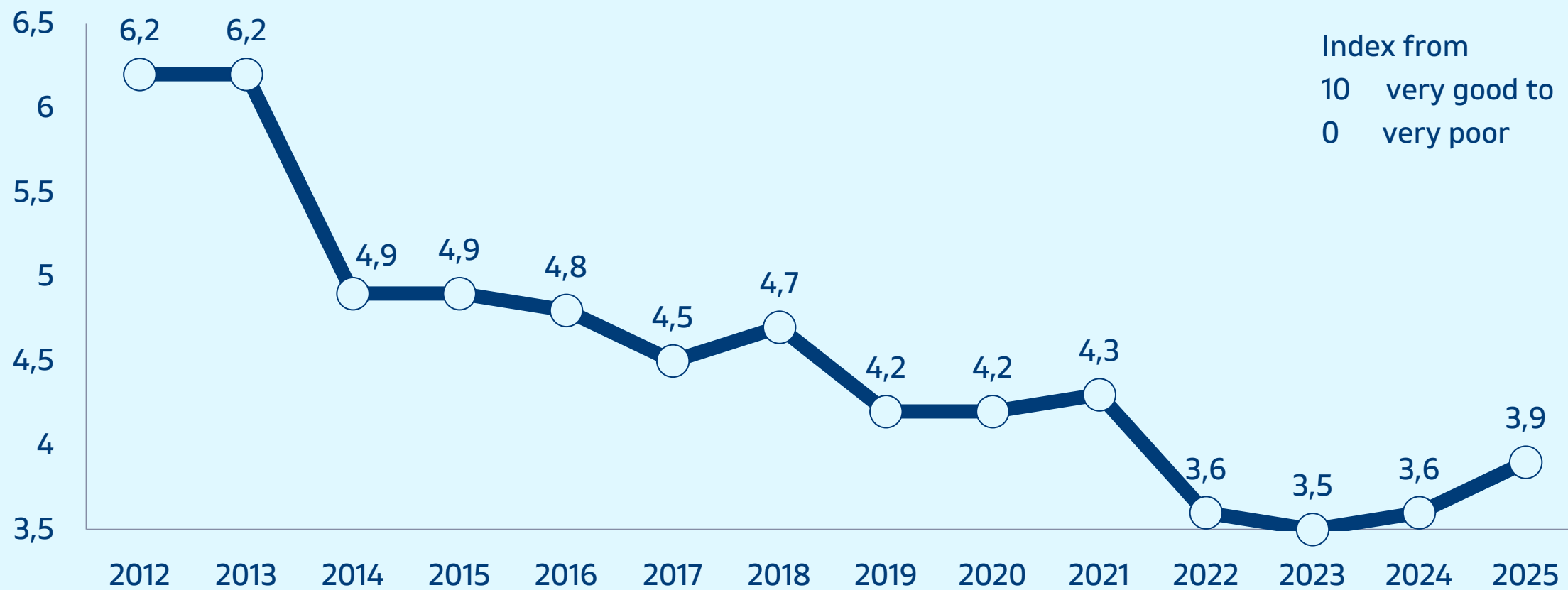
**68 per cent goes  
in exports!**

## Expected sales development 2007–2025





# MedTech Innovation Climate Index 2012–2025



## 1. Introduction and National Med Tech Market

## 2. National Health System

- National Health Care Market
- Public and private health care System

## 3. Market Drivers

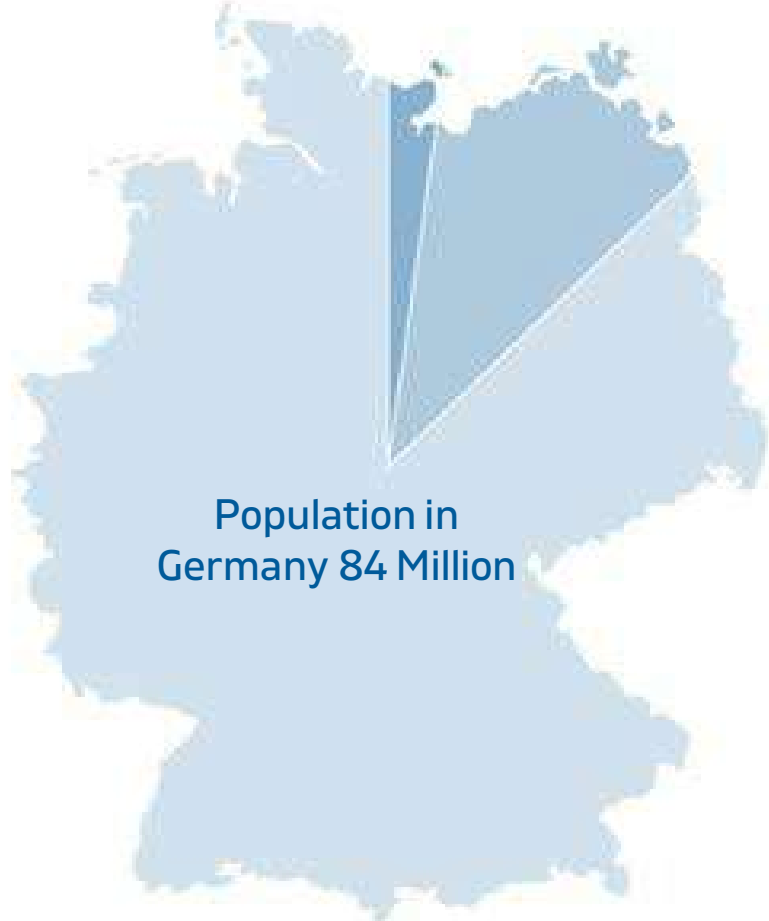
- Reimbursement system
- Market access
- reimbursement assessment
- reimbursement-process and forms

## 4. Key topics to have to know for reaching the Market

- AOB
- Q&A

# The majority of people in Germany have statutory health insurance

## “Gesetzliche Krankenversicherung (GKV)”



**75 Million Statutory health insurance (GKV) insured persons**

**88%**

**9 million Private health insurance companies**

**11%**

**1 million other \***

**1%**

\* Entitlement to health care as Social welfare recipients, war damage pensioners, recipients of maintenance assistance out of dem Equalization of burdens, free Police medical care and the German Armed Forces, uninsured persons, without indication of the existence of a health insurance

# Statutory health insurance (GKV)



AOK General local health insurance  
Allgemeine Ortskrankenkassen

BKK Company health insurance  
Betriebskrankenkassen

IKK Guild health insurance  
Innungskrankenkassen

KBS Miners guild-Railway-Sea  
Knappschaft-Bahn-See

LKK Agricultural Health insurance  
Landwirtschaftliche Krankenkasse

EK Association of Substitute Health Insurance (Ersatzkassen)

TK Technicians Health Insurance (Techniker Krankenkasse)

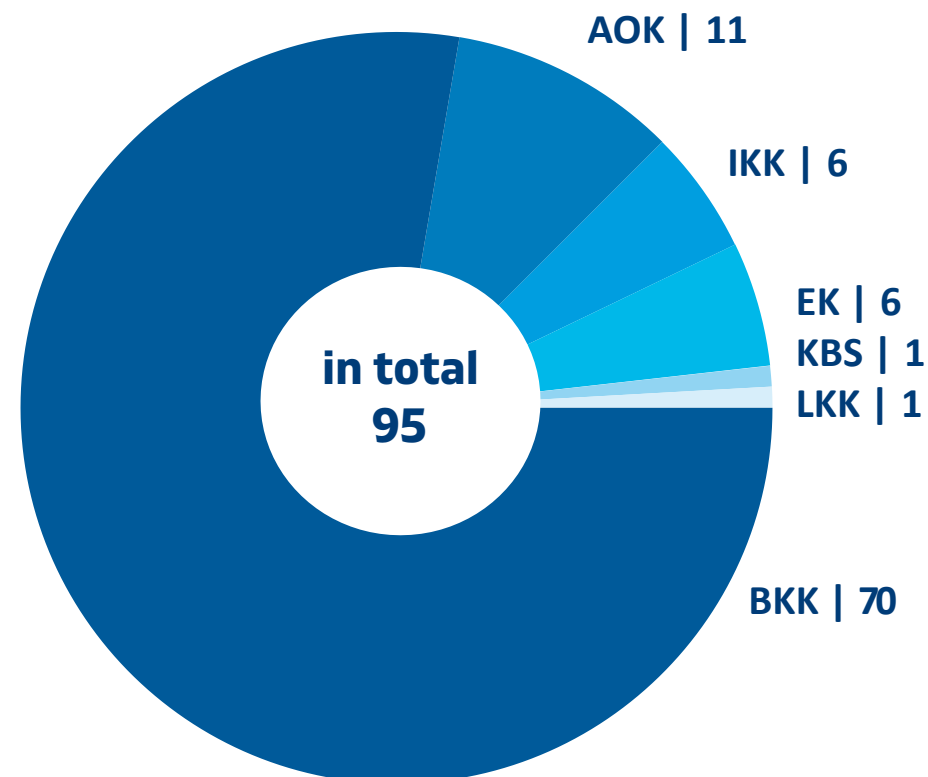
BARMER

DAK German employees' health insurance (Deutsche Angestellten Krankenkasse)

KKH Commercial health insurance (Kaufmännische Krankenkasse)

Hkk Commercial health insurance (Handelskrankenkasse)

HEK Hanseatic Health insurance (Hanseatische Krankenkasse)



