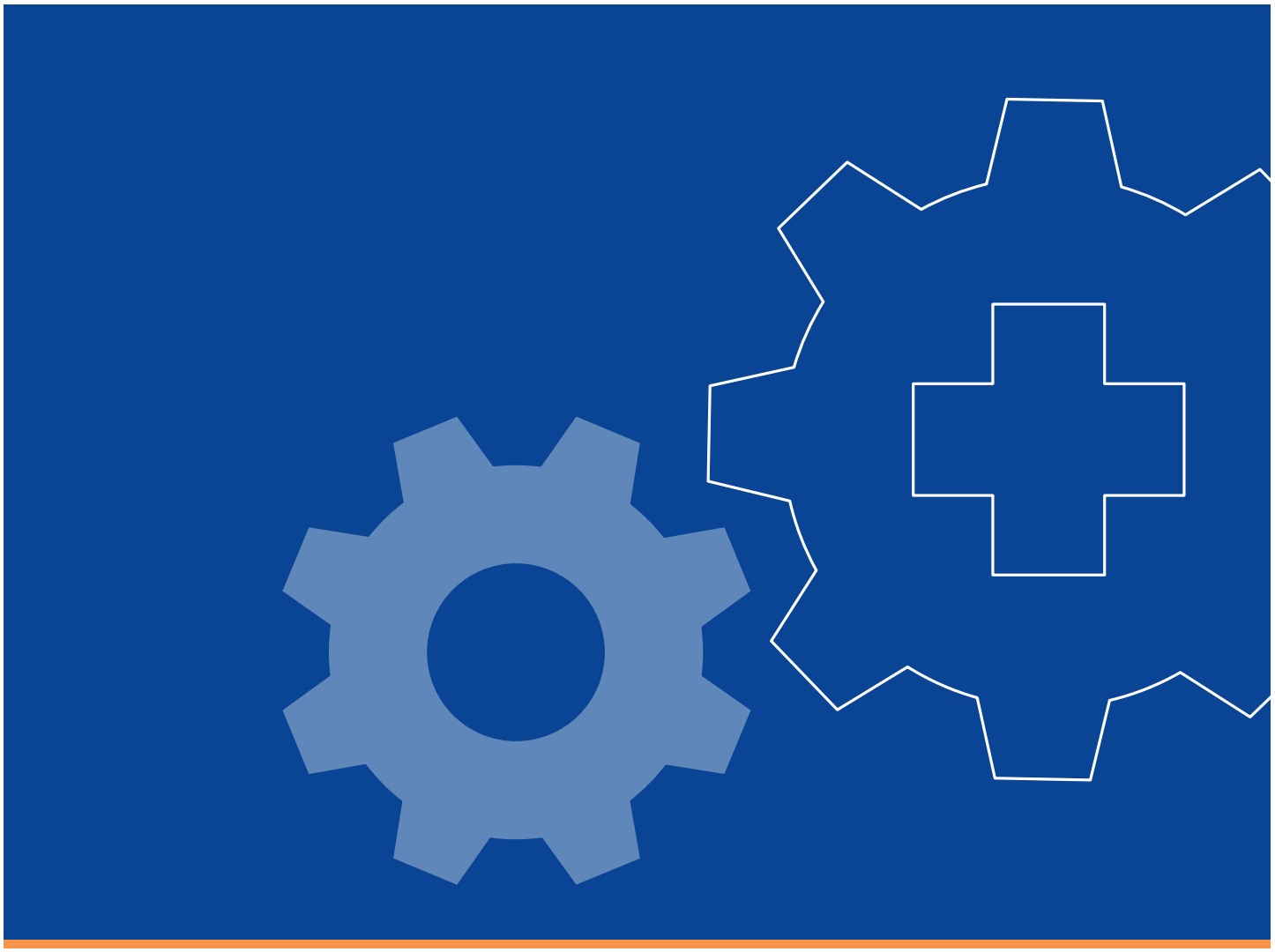
HEALTHCARE HEADS

MARKET ACCESS NAVIGATORS

WHITEPAPER

Market Access to the German healthcare system

A Reimbursement and Market Access Guide for the Medical Industry



Executive Summary

The German healthcare system is one of the oldest in the world and has developed into a highly complex system over the last centuries. On the