AiM

Reimbursement of Medical Devices in Germany

2024/2025

Finding Your Way into the German Medical Device Market

AiM has been supporting the medical device industry for almost two decades. We mainly focus on reimbursement and pricing analysis, market access consultations, appraisal of clinical evidence as well as support for study designs. To date, we have concluded over 900 projects for more than 250 clients.

Since 2014, AiM has been a member of the IGES Group, an independent provider of research and consultancy services for the life sciences industry, covering the entire range of services from market data, regulatory, health technology assessment (HTA) to the analysis of clinical services.

This guide explains the basic principles of the German medical device regulations with a particular focus on reimbursement. It has been written with utmost care.

However, no document can replace a face-to-face meeting and qualified consultancy. We look forward to hearing from you.

AiM – Assessment in Medicine, Research and Consulting

The German Market and Access to it

Germany – Europe's Most Important Destination for Medical Devices

Market Access

Germany's advantages for medical device companies are rapid market approval processes and the quality and cost-effectiveness of its clinical research.

German hospitals are open to innovation and in favor of medical technology that enables them to cure patients better and more efficiently.

The world market for medical devices has a volume of 536 bn Euro. The USA have the largest market with 185 bn USD. The German market is by far Europe's largest market.

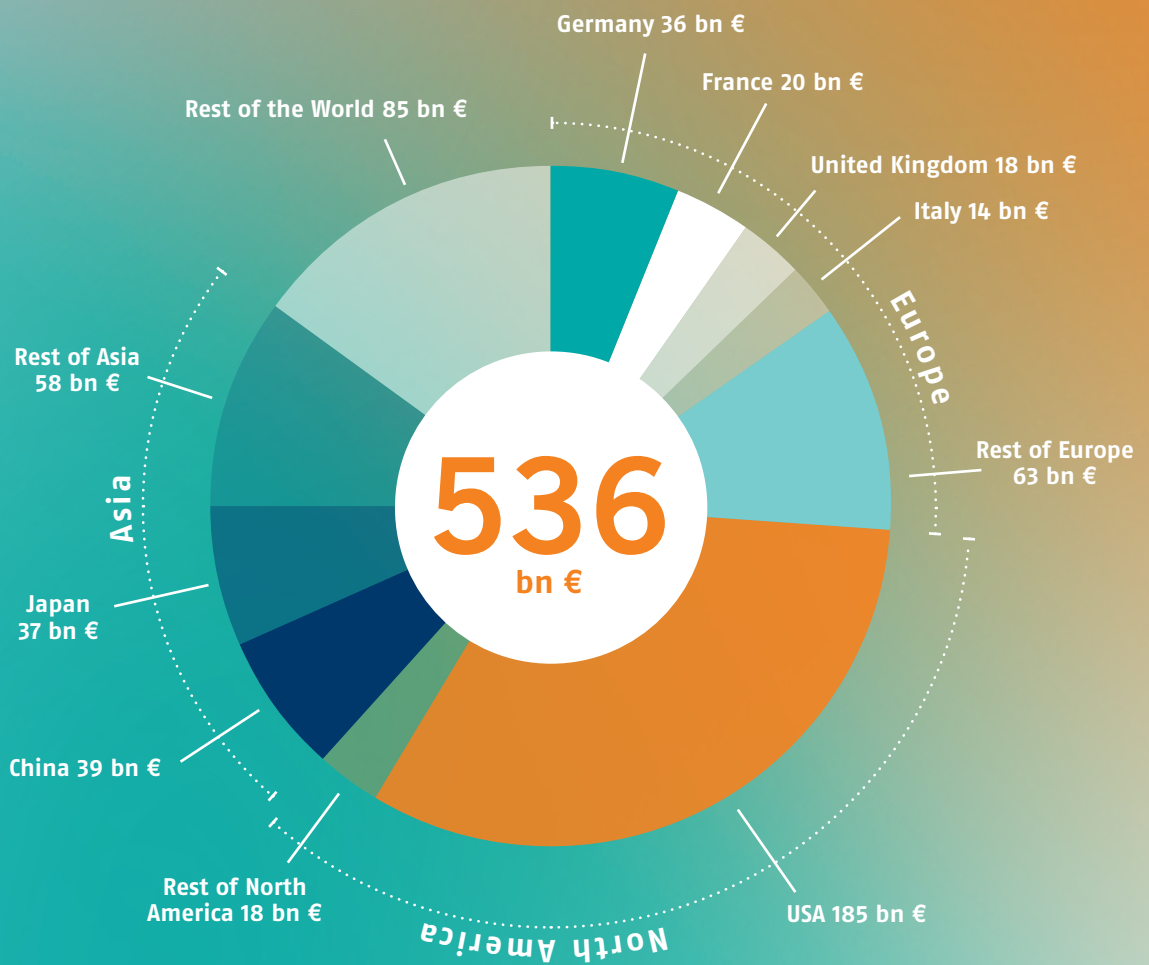
Population (in m)	
EU 27 + UK:	515,2
Germany:	83.8
France:	67.9
UK:	67,3
Italy:	58,9
Spain:	47,6