# The insured persons in the statutory health insurance (GKV)

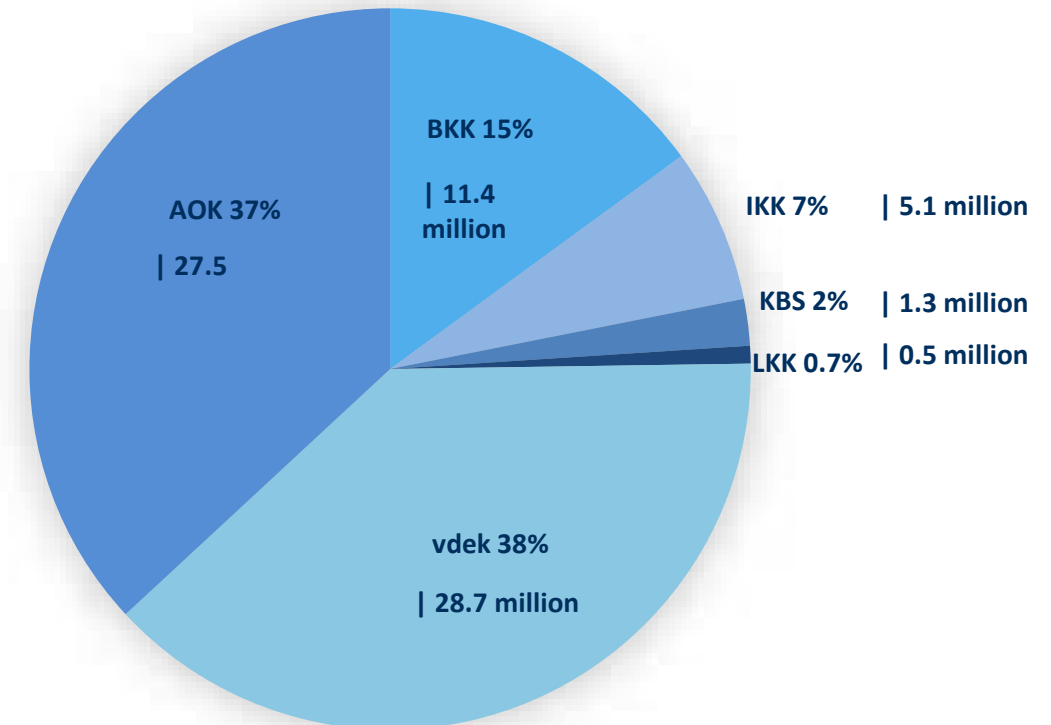


## 75.0 million insured persons

- 58.8 million GKV-members including pensioners
- 35.2 million (60.1%) compulsory members
- 15.9 million non-contributory insured persons

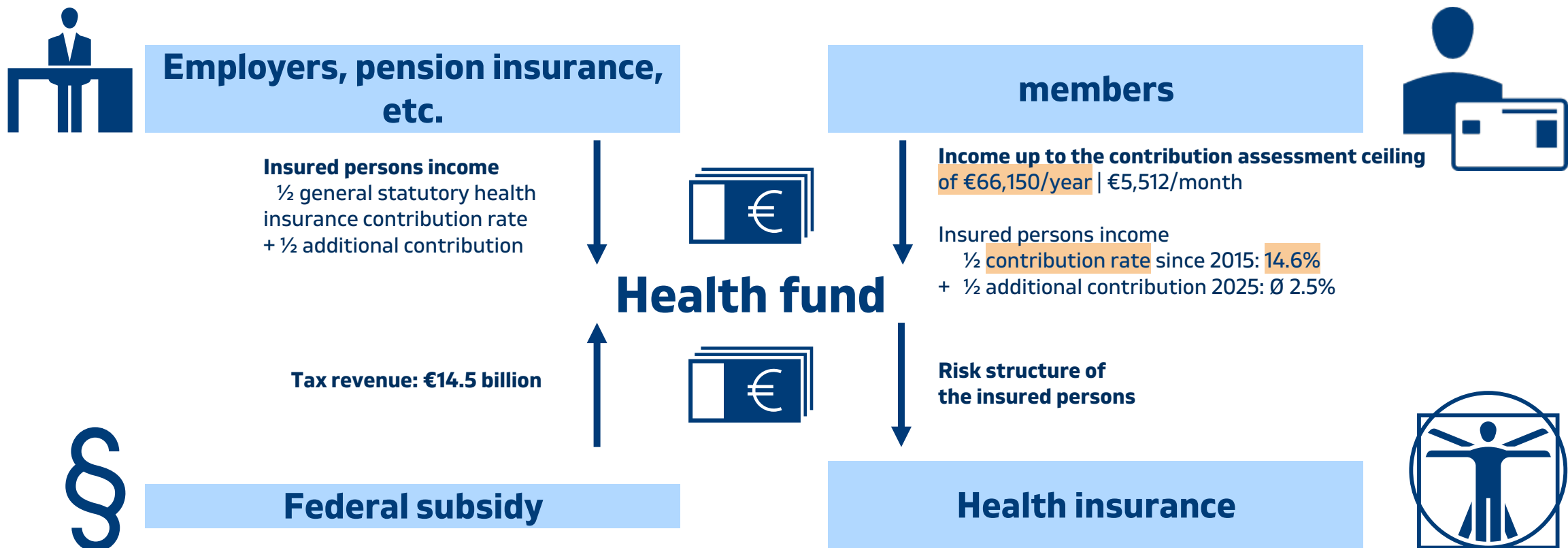
## Obligation to take out health insurance :

- employees (2024: to 69.300 € / 5,775 € )
- trainees and interns
- unemployed
- pensioner
- students
- etc.



# Revenues of statutory health insurance funds

in 2024: 284.2 billion euros



# Reimbursement principles

## comparison of statutory and private health insurance

### Statutory health insurance (GKV)

#### principle of benefits in kind

- Health insurance provides healthcare services

### Private health insurance (PKV)

#### Cost reimbursement principle

- The insured person pays the costs of the treatment.
- Private health insurance reimburses costs

Doctors who treat patients insured by a private insurance company charge according to the so-called Scale of Fees for Doctors (GOÄ).

Material costs are reimbursed separately in accordance with § 10 GOÄ.



# Services of the statutory health insurance



## entitlement to benefits

- > prevention of diseases and their worsening
- > early detection of illness
- > treatment of illness
- > transition in various supply areas

## Benefit in kind

- drug
- bandages
- aids
- Digital Health Services ( DiGA )
- drug-like medical devices

## Service

- > information / advice
- > medical / dental treatment
- > hospital
- > cures
- > remedies



# Requirements for the reimbursement of medical devices in Germany

1. **CE marking (proof of safety and performance)**
2. **Quality and effectiveness of services (§ 2 SGB V)**
3. **Principle of economic efficiency (§ 12 SGB V)**
4. **Listing in the list of assistive devices (§ 139 SGB V)**
5. **A doctor's prescription is usually required.**
6. **Contractual remuneration agreements**



1. Introduction and National Med Tech Market
2. National Health System
  - National Health Care Market
  - Public and private health care System
- 3. Market Drivers**
  - **Reimbursement system**
  - **Market access**
  - **reimbursement assessment**
  - **reimbursement-process and forms**
4. Key topics to have to know for reaching the Market
  - AOB
  - Q&A

# Material Costs



## Prohibition Requirement (§ 137c SGB V)

- Capital goods
- Consumables
- Case-based lump sum
- Additional remuneration (ZE)
- NUB (New Examination and Treatment Methods)



## Permission Requirement (§ 135 SGB V)

- EBM code
- Agreement on material costs
- Agreement on consultation hour requirements
- Invoice



## Approval (Prescription) (§ 31, 32, 33 SGB V)

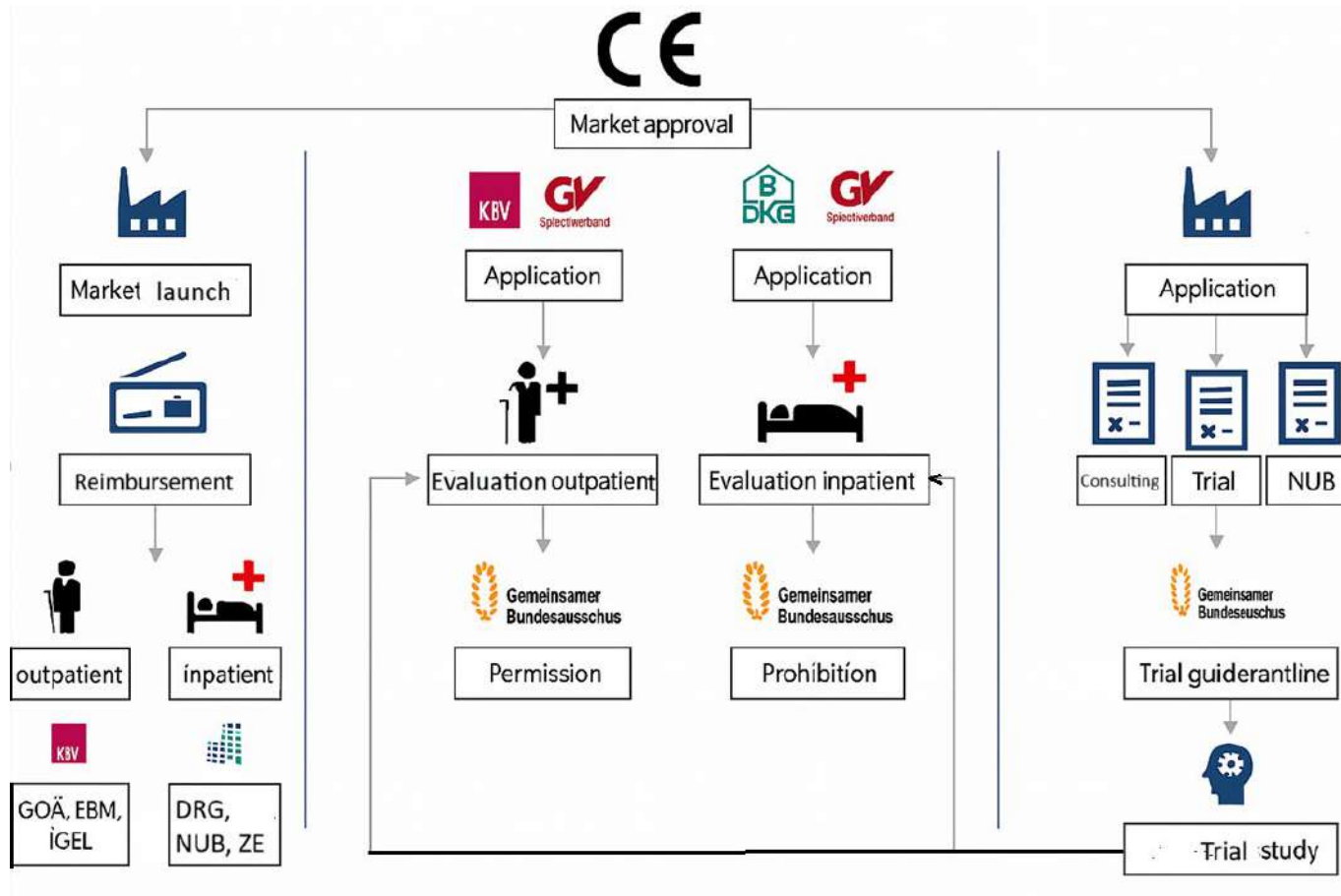
- Medical aids
- Dressings
- Medical devices similar to medicinal products

# The main forms of remuneration



# Market access and method evaluation

Legacy  
products



# Material costs in the aDRG system

## DRG Cost Matrix

**A DRG flat rate covers personnel and material costs. Nursing costs have for several years been financed through a DRG payment per hospital day. In the calculation performed by the responsible DRG institute (InEK), material costs for implants/transplants are listed separately.**

