

Reimbursement of Medical Devices in Germany

2020/2021

Finding Your Way into the German Medical Device Market

The German Market and Access to it

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AiM has been supporting the medical device industry for over a decade. 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 700 projects for more than 150 clients.

<p>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.</p>	<p>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.</p> <p>However, no document can replace a face-to-face meeting and qualified consultancy. We look forward to hearing from you.</p> <p>AiM – Assessment in Medicine, Research and Consulting</p>
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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 446 billion USD. The USA have the largest market with 169 billion USD, Germany has the second largest market with 44 billion USD, and Japan's market is the third largest with 39 billion USD. The German market is by far Europe's largest market; it is bigger than the French and the UK market combined.

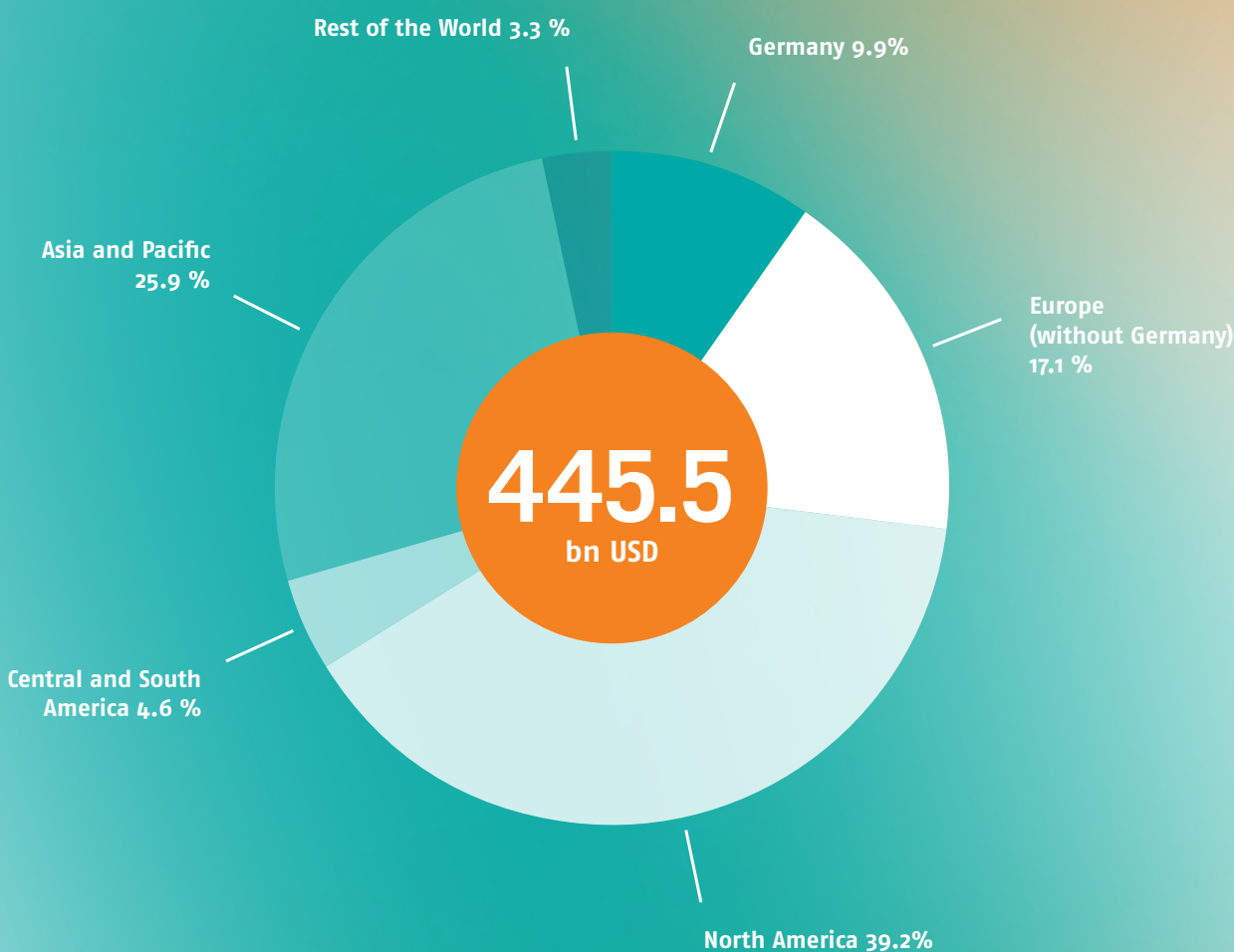
Population (in m)	
EU 27 + UK:	513.5
Germany:	83.0
France:	67.0
UK:	66.7
Italy:	60.4
Spain:	46.9