Source: OECD, data for 2022

Hospital Bed Density (Per 100k)	
EU 27 + UK:	448
Germany:	776
France:	565
UK:	242
Italy:	312
Spain:	296

Source: OECD, data for 2021.

World Market for Medical Devices in 2023



Source: statista.de, prognosis for 2023.

European CE Marking

Medical devices and IVDs must bear the CE marking to be brought to the European Union market. The CE marking indicates to EU regulators that the device fulfills the respective requirements of the MDR.

The new EU Medical Device Regulation (MDR) replaced the Medical Devices Directive (93/42/EEC) and the Active Implantable Medical Devices Directive (90/385/EEC).

The MDR entered into force on May 25, 2017. Manufacturers of already CE-certified medical devices had a transition period until May 26, 2021, to comply with the regulation's requirements. For some products, the MDR provides for an extension of the transition period.

Medical Devices Classes

Depending on their potential risk, medical devices are divided into four classes (with the exception of active implantable devices and in-vitro diagnostic medical devices).

Class I
Wheelchairs, crutches, hospital beds, bandages

Class IIa
Diagnostic ultrasound devices, hearing aids, contact lenses, dental fillings

Class IIb
Dental implants, defibrillators, respiration and dialysis devices

Class III
Coronary stents, heart valves, endoprotheses, absorbable surgical sutures

How to Obtain CE Marking for Your Medical Device or IVD

A medical device manufacturer has sole responsibility for maintaining compliance with the applicable EU Directives and securing CE marking for the product, regardless of whether the manufacturer outsources any or all components of the manufacturing operation.

The CE Marking Generally Requires the Following Steps:

1. Preparation of a CE Marking Technical File (or a Design Dossier for a Class III device). This file must include data demonstrating compliance with the Mdr.

2. Establishment and maintenance of a compliant quality management system (typically by implementing ISO 13485).

3. Appointment of a European Authorized Representative for companies with no physical location in Europe.

4. Obtaining the CE (and QMS) certificates from a Notified Body. For some medical devices (for instance Class I non-sterile, non-measuring devices), self-certification of compliance with the applicable directives is sufficient.

Understanding the German Health Care System

Health insurance is mandatory for German citizens. 73.6 million Germans are covered by statutory health insurance (Gesetzliche Krankenversicherung (GKV)) around 8.7 million Germans are covered by private health insurance (Private Krankenversicherung (PKV)) and via state aid.

Statutory health insurance is provided by slightly less than 100 statutory health insurance funds. These funds provide comprehensive health care. The statutory health insurance is a compulsory insurance system which may only be left in favor of the private health insurance if certain requirements (annual income, liberal profession, etc.) are met.