	1	2	3	4a	4b	5	6a	6b	6c	7	8	Total
General Ward	289,68	0,00	20,31	18,14	1,18	0,00	27,99	0,47	1,15	134,03	385,13	878,08
Intensive Care Unit	1,30	0,00	0,02	0,17	0,01	0,00	0,45	0,00	0,00	0,38	0,95	3,28
Operating Room	372,39	0,00	333,10	11,39	1,81	316,79	183,14	229,29	105,71	223,24	262,38	2.039,24
Anesthesia	298,68	0,00	200,99	15,28	0,19	0,00	50,59	0,16	11,42	33,24	88,28	698,83
Cardiology Diagnostics/Therapy	0,00	0,00	0,01	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,01
Endoscopic Diagnostics/Therapy	0,03	0,00	0,08	0,00	0,00	0,00	0,05	0,00	0,00	0,06	0,03	0,25
Radiology	7,44	0,00	11,86	0,04	0,00	0,00	1,15	0,01	5,66	2,98	6,89	36,03
Laboratories	1,24	0,00	4,62	0,48	0,05	0,00	1,62	0,00	5,76	0,93	2,57	17,27
Diagnostic Areas	1,97	0,14	2,33	0,03	0,00	0,00	0,21	0,00	0,01	0,30	1,18	6,17
Therapeutic Procedures	4,41	0,87	57,53	0,11	0,00	0,00	1,44	0,01	7,75	1,80	19,94	93,86
Patient Admission	38,36	5,32	25,07	0,76	0,00	0,00	4,58	0,02	0,00	6,26	21,87	102,24
Total	1.015,50	6,33	655,92	46,40	3,24	316,79	271,22	229,96	137,46	403,22	789,22	3.875,26

InEK DataBrowser – Costs of the 2022 data submission grouped according to 2024 (“Report browser”), values in [€], N = 6,939 patient cases

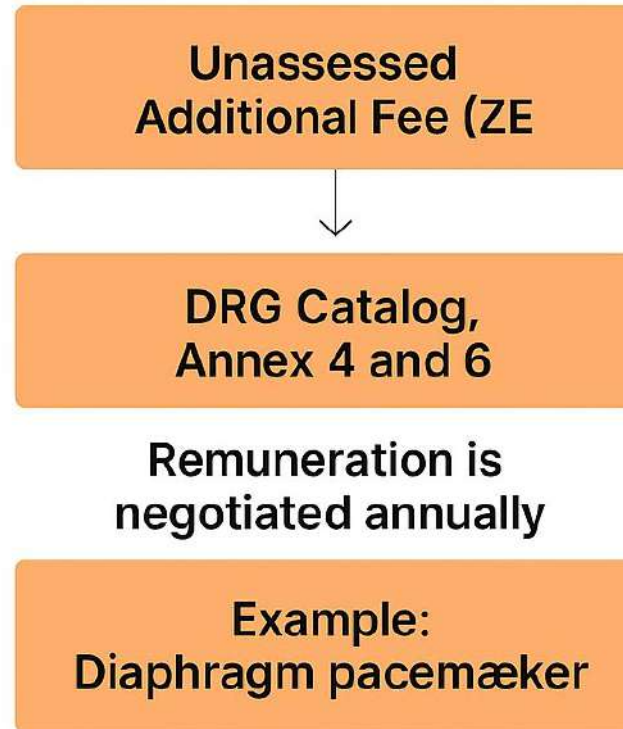
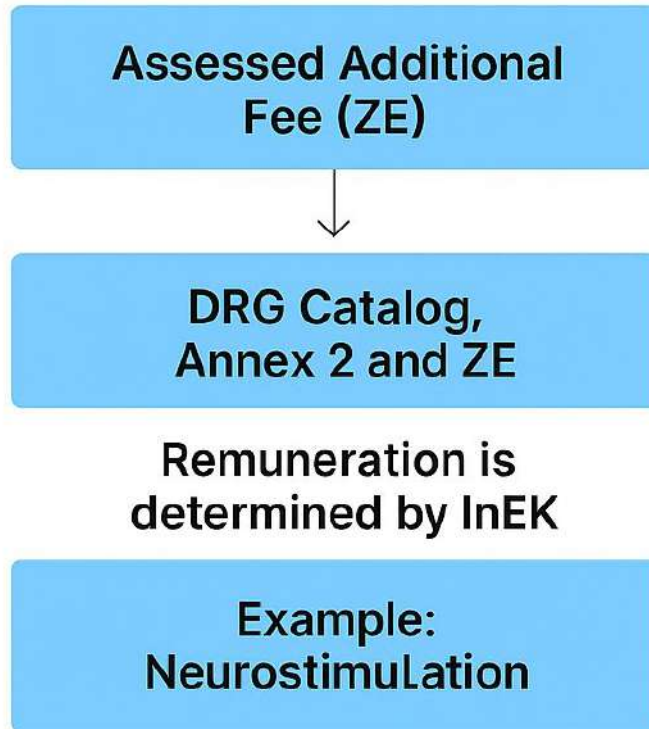
### Legend of cost columns:

**1: Personnel costs, medical service; 2: Personnel costs, nursing service; 3: Personnel costs, medical-technical service/functional service; 4a: Material costs, pharmaceuticals; 4b: Material costs, pharmaceuticals (individual costs/consumption); 5: Material costs, implants/transplants; 6a: Material costs, other medical supplies; 6b: Material costs, other medical supplies (individual costs/consumption); 6c: Material costs for medical services obtained from third parties; 7: Personnel and material costs, medical infrastructure; 8: Personnel and material costs, non-medical infrastructure**

Illustration: DRG I30B (“Complex interventions on the knee ...”)