Source: Eurostat, data for 2019

Hospital bed density (beds per 100,000 inhabitants)	
EU 27 + UK:	504.3
Germany:	800.2
France:	598.0
Italy:	318.1
Spain:	297.3
UK:	253.7

Source: Eurostat, data for 2017

World Market for Medical Devices (by regions)



Source: AiM based on SPECTARIS, Jahrbuch 2019/2020, p. 15, data for 2019

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 EU Directives, such as the Medical Devices Directive (MDD), the In Vitro Diagnostic Device Directive (IVDD) or the Active Implantable Medical Device Directive (AIMD).

The Medical Device Regulation and the In Vitro Diagnostic Regulation will come into force in May 2020, reforming the previous medical device system and implementing a large number of changes. However, the general concept described below will remain in place.

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	Class IIa	Class IIb	Class III
Wheelchairs, crutches, hospital beds, bandages	Diagnostic ultrasound devices, hearing aids, contact lenses, dental fillings	Dental implants, defibrillators, respiration and dialysis devices	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 his product, regardless of whether he 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 applicable directives (MDD, IVDD, AIMD).
- 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. 73.2 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 around 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.

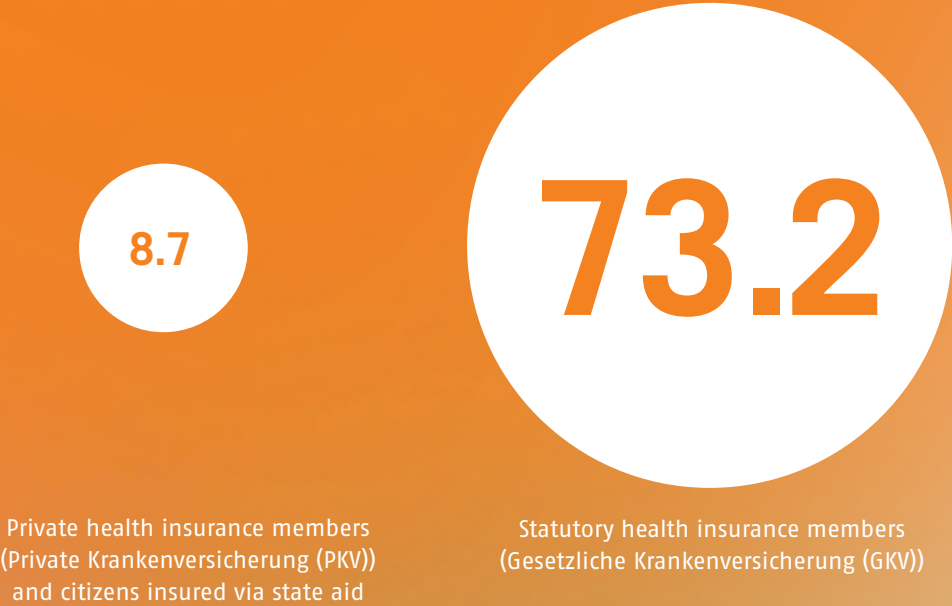
5 Largest Statutory Health Insurance Funds by Members in m:

Techniker Krankenkasse, TK	10.5
Barmer	9.1
DAK-Gesundheit	5.7
AOK Bayern	4.5
AOK Baden-Württemberg	4.3