5 Largest Statutory Health Insurance Funds by Members in m:

Techniker Krankenkasse, TK	11.6
Barmer	8.5
DAK-Gesundheit	5.5
AOK Bayern	4.6
AOK Baden-Württemberg	4.6

Source: Krankenkassen.de; data for 2024

Private and Statutory Health Insurances by Members
(in millions)

Private health insurance members
(Private Krankenversicherung (PKV))
and citizens insured via state aid

Statutory health insurance members
(Gesetzliche Krankenversicherung (GKV))

Source: statista.de, data for 2022

Healthcare Expenditure

Total annual healthcare expenditure in Germany is 498.1 billion euros, of which 265.6 billion euros are spent by the statutory health insurance funds. Private health insurance companies spend 38.1 billion euros.

Statutory health insurance

Private health insurance

Other healthcare expenditure
(private households, nursing,
other organizations)

Total healthcare expenditure in Germany is
494.6 billion euros

Source: German Federal Statistical Office, data for 2023

General Concept of Reimbursement of Medical Devices in Germany

A crucial factor for the reimbursement of a medical device is whether it will be used in a hospital (inpatient) or ambulatory (outpatient) setting. In the following, the reimbursement system for patients with statutory health insurance (GKV) is explained.

Inpatient

Reimbursement of Innovative Medical Devices in the Hospital

There are different medical devices reimbursement pathways which can be used in inpatient medical services. These pathways are explained in the following. However, competition and market environment play a crucial role in identifying the ideal solution for bringing a new medical device to German hospitals.
Both aspects – regulatory pathways and market situation – have to be considered carefully.

1

Reservation of Prohibition

In the inpatient setting, new medical services are reimbursed without prior assessment, as long as fundamental principles of quality and cost-effectiveness are not violated. This is due to the so-called reservation of prohibition (Article 137c of the Social Security Code V) which, in principle, permits immediate provision of new medical services in inpatient settings and their reimbursement by the statutory health insurance. Owing to this reservation of prohibition, innovative medical devices can generally be applied quickly to clinical practice.

2

German Diagnosis Related Groups (G-DRG)

In the inpatient sector, the billing of services for treating patients is based on the so called German Diagnosis Related Groups (G-DRG), a fee-per-case-system. There are around 1,300 different DRGs in Germany. The DRG classification system uses case related coding rules that apply to diagnoses (ICD-10 German modification) and procedures (Operations and Procedure Codes (OPS)).

With the DRG-case-based-flat-rate, all costs related to the treatment and the hospitalization of the patient, including medical devices, are covered. The G-DRG system's contents are revised annually by the Institute for the Hospital Remuneration System (InEK). Each DRG compensation amount is based on empirical data which is continuously collected from several hundred German clinics.

There is a time lag between the availability of a new procedure code and an adequate DRG assignment. InEK-conducted G-DRG updates are based on the above mentioned empirical data from previous years.

Reimbursement Timeframe for New Medical Devices
The new medical device is reimbursed immediately if it is part of an established method that is already in effect in the reimbursement system. If the device fully or partially constitutes a new method, exploring innovation reimbursement pathways such as the NUB procedure is advisable, particularly if the device is significantly more expensive than the current standards. Depending on the setting in question (inpatient or outpatient) and the evidence available in support of the new device, establishing nationwide reimbursement can be complex and may take several years.

3

Request for a New OPS

Often, using a novel medical device requires a different procedure to that of the standard medical device. For this reason, new OPS codes for novel procedures can be requested by actors from the health care system. Such requests may be filed at the BfArM (Federal Institute for Drugs and Medical Devices) once a year. This should be done jointly with a German medical society which confirms that the new procedure is scientifically in line with appropriate medical treatment. The BfArM's decision will take about one year. If successful, the newly created OPS code will be assigned to a DRG.

4

New Methods of Treatment and Screening (NUB)

The NUB procedure (NUB: New Methods for Treatment and Screening) is a payment scheme for remunerating cost-intensive, innovative services and technologies that are used in addition to the procedures included in the valid DRG case-based flat rate. This procedure is only open to technologies / procedures that are considered new in Germany.