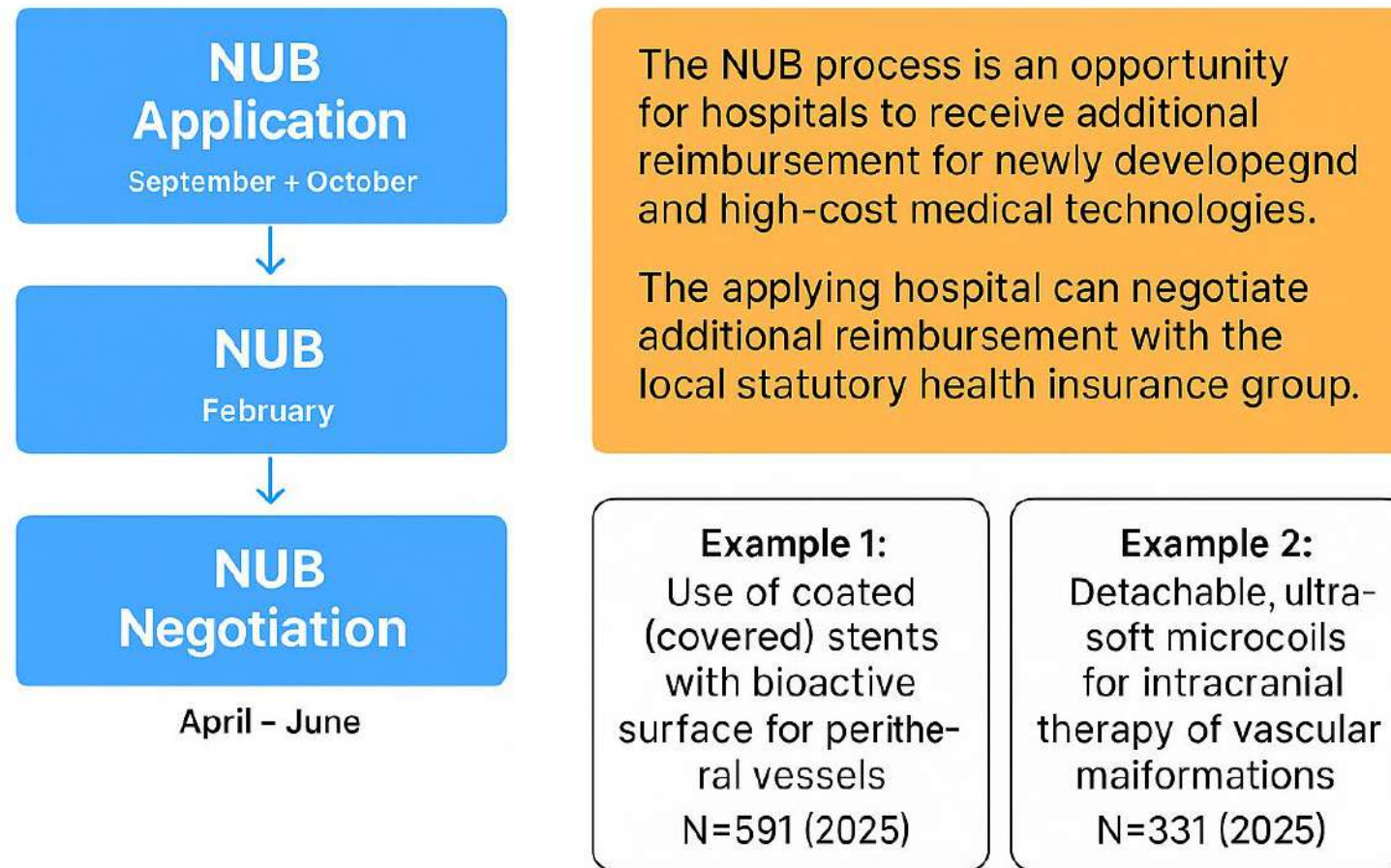


## Additional Fee (ZE) in the aDRG system



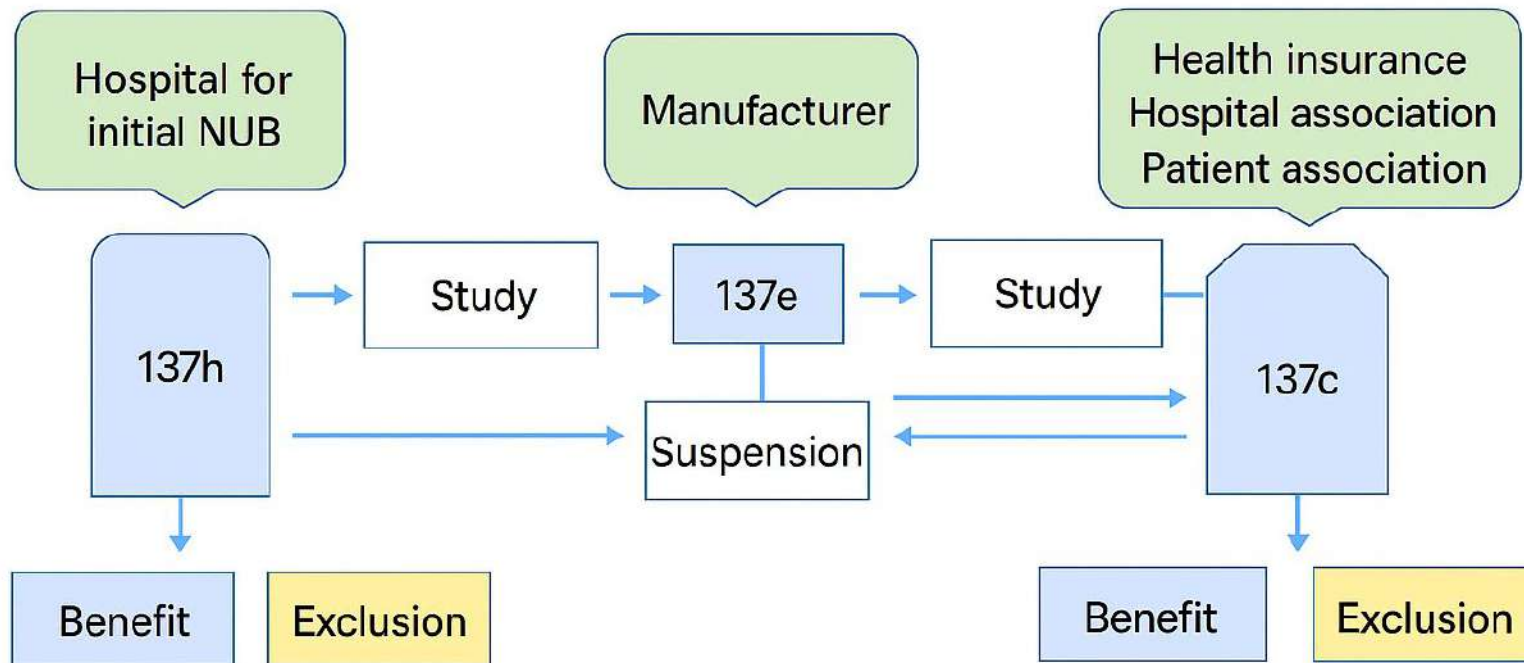
**Next to DRG, some medical products are additionally reimbursed with Additional Fee (ZE)**

# NUB in the aDRG-System



# NUB in the aDRG system Special regulation § 137 h SGB V

## High-risk medical devices Risk class IIb and III



In hospitals, the prohibition reservation applies. Assessments by the G-BA (Joint Federal Committee) are carried out through initiatives based on the requirements of §§ 137c, 137e, and 137h.

# Dossier creation and application

## Scientific Methods

- CRD + Cochrane
- HTA (Working Group 3)
- DIMDI HTA
- CCOHTA HE



## Methods of Decision-Makers

- G-BA Rules of Procedure
- G-BA Annexes
- IQWiG General Methods V 7.0
- IQTiG Methodological Foundations V 2.1

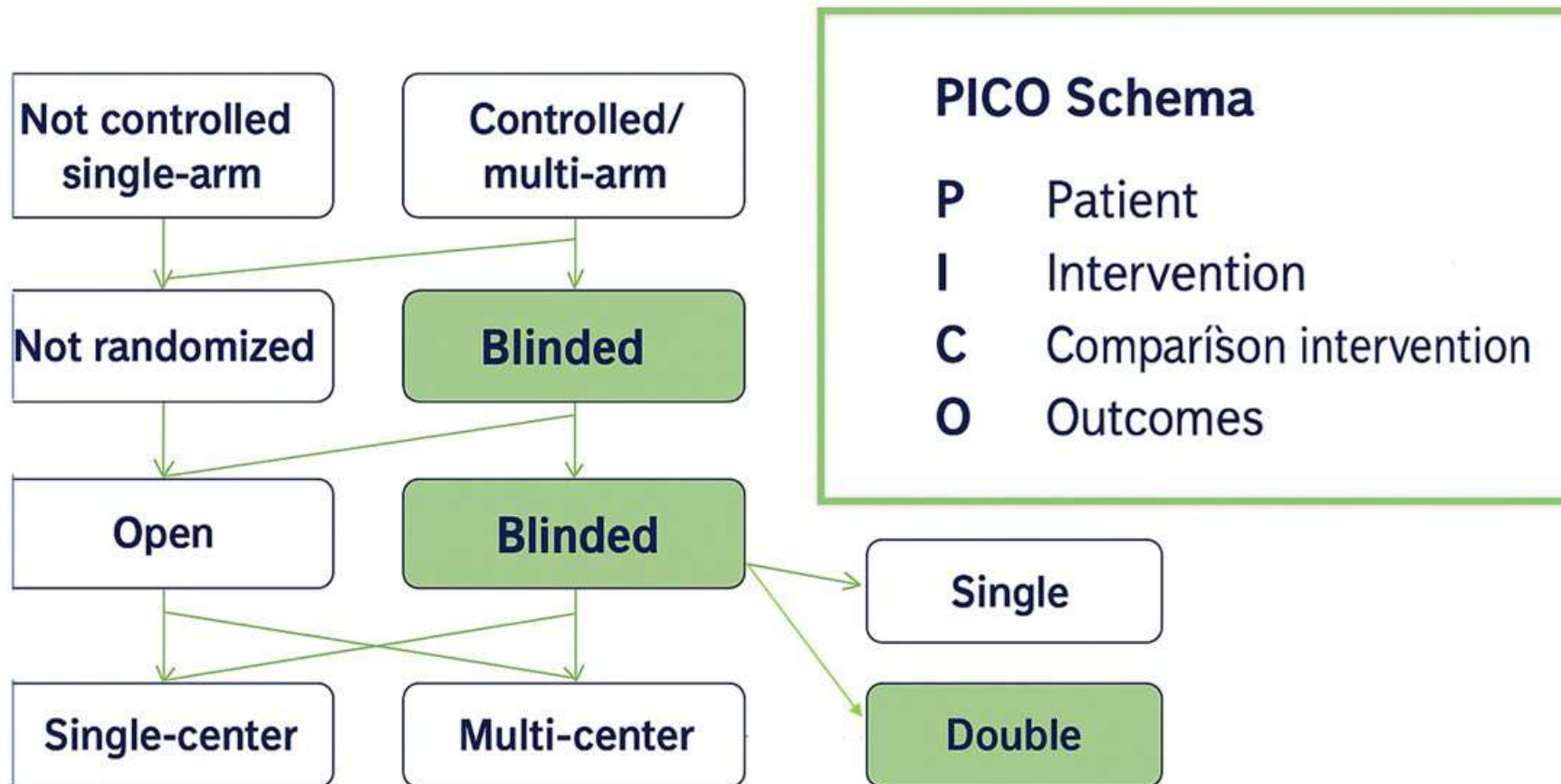


## SGB V

- § 139 HMV
- AMR for Medical Devices
- § 135 Outpatient
- § 137c Hospital
- § 137 e/h Testing
- NUB, § 137 h



# Study Design



# Hybrid DRG classification (outpatient services in the hospital)

## "Translation" of the OPS service catalog into hybrid DRG by InEK

Identification of the "intended" services

- Cases of suitable "mother" DRGs
- OPS from the service catalog as a positive list
  - where necessary, expanded to include non-specific OPS or similar services
  - *Deletion of individual OPS (following the amended eBA meeting of 31.10.2025)*
- VWD < 3 days
- Age > 17 years
- No high level of care (grade 4/5): OPS 9-984.9 and OPS 9-984.a
- Exclusion of context factors
  - Diagnoses or procedures that generally argue against an outpatient setting
  - *Exclusion of cases with ZE benefits (according to the amended eBA meeting of 31.10.2025)*
- DRG-specific exceptions
  - Case attributes that exclude DRG-specific hybrid DRGs





## Hybrid DRG 2026 incl. material costs

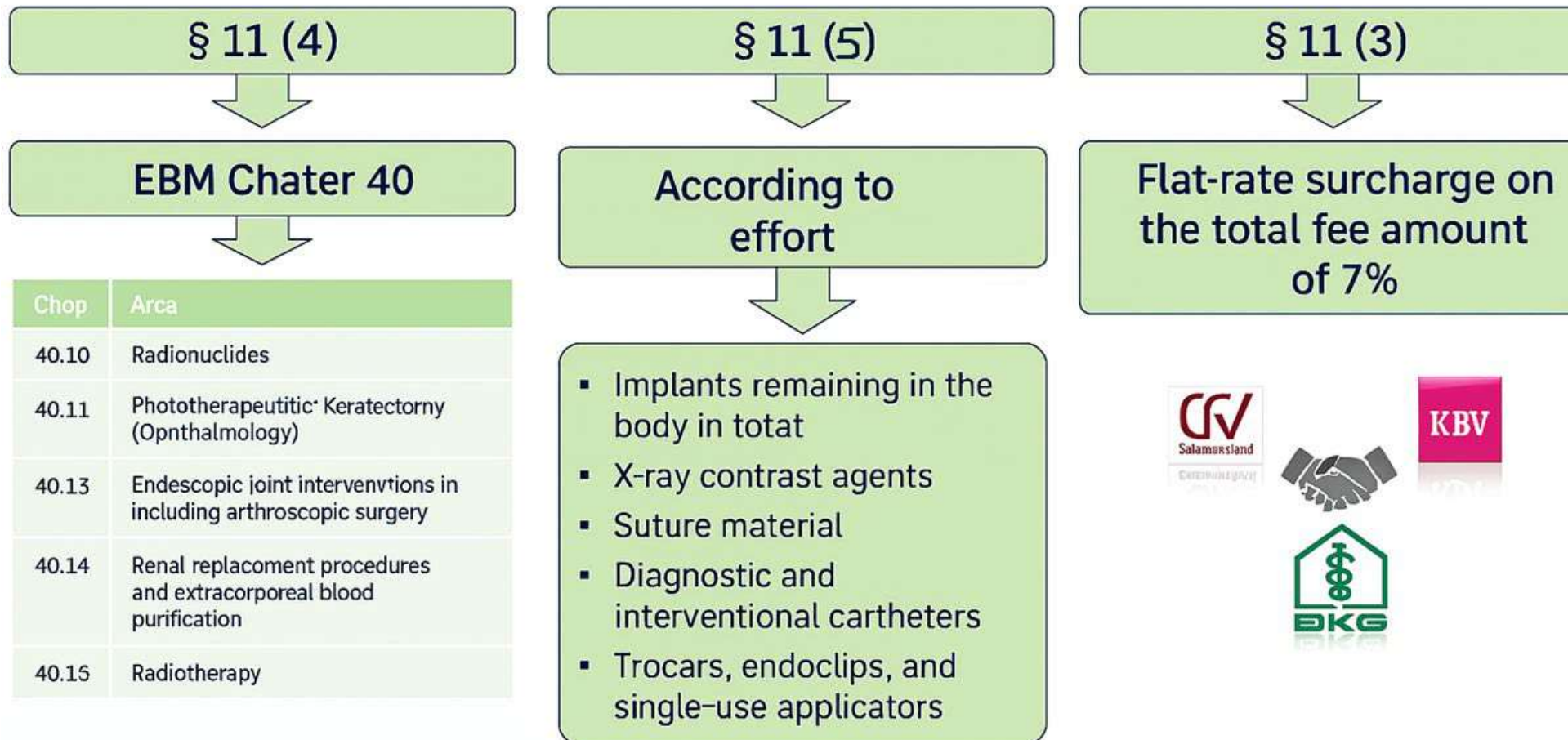
Hybrid DRG	Mother DRG	Designation of the "parent DRG"	Price (Annex 2a) Change value 5.17%	Price (Annex 2b) Guideline value 2.98%
E02M	E02D	Other OR procedures on the respiratory organs, age > 17 years, more than 1 BT, without specific intervention on the larynx or trachea, without moderately complex intervention, without extremely severe CC, without endoscopic lung volume reduction , without other moderately complex intervention	€2,053.87	€2,011.30
F01M	F01C	Implantation of an artificially induced cardioverter defibrillator (AICD), three-chamber pacing or defibrillator or intracardiac pulse generator, without complicating factors or implantation of a pressure sensor in the pulmonary artery	€10,281.49	€10,067.56
F01N	F01E	Implantation of an artificial cardioverter defibrillator (AICD), dual-chamber pacing, or complex lead removal , without implantation of a pressure sensor in the pulmonary artery, without implantation of an intracardiac pulse generator, age > 17 years	€7,642.84	€7,484.31
F01O	F01F	Implantable cardioverter defibrillator ( AICD ), single-chamber pacing, without additional cardiac or vascular intervention, without intracranial pressure > 392/368/- p, without external severe coronary artery disease , without complex lead removal , without pulmonary artery pressure sensor, without pulse generator , age > 17 years	€6,294.39	€6,163.41
F02M	F02A	Generator replacement of an AICD cardioverter -defibrillator (AICD), dual- or triple-chamber pacing	€6,623.80	€6,489.52
F02N	F02B	Generator replacement of an AICD cardioverter -defibrillator ( a single-chamber pacemaker ).	€5,193.46	€5,088.25
F19M	F19B	Other transluminal interventions on the heart, aorta, and pulmonary vessels without extremely severe CC or ablation via the renal artery or complex recanalization of coronary vessels.	€4,981.46	€4,877.78
F24M	F24B	Percutaneous coronary angioplasty with complex diagnosis and highly complex intervention or with certain recanalization procedures, age > 15 years, without extremely severe CC	€3,781.06	€3,702.33