Source: AiM, data for 2019

Private and Statutory Health Insurances by Members

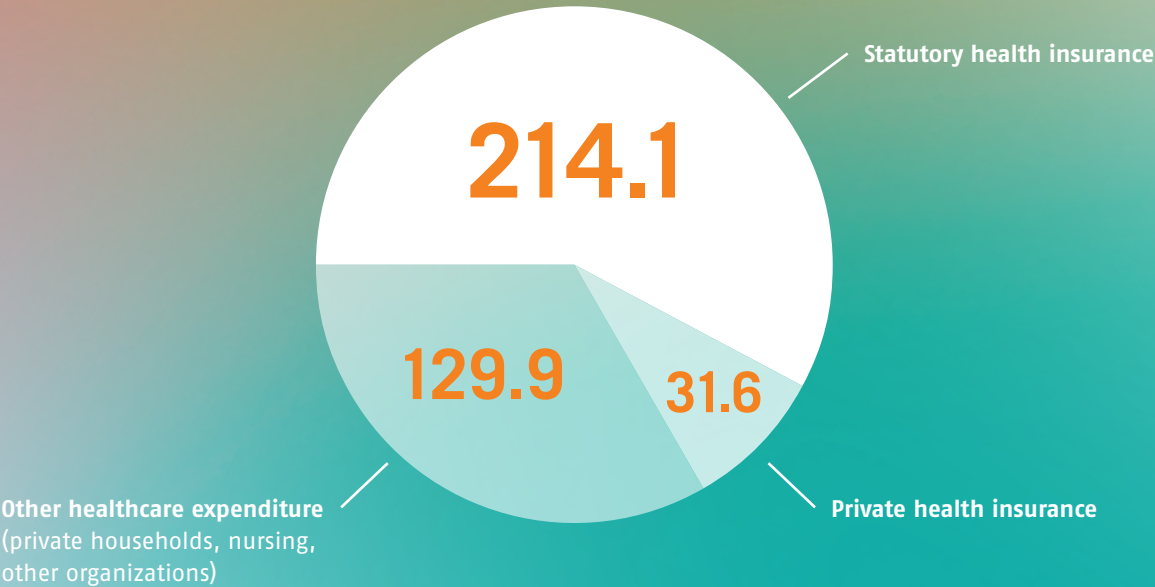
(in millions)



Source: statista.de, data for 2019

Healthcare Expenditure

Total annual healthcare expenditure in Germany is 375.6 billion euros, of which 214.1 billion euros are spent by the statutory health insurance funds. Private health insurance companies spend 31.6 billion euros.



Total healthcare expenditure in Germany is **375.6 billion euros**

Source: AiM based on German Federal Statistical Office, data for 2017

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 more than 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 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 DIMDI (German Institute of Medical Documentation and Information) 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 DIMDI'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 →

5

Additional Charges (Zusatzentgelt)

→ 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.

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 2020, there are a total of 218 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.

Hospitals and Physicians in Germany

1,942

Total Number of Hospitals in Germany

497,182

Total Number of Hospital Beds

77.8%

Rate of hospital
bed utilization

19,442,810

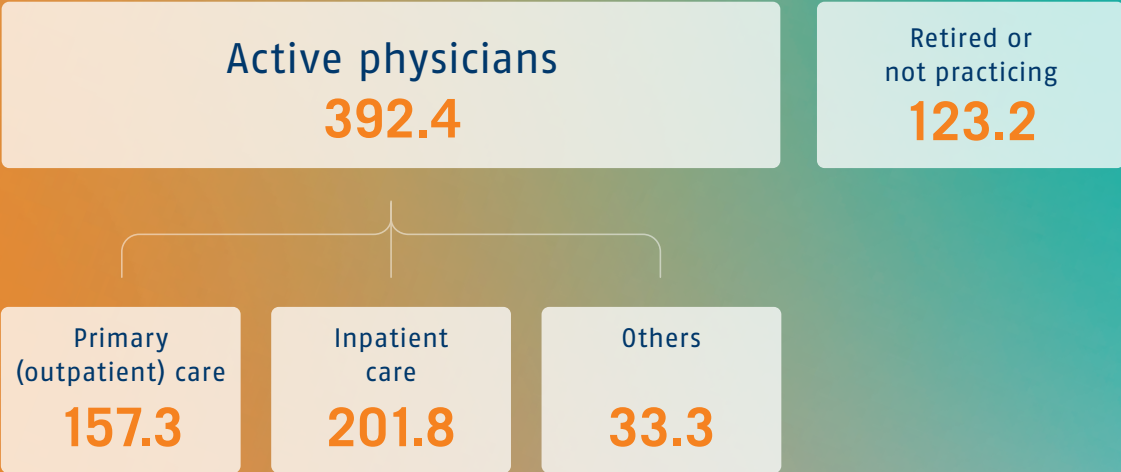
Total annual number of cases
treated in Germany

894,400

Total hospital staff

Source: German Federal Statistical Office, data for 2017

Structure of Medical Profession in Germany (in thousands)



Source: IGES based on Bundesärztekammer (German Medical Association), data for 2018

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 popular yet. 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 146,000 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 GKV. Payments by the GKV 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