Hospitals can file electronic requests to the InEK once a year to enquire whether the conditions for negotiations have been set for hospital-specific temporary extrabudgetary payments (NUB payments). If the request receives a favorable reply, the hospital can enter into negotiations with the respective local healthcare payer.

Every hospital must apply separately. The "on-top" payment, provided the application is approved, will only →

→ be available to the hospital that negotiated successfully. Approved applications are subsequently monitored by the InEK. And at some point in the future, InEK will integrate the corresponding procedure into the standard DRG system.

This procedure is widely used, but very often unsuccessful: because the requests for NUB payments are rejected if the method at stake has already been included in an existing DRG or is not considered innovative.

It should be noted that the InEK makes no decision on the actual amount of the "on-top" payment. This is directly negotiated between the successful hospital applicants and the GKV.

5

Additional Charges (Zusatzentgelt)

In addition to the NUB procedure, a further option for invoicing an extra fee on top of the DRG-case-based flat-rate exists, which, however, is not restricted to innovations. This is termed "additional charge" (Zusatzentgelt). In 2024, there are a total of 233 additional charges. Hospitals and medical societies can apply for the implementation of such an additional charge. If appropriate, the InEK will create an additional charge on its own initiative. In most cases, the monetary value of the additional charge is based on empirical cost data supplied by reference hospitals.

The Planned Hospital Reform

The German government's planned hospital reform is currently in the legislative process, after the draft bill was passed in May 2024. According to the Minister of Health, it would be the largest hospital reform in 20 years. At the present time, it is not possible to predict whether and how exactly this legislative project will be implemented. However, as the planned rules would have a significant impact on the structure and financing of hospitals, we will briefly outline what the current plans comprise:

A key aspect will be the introduction of a new reimbursement system. Hospitals that are indispensable for meeting the demand for medical care will be reimbursed largely independently of the volume of services they provide. This would be a key difference to today's DRG system by which hospitals only get paid per case (numbers) they treat. Additionally, in the short term, the calculation basis for hospital payments will be adjusted.

65 service groups (Leistungsgruppen) will be introduced to which all current hospital services will be assigned. The federal states will decide which hospitals meet these criteria (the current responsibility of the federal states for hospital planning remains unaffected). In order to be assigned to a service group, quality standards must be met by the hospitals. The requirement for meeting the quality criteria is defined at the federal level.

Additionally, through new cross-sectoral healthcare facilities (so-called Level 1i hospitals) local inpatient hospital treatment will be combined with outpatient and nursing services. These facilities should offer local, basic medical care by concentrating interdisciplinary and interprofessional services.