Prices plus €30 for  
follow-up treatment in the hospital.

Material/MD included !!!



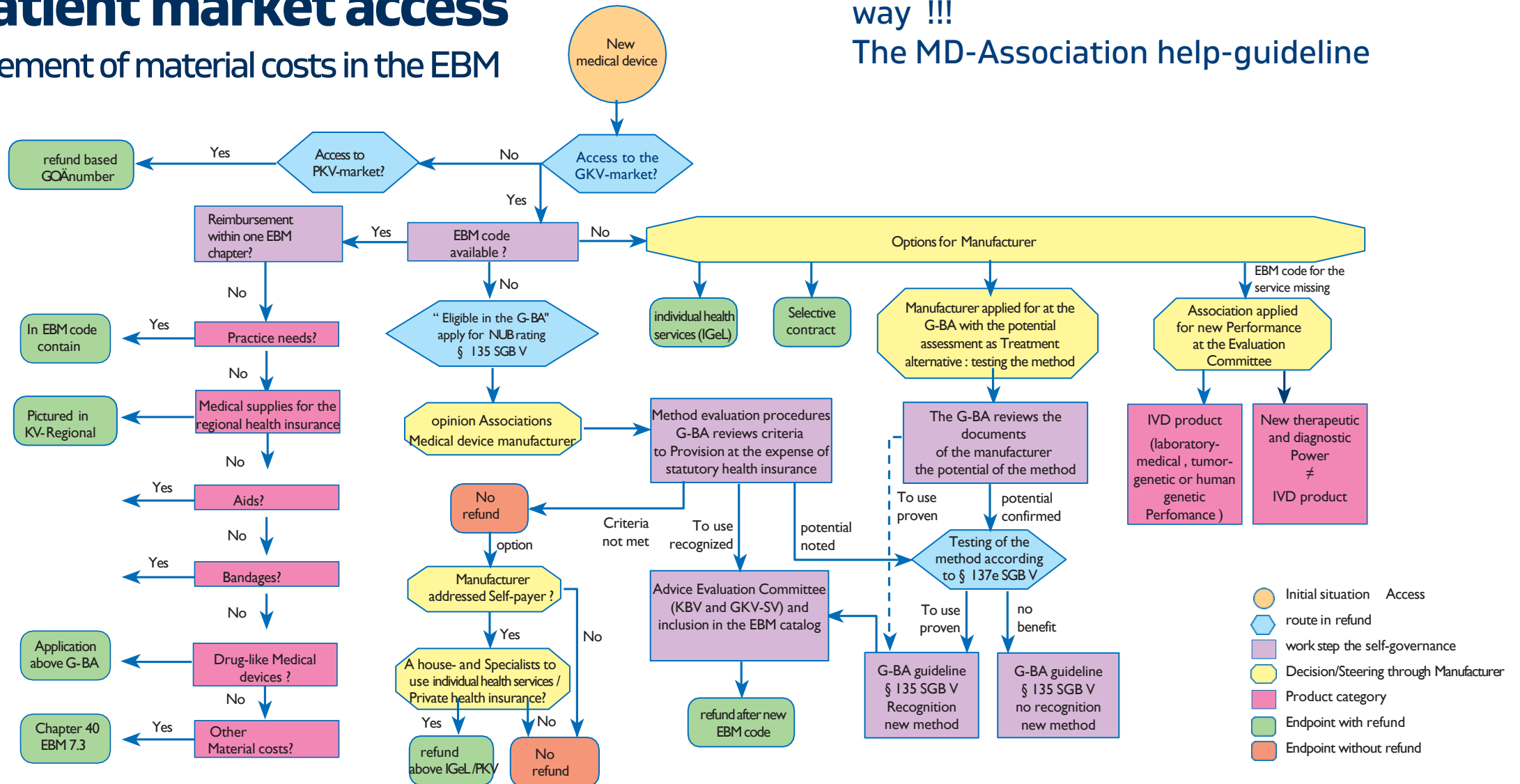
# Outpatient surgery reimbursement for hospitals in 2026 (AOP)



## Outpatient market access

reimbursement of material costs in the EBM

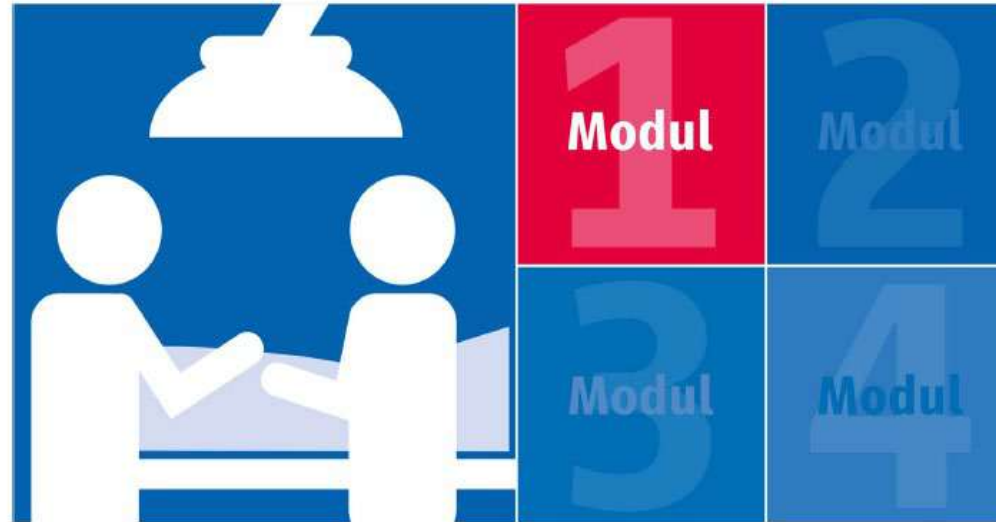
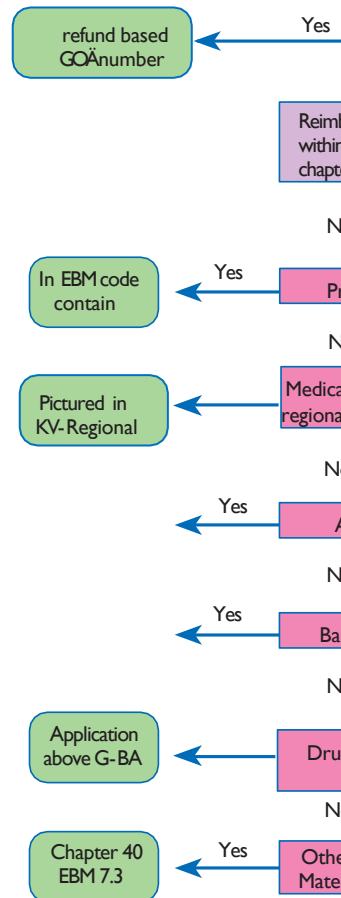
Reimbursement, a special german way !!!  
The MD-Association help-guideline



# Outpatient ma

reimbursement of mater

it, a special german  
ation help-guideline

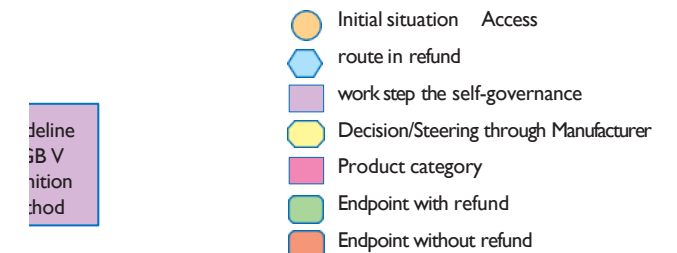
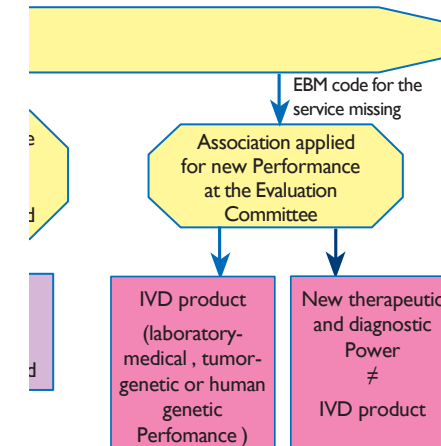


Reimbursement, a special german way !!!  
The MD-Association help-guideline

Zugang ins deutsche Erstattungssystem

## Modul 1 „Ambulant“

Marktzugang im ambulanten Bereich – Spezielle Regelungen zu Hilfsmitteln, Verbandmitteln und In-vitro-Diagnostika



# Billing of material costs in the EBM

In Chapter 7.3 of the general provisions of the EBM, it states:

Unless otherwise specified, the fee schedule items do **not include**:

- Costs for medications, dressings, materials, instruments, objects, and substances that are consumed after use or that the patient retains for further use.
- Costs for disposable infusion sets, disposable infusion catheters, disposable infusion needles, and disposable biopsy needles.