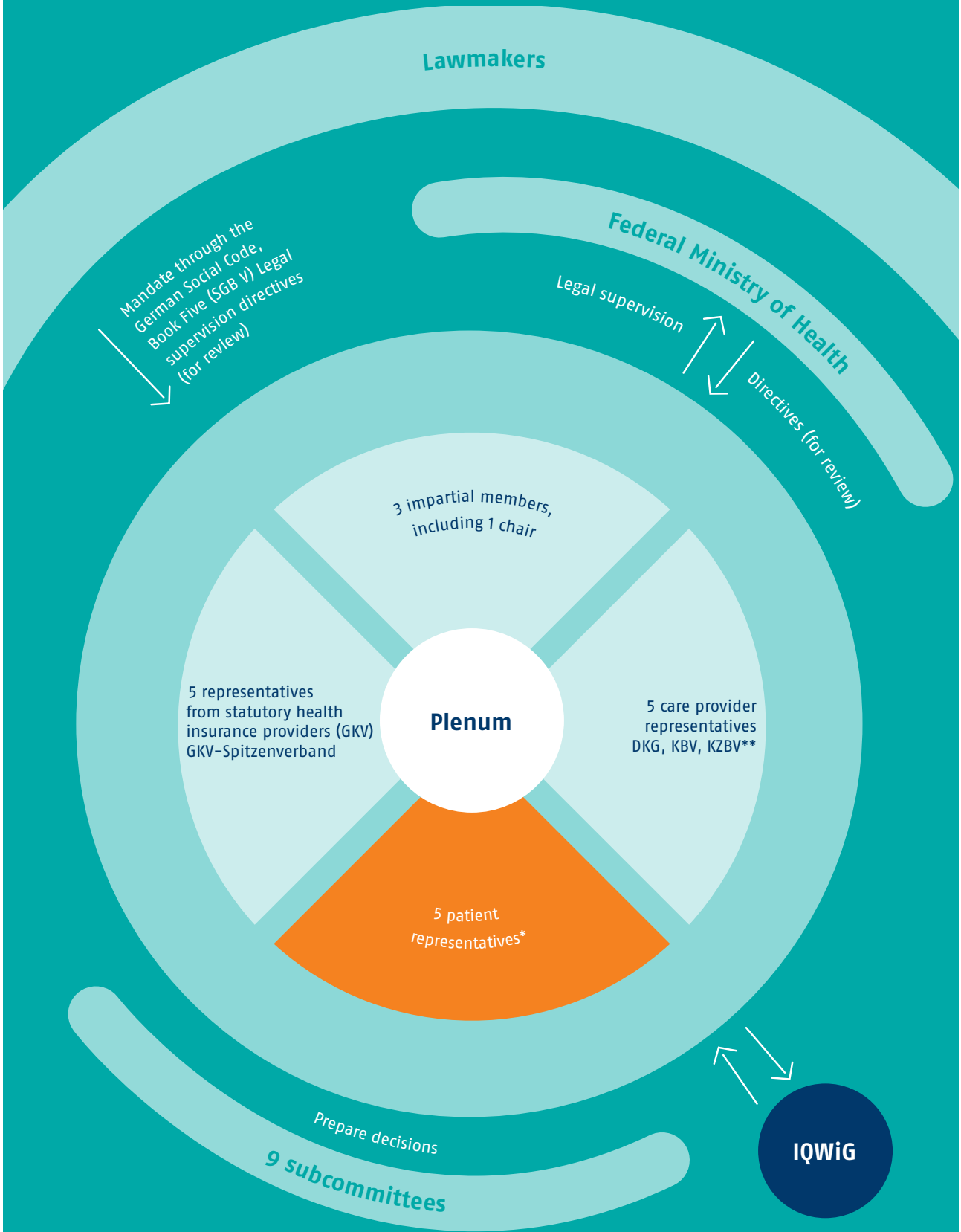
Authorization Right

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).

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, evaluations, concepts and strategies. Since its foundation, it has conducted over 2,000 research and consulting projects.

CSG

CSG (Clinical Study Group) is a full-service contract research organization, offering services in planning, implementing and analyzing clinical-scientific studies.

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 with almost 40 years of experience.

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.

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 (HEOR).

AiM

AiM (Assessment in Medicine) is a health-economic consulting agency for the medical device industry, dedicated to reimbursement programs. Health technology assessment dossiers are founded on scientific methodologies.

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)

Glossary

DIMDI: Deutsches Institut für Medizinische Dokumentation und Information (German Institute of Medical Documentation and Information)

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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