Hospitals and Physicians in Germany

1893 Total Number of Hospitals in Germany

480.382 Total Number of Hospital Beds

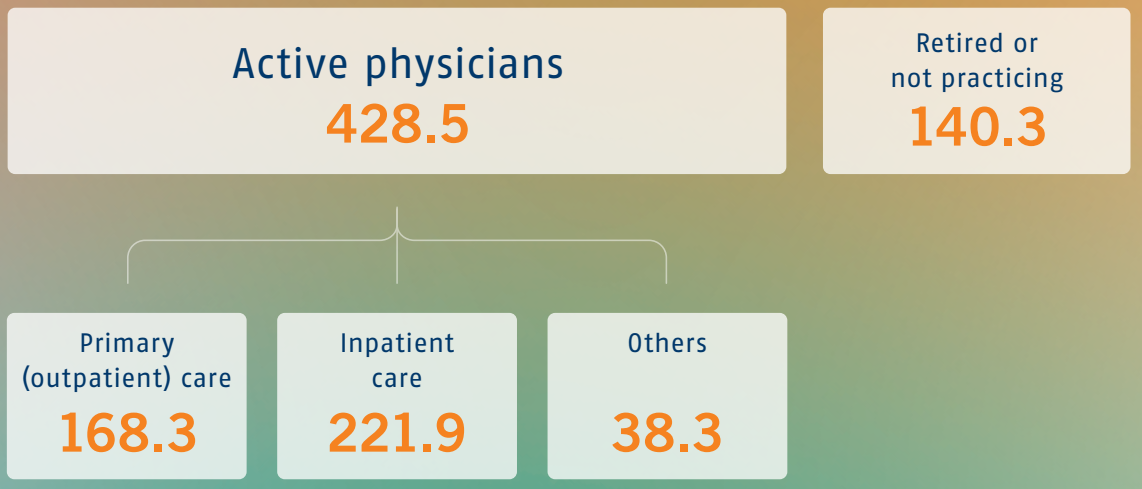
69.0%
Rate of hospital bed utilization

16.802.693
Total annual number of inpatient cases treated in Germany

1.264.000
Total hospital staff

Source: German Federal Statistical Office, data for 2022

Structure of Medical Profession in Germany (in thousands)



Source: IGES based on Bundesärztekammer (German Medical Association), data for 2023

Two Special Regulations

§ 137e SGB V – Testing Regulation:
The generation of high-quality, clinical evidence through clinical trials has been considered as insufficient in Germany. As a response to this, a "coverage with evidence development" program has been implemented. The evidence generated is to be used as a basis for G-BA decisions on coverage. The clinical trial can be initiated by the G-BA or the medical device manufacturer. This procedure was introduced in 2013, but has not become very widespread. The entire procedure can easily take up to 60 months.

§ 137h SGB V – NUB with Method Assessment:
With the introduction of § 137h SGB V in 2016, some new methods must undergo an official health technology assessment (HTA) process associated with the NUB scheme. If it is the first NUB application and the medical device involved belongs to class IIb or III, and the new diagnostic or therapeutic method provides a new theoretical scientific concept, an official method assessment process will be initiated with a subsequent G-BA decision regarding coverage.

Outpatient

Reimbursement of Medical Devices in Primary (Ambulatory) Care

1

The Uniform Evaluation Scale (EBM)

Outpatient services (ambulatory services) are mainly provided by private practitioners in the community. There are around 166,000 physicians working in outpatient care in Germany. These practitioners are by law members of their respective regional Kassenärztliche Vereinigung (Association of the Statutory Health Insurance Physicians (ASHIP)). The physicians are paid by their respective ASHIP which, in turn, is paid by the GKVs. Payments by the GKVs to ASHIP are usually based on a "per physician member" or a "per insured person" basis. ASHIP funds pay their members on the basis of the "Uniform Evaluation Scale" catalogue, also known as EBM (Einheitlicher Bewertungsmaßstab). Physicians are only able to invoice services that appear on the EBM. The EBM is set by a committee of GKV and ASHIP representatives called Evaluation Committee (Bewertungsausschuss). The payment scheme for outpatient physicians is based on the mix of services delivered, the number of patients served, and a fixed budget distribution system.