In Chapter 7.4, there is a type of opening clause that allows billing for costs not included in the GOP only in accordance with the overall agreements. The overall agreements are concluded and continuously updated by each Association of Statutory Health Insurance Physicians together with the health insurance funds.

A distinction is made between practice requirements and consultation requirements. Practice requirements include the basic equipment of a medical practice. The costs of practice requirements are covered by the fee for the medical service.

# Billing of material costs in the EBM

Material costs apply to medical products that:

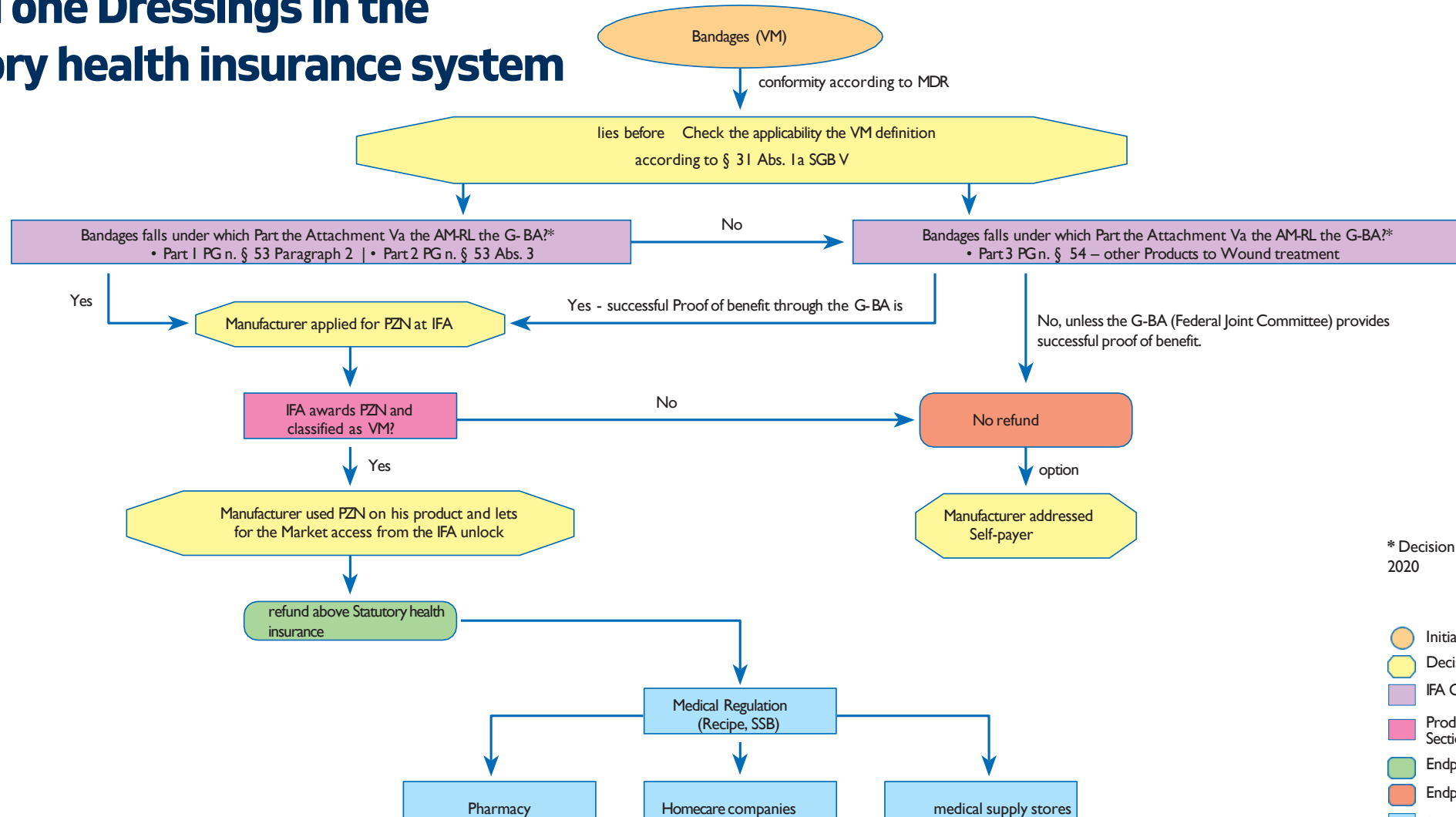
- are not covered by EBM fees,
- cannot be reimbursed through consultation requirements,
- are not considered practice requirements,
- are not listed in EBM Chapter 40 (flat-rate material costs).

These products can be billed separately by the physician.

The invoice is submitted to the Association of Statutory Health Insurance Physicians (KV) together with the patient's treatment certificate.

There is the option of an assignment declaration to the supplier.

## Refund one Dressings in the statutory health insurance system



\* Decision the G-BA from the 20. August 2020

- Initial situation
- ⬡ Decision / steering through Manufacturer
- ⬡ IFA GmbH
- ⬡ Product assignment according to Section P AM-RL the G-BA
- ⬡ Endpoint with refund
- ⬡ Endpoint without refund
- ⬡ Supply route

# Medical Aids under the Statutory Health Insurance (GKV)

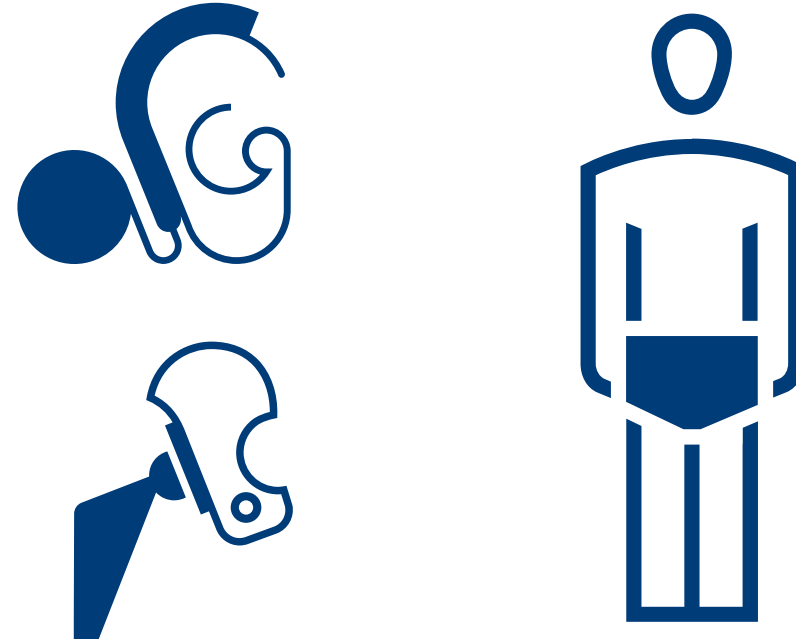
## § 33 Para. 1 SGB V

### Products such as:

- **body replacement parts**
- **orthopedic aids**
- **other medical aids**

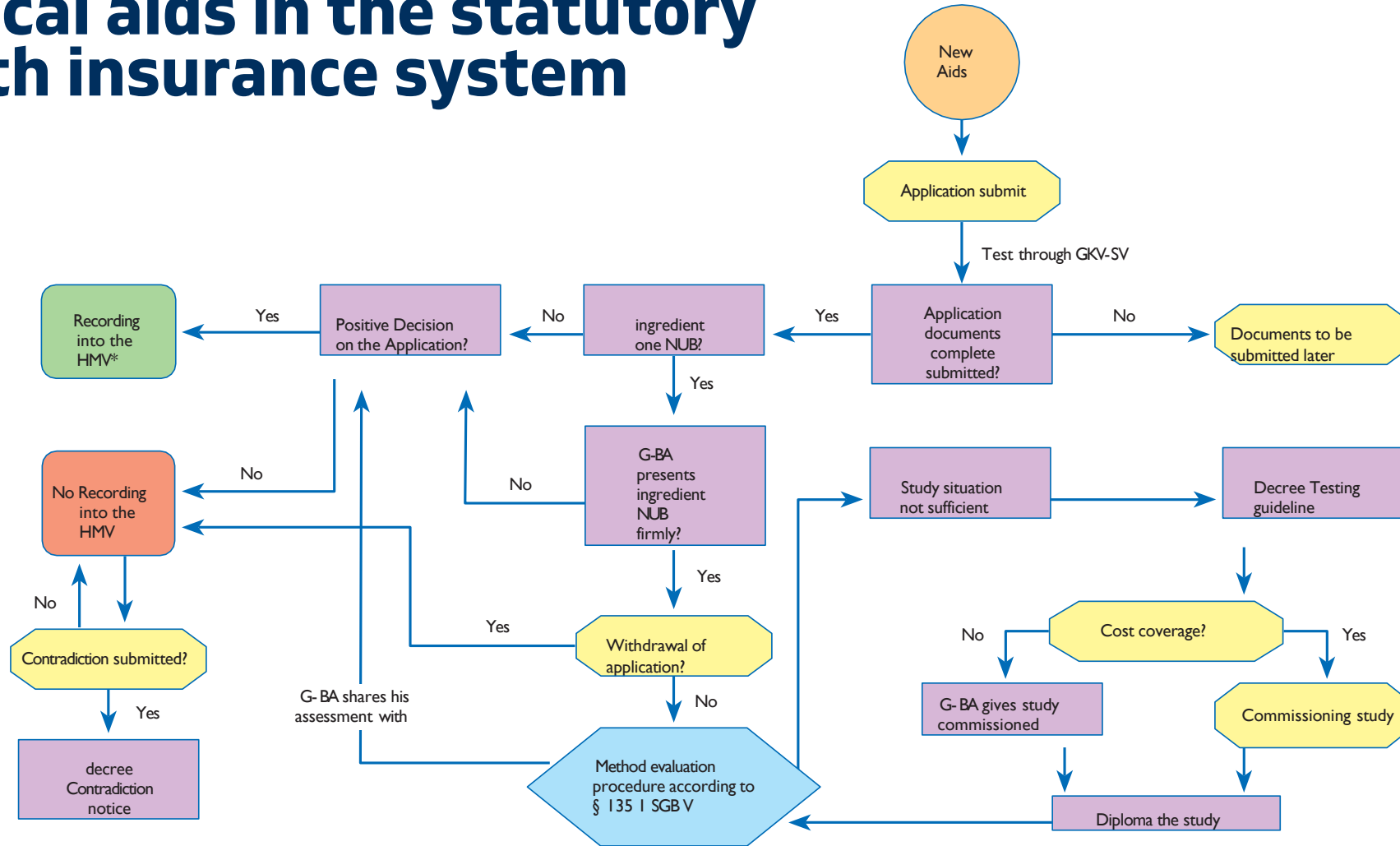
### When they are individually necessary to:

- **ensure the success of medical treatment**
- **prevent an impending disability**
- **compensate for a disability**





# Medical aids in the statutory health insurance system



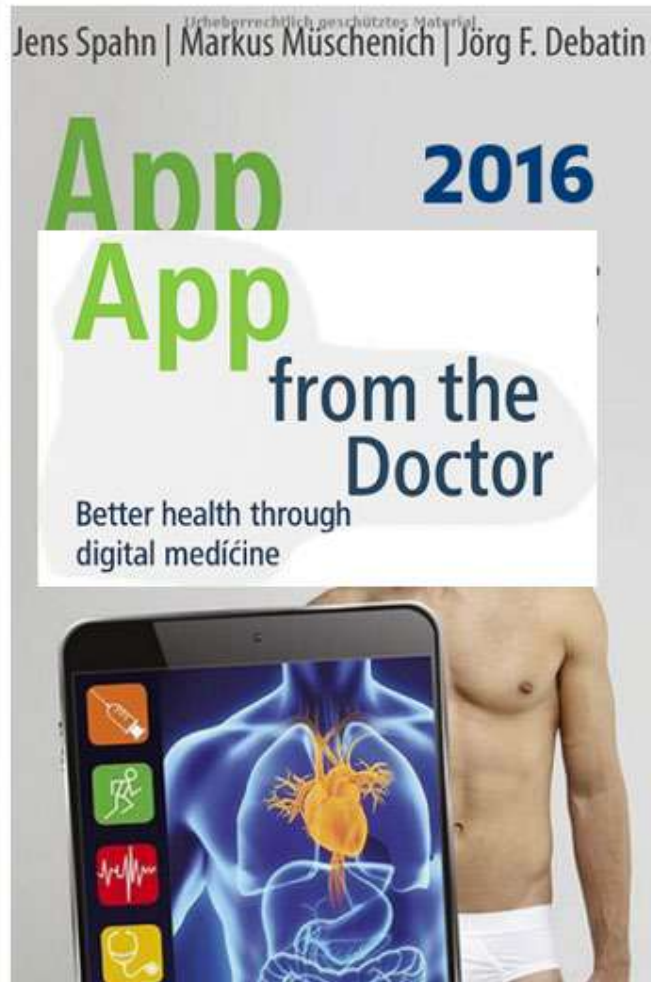
\* It follows the Award one Assistive device number and Announcement in the Federal Gazette. It becomes on it pointed out, that the refund one Aids also without one Assistive device number take place may. The Approval is however more difficult.

- Initial situation
- Decision/Steering
- through Manufacturer work step the
- self-governance
- Access route in
- refund
- Endpoint with refund
- Endpoint without refund

# Medical aids in the statutory health insurance system (Hilfsmittelverzeichnis)

1. Suction devices
2. Adaptation aids
3. Application aids
4. Bath aids
5. Bandages
6. Radiation devices
7. Visual aids for the blind
8. Insoles
9. Electrostimulation devices
10. Walking aids
11. Aids against pressure ulcers
12. Aids for tracheostomy and laryngectomy
13. Hearing aids
14. Inhalation and respiratory therapy devices
15. Incontinence aids
16. Communication aids
17. Aids for compression therapy
18. Wheelchairs / mobility aids
19. Nursing care articles
20. Positioning aids
21. Measuring devices for body conditions/functions
22. Mobility aids
23. Orthoses / splints
24. Prostheses
25. Visual aids
26. Seating aids
27. Speech aids
28. Standing aids
29. Stoma articles
30. Not occupied
31. Shoes
32. Therapeutic exercise devices
33. Toilet aids
34. Hairpieces
35. Epitheses
36. Ocular prostheses
37. Breast prostheses
38. Arm prostheses
99. Miscellaneous

# From "app from the doctor" to "app on prescription"



**2019** Law: for Better Care through Digitalization and Innovation

**2020** Regulation on the procedures and requirements for reviewingursement eligibility of digital health applications in statutory health insurance (Digital Health Applications Regulation – DiGAV)

**2021** Digital Care and Nursing Modernization Act (DVPMG)

**TOGETHER DIGITAL**  
Presidenzen in der Zukunft  
Presidenzen in der Zukunft  
**2023** Law to Accelerate the Digitalization of Healthcare (Digital Act – DigiG)

# DiGA definition according to § 33a SGB V

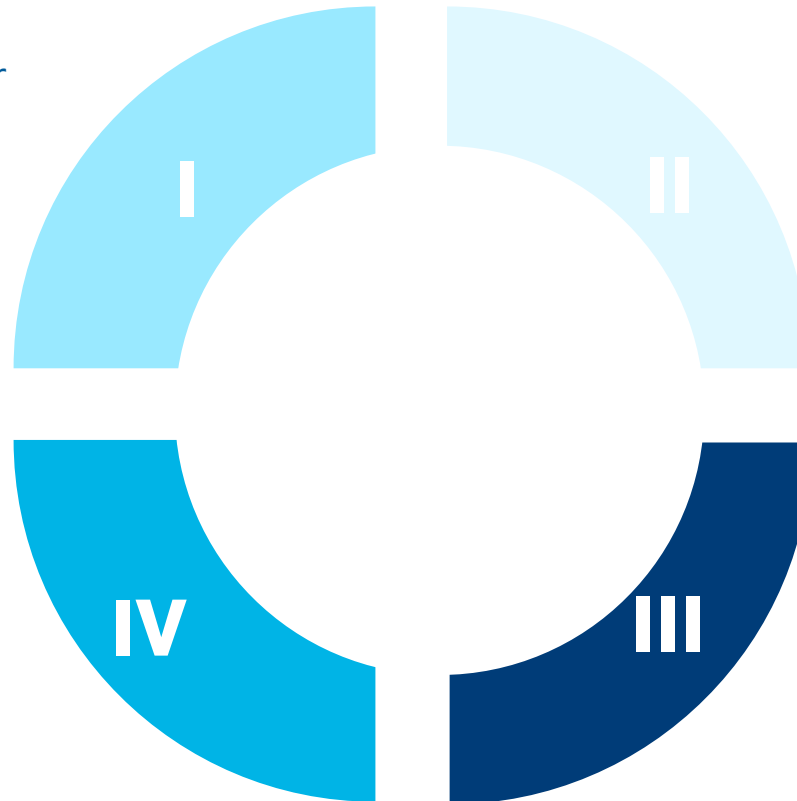
## Low-risk medical device

Medical device that is assigned to risk class I or IIa according to MDD or MDR

> Expansion to higher risk class ( IIb )

## Support for

> Insured persons  
> Care provided by service providers  
(Doctors, healthcare providers and midwives)



## Main function

is "essentially" based on digital technologies

> Medical device accessories excluded  
> Information chain "Implant/Assistive Device-DiGA-ePA " (§ 374a SGB V) provided for

New: Loan and telemonitoring

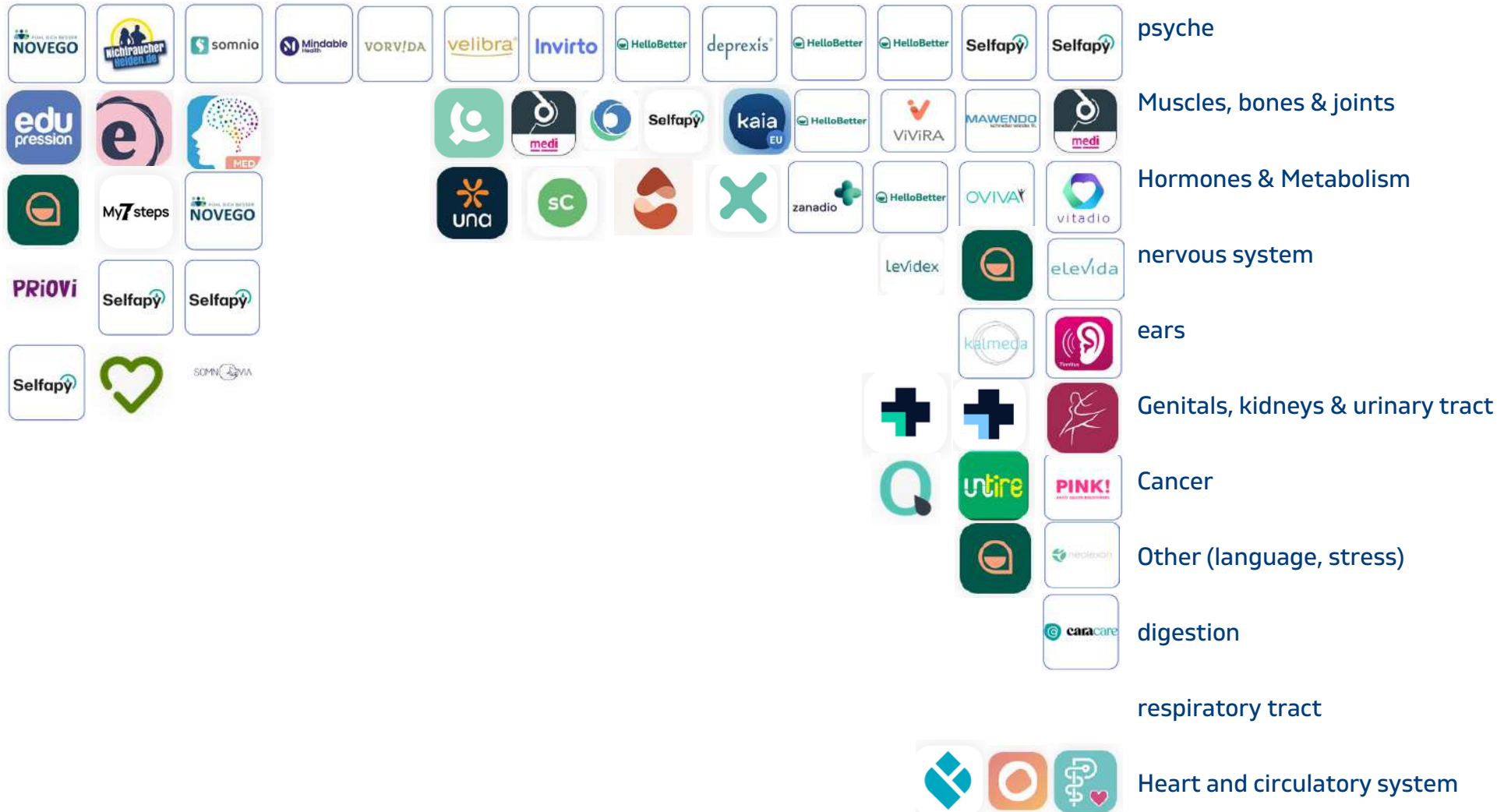
## To use

Detection, monitoring, relief, and compensation of illnesses, injuries, and disabilities