2

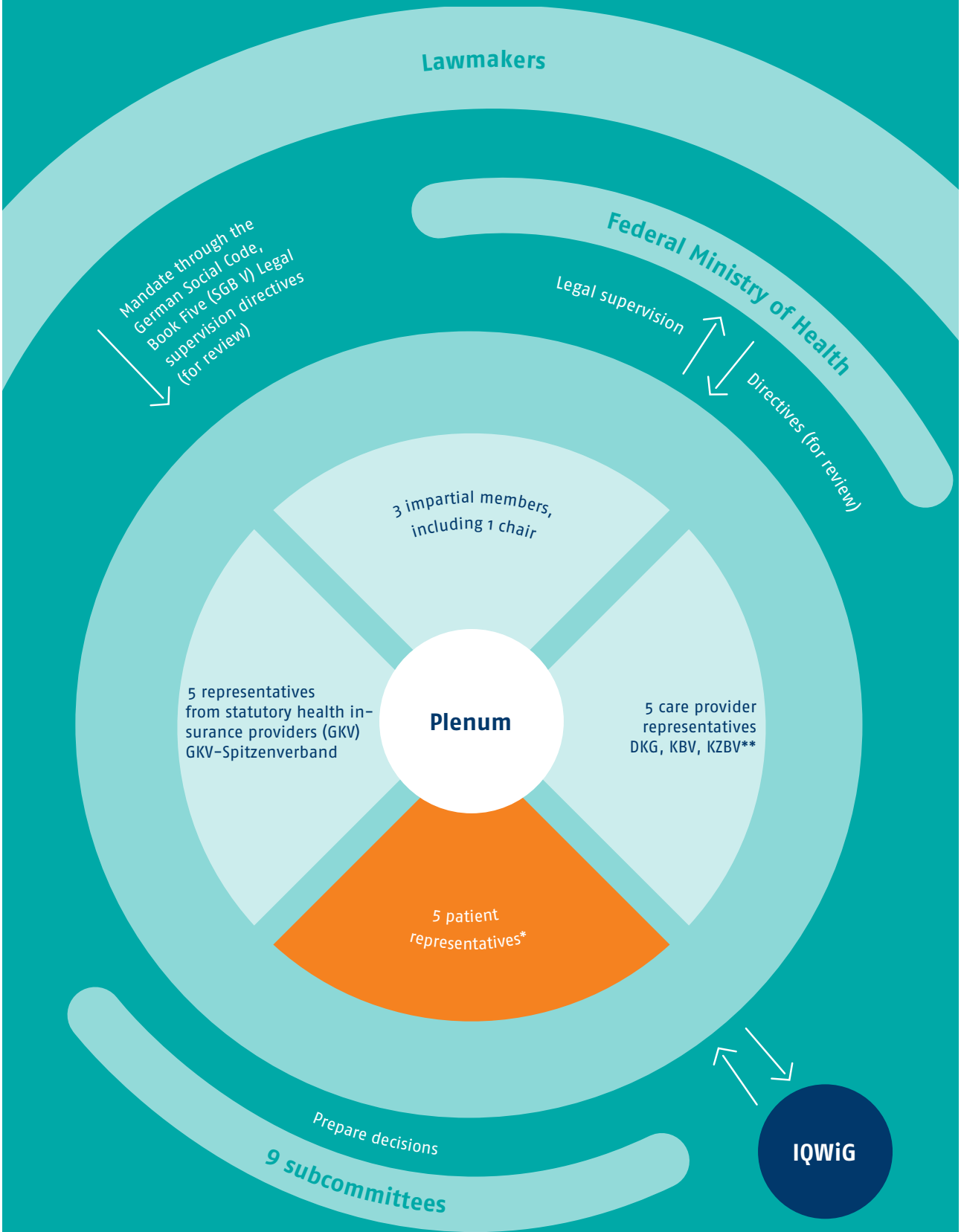
Authorization Right

The so-called "Authorization Right" (Article 135 § 1 of the Social Security Code V) applies to all ambulatory medical services: Any novel diagnostic and therapeutic procedure must be evaluated before being reimbursed. Only procedures which "show a benefit, are medically necessary and efficient" can be reimbursed. The decision for accepting a new procedure for GKV coverage has to be ratified by the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA, see page 19). During the evaluation procedure, the Federal Joint Committee may request a health technology assessment (HTA) from the Institute for Quality and Efficiency in Healthcare (IQWiG = Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen). It should be noted that setting the actual payment amount for an EBM listed procedure is the responsibility of the Evaluation Committee. If the G-BA evaluation is positive, the medical service must be covered by the GKV. The medical service is then reimbursed throughout Germany by all GKV-funds.

Federal Joint Committee (G-BA)

Highest decision-making body of the joint self-government of physicians, hospitals and health insurance funds in Germany.

It issues directives for the GKV benefit catalogue and therefore specifies which services in medical care are reimbursed.