No prevention

> New: Pregnancies with specific digital care and support needs

## Status quo: Main indications



1. Introduction and National Med Tech Market
2. National Health System
  - National Health Care Market
  - Public and private health care System
3. Market Drivers
  - Reimbursement system
  - Market access
  - reimbursement assessment
  - reimbursement-process and forms
- 4. Key topics to have to know for reaching the Market**
  - **AOB**
  - **Q&A**

# Current Challenges

- **Price pressure (GPO; SHI)**
- **Market access**
- **Different Cashier strategies (tools)**
- **Bureaucracy**



# Role of manufacturers

- **Product innovation & evidence**



- **Price positioning**



- **Support for service providers in the assistive technology sector**





# Success factors

- **Proof of medical Benefits**
- **Economic arguments**
- **Partnerships**
- **Market and contract knowledge**

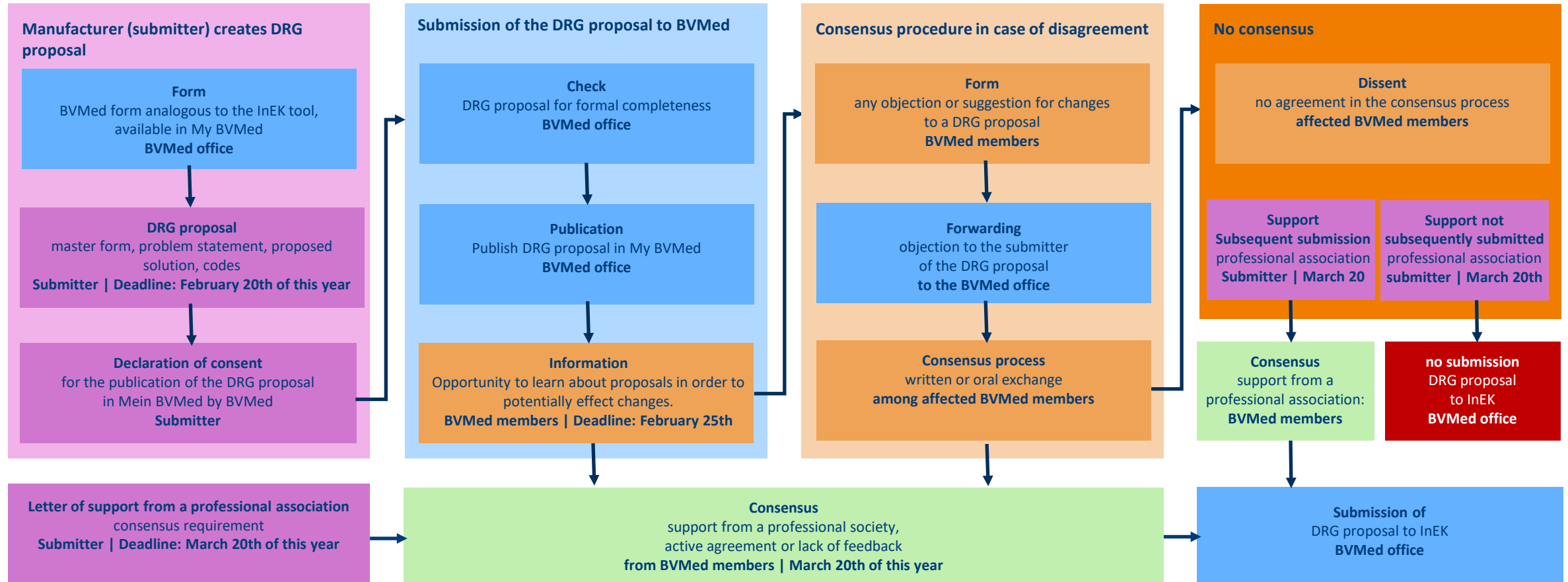


# Success factors with BVMed support

- **Applications for OPS and a-DRG**
- **Applications for new services in the EBM**
- **Guidelines for reimbursement**
- **G-BA statements**
- **BVMed Academy offers a variety of webinars and workshops on market access**  
**<https://www.bvmed.de/startseite>**

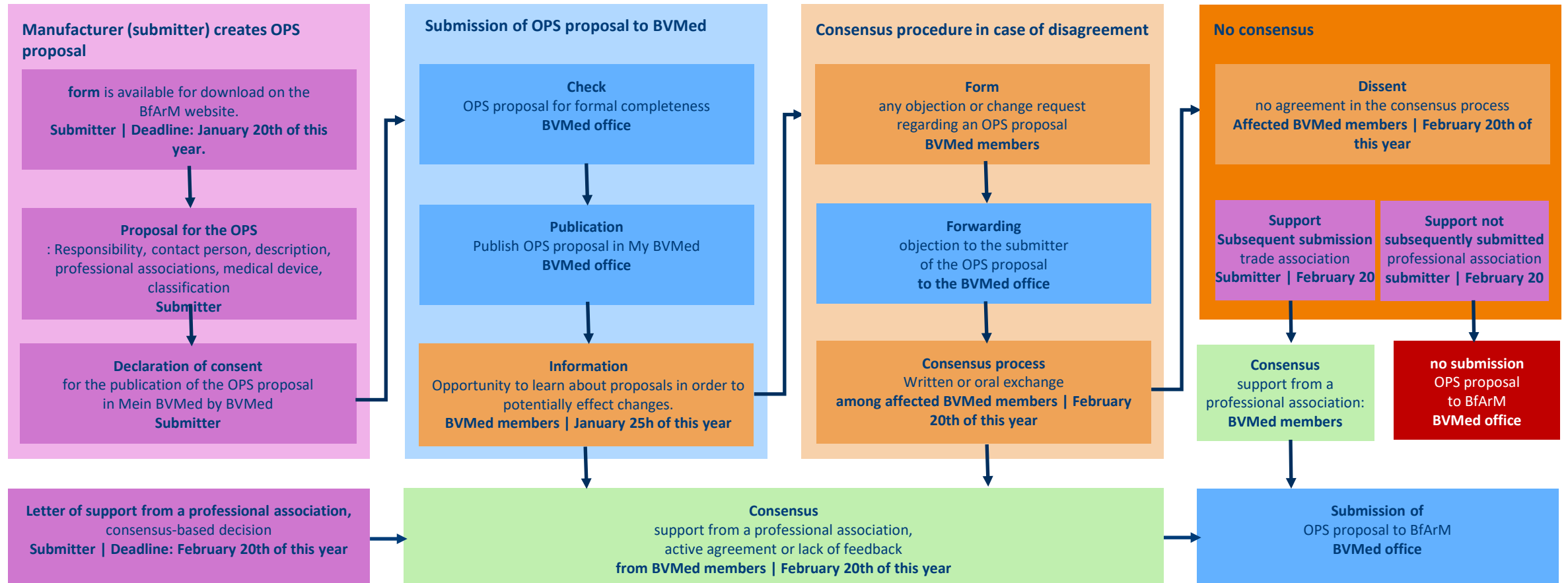


# Success factors with BVMed support DRG proposal process in BVMed



# Success factors with BVMed support

## OPS proposal procedure in BVMed



# Advantages of Germany as a medtech location



*Multiple answers possible*

## **Medical technology is part of the solution!**

Our technologies, products and processes contribute to better patient care, more efficient processes and reduced workload for medical staff.

This can only be achieved with the help of modern technologies:

**1.**

Medical technology helps to cushion the effects of the shortage of skilled workers in the healthcare sector and keep costs under control.

**2.**

Our AI-supported technologies relieve doctors of routine tasks, make diagnoses more precise and therapies more individualised.

**3.**

At the same time, we are working to reduce climate-damaging greenhouse gas emissions in the healthcare sector with energy- and resource-saving innovations.

## Link

**BfArM** Federal Institute for Drugs and Medical Devices  
**B**undesinstitut für **A**rzneimittel und **M**edizinprodukte  
[https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/\\_node.html](https://www.bfarm.de/DE/Medizinprodukte/Aufgaben/DiGA-und-DiPA/_node.html)

**BVMed** German Medical Technology Association  
**B**undesverband **M**edizintechnologie e. V.  
<https://www.bvmed.de/>

**FBFG** Department of Specialist and Wholesale Trade for Medical Devices  
**F**achbereich **F**ach- und **G**roßhandel für Medizinprodukte  
<https://www.bvmed.de/verband/ueber-uns#2-struktur-geschäftsstelle-gremien>

**G-BA** Joint Federal Committee  
**G**emeinsamer **B**undesausschuss  
<https://www.g-ba.de/>

**G-DRG** German **D**iagnosis **R**elated **G**roups  
<https://www.g-drg.de/>

**IQWiG** Institute for Quality and Efficiency in Health Care  
**I**nstitut für **Q**ualität und **W**irtschaftlichkeit im **G**esundheitswesen  
<https://www.iqwig.de/>

**EBM** Uniform Assessment Standard  
**E**inheitlicher **B**ewertungsmaßstab  
<https://www.kbv.de/praxis/abrechnung/ebm>

## Contact



**Olaf Winkler**  
Head of Industrial Health  
Market Division  
[winkler@bvmed.de](mailto:winkler@bvmed.de)



**Isabel Knorr**  
Manager Market Access  
and Reimbursement  
[knorr@bvmed.de](mailto:knorr@bvmed.de)

### Follow BVMed!

Newsletter:  
[bvmed.de/abo](https://bvmed.de/abo)

Twitter: [@bvmed](https://twitter.com/bvmed)

LinkedIn: [@bvmed](https://www.linkedin.com/company/bvmed)

Instagram: [@bvmed.de](https://www.instagram.com/bvmed.de)