* Entitled to take part in discussions and submit petitions, but not to vote

** Care providers are entitled to vote only on issues affecting their area of expertise. Otherwise these votes are allocated proportionally in accordance with the bylaws, section 14a, paragraph 3.

Abbreviations:
GKV-Spitzenverband = National Association of Statutory Health Insurance Funds
DKG = German Hospital Federation
KBV = National Association of Statutory Health Insurance Physicians
KZBV = National Association of Statutory Health Insurance Dentists

3

Individual Contracts

There are high demands placed on the clinical evidence for evaluating a new procedure. For this reason, many innovative medical services are first reimbursed on the basis of individual, regional and time-limited contracts between the providers and payers, which typically have lower demands on the clinical evidence.

4

Individual Healthcare Services (IGeL)

Some procedures which are neither listed in the EBM nor covered by individual contracts between provider and payers can be received by the patients, but have to be paid out of the pocket. These services are called IGeL (short for Individuelle Gesundheitsleistungen; individual healthcare services). In general, they are paid entirely by the patients, as GKV does not consider them as "necessary, appropriate, and economic". Illustrative IGeL services are intraocular tension measurement, some ultrasound diagnostic methods and cosmetic therapies. The annual total volume of the IGeL services performed in Germany is 1 billion euros.

5

Budget Constraints

The precise amount which physicians receive for their medical services varies as it is linked to the actual annual budget of their respective Kassenärztliche Vereinigung (Association of the Statutory Health Insurance Physicians (ASHIP)). This means that physicians in one part of Germany may receive a different amount for an identical service than physicians working in another part of Germany who are members of a different ASHIP. Furthermore, in certain cases, the EBM amount per doctor may also be restricted, for instance a doctor who performs a certain medical procedure too often may receive a partial deduction of EBM points.

6

Medical Devices for Home-Use: List of Assistive Devices

Medical devices that are used at home (for instance hearing aids, surgical stockings, orthopedic insoles) and are reimbursed under GKV schemes are listed in a specific directory, the Catalog of Assistive Devices (Hilfsmittelverzeichnis). This directory sets the list of recommendations for such devices and is almost binding. Manufacturers can apply to have medical devices included on this list. The application is submitted to the Federal Association of Statutory Insurances (GKV-Spitzenverband Bund).

7

DiGA

DiGA (Digitale Gesundheitsanwendungen) was introduced in Germany in 2020 as part of the Digital Healthcare Act (Digitale-Versorgung-Gesetz). This legislation allows patients to access certain approved digital health applications via prescription, with costs covered by statutory health insurance (GKV). DiGA are digital tools, such as apps or software programs, designed to assist with diagnosing, treating, or managing diseases.

DiGA are medical devices and accordingly subject to different risk classes per CE marking. DiGA, per definition, can be risk class I or IIa; however, the accepted risk classes were increased in 2024 to include IIb devices.

The introduction of DiGA represents a significant step towards integrating digital health tools into mainstream healthcare in Germany.

8

Annex V for Wound Care Products

For drug-alike medical devices there has always been a reimbursement positive list managed by the G-BA: Annex V of the Drug Guideline (Arzneimittel-Richtlinie). Recently, while legally defining the term "bandage", it was also decided that so-called "other wound products" which act by means of pharmacological, immunological or metabolic components, also need a listing on Annex V in order to be reimbursable. In this sense, a grace period for products already in the market will end December 2024, while a prolongation of the grace period is currently discussed. As of now, there is no general standard on the evidence requirements needed for the application to be included on this positive list. To remedy this, the G-BA has already implemented a consultation process open to manufacturers, though.

9

AOP Catalogue

Outpatient procedures provided in hospitals are defined in the AOP catalogue ("Katalog ambulant durchführbarer Operationen"). This catalogue contains a positive list of outpatient procedures (surgeries and interventions) that can be performed and reimbursed in hospitals on an ambulatory basis. AOP procedures have so far been reimbursed by EBM codes (outpatient SHI tariff). Recently, it was decided that the AOP catalogue would be expanded to allow more outpatient procedures in hospital. Effectively, hospitals now can do services from the AOP catalogue only in an inpatient setting when patient or procedure characteristics speak against an ambulatory service. Hence, this should result in a fewer number of inpatient cases. This scheme began to be implemented early 2023 and further expansions are still underway for 2025 and beyond.

10

Hybrid-DRGs

Along with the changes to the AOP catalogue, a new reimbursement scheme was introduced in 2024: the Hybrid DRGs. These lump sums, a modified version of their inpatient counterparts, are paid either to the hospital or to the outpatient office doing a defined ambulatory surgery or intervention. The equal payment shall ensure that there is no monetary incentive to steer patients only towards hospitals or only towards offices for these ambulatory procedures. The services subject to this new reimbursement scheme are specifically defined and are a subset from the overall AOP catalogue. The list of Hybrid DRG services will be expanded for 2025 and is expected to grow further for 2026.

IGES Group

The Knowledge Corporation

Independent and innovative since 1980, the IGES Group focuses on research, development and consulting for life sciences and health care.

iGES

The IGES Institute is the core of the IGES Group. It offers comprehensive services based on expertise: Studies, reports, publications, concepts and strategies for health, transport, education and housing.

CSG

CSG (Clinical Study Group) is a full-service contract research organization.

IMC clinicon

IMC clinicon is a consulting and services institute for the hospital sector, providing in-depth data and analysis on German hospitals.

HealthEcon

HealthEcon, based in Basel, Switzerland is a consulting firm for health technology assessment, European market access and value strategy for the pharmaceutical industry.

Device Access

Device Access, based in Southampton, UK, supports medical device manufacturers from across the world to get great technologies to NHS patients faster, through NICE approvals.

MEDITECH ACCESS

MediTech Access, based in Versailles, France, provides comprehensive market access and pricing strategies for France.

synergus RWE

evidence for decisions

Synergus RWE, based in Stockholm, Sweden, supports the development and execution of real-world evidence strategies and market access strategies for medical devices, diagnostics and digital health solutions.

AiM

AiM (Assessment in Medicine) is a health-economic consulting agency for the medical device industry, dedicated to reimbursement programs.

AiM's Services

Health Economics & Outcomes Research

- Value demonstration
- Health technology assessment (HTA)
- Health economic evaluation

Real-World and Care Provision Analysis

- Demand and access
- Quality of care
- Utilization and expenditure

Market Analysis

- Assessment of inpatient and ambulatory sector potentials
- Competition and regulation analysis

Strategic Consultation

- Pricing and market access
- Portrayal of individual product reimbursement pathways
- Assistance with review process conducted by the Federal Joint Committee (G-BA) / Institute for Quality and Efficiency in Healthcare (IQWiG); consulting for new examination and treatment methods (NUB)

OPTiMAX access

Optimax Access, based in Southampton, UK, provides pharmaceutical and medical devices companies with a comprehensive range of services related to Health Economics and Outcomes Research.

Glossary

AOP: Katalog ambulant durchführbarer Operationen (Catalog of outpatient surgeries)

BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte (Federal Institute for Drugs and Medical Devices)

EBM: Einheitlicher Bemessungsmaßstab (Uniform Evaluation Scale)

G-BA: Gemeinsamer Bundesausschuss (Federal Joint Committee)

G-DRG: German Diagnosis Related Groups

GKV: Gesetzliche Krankenversicherung (Statutory Health Insurance)

HTA: Health Technology Assessment

IGeL: Individuelle Gesundheitsleistungen (Individual Healthcare Services)

InEK: Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System)

IQWiG: Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Healthcare)

NUB: Neue Untersuchungs- und Behandlungsmethoden (New Methods for Treatment and Screening)

OPS: Operationen- und Prozedurenschlüssel (Surgery and Procedure Code)

PKV: Private Krankenversicherung (Private Health Insurance)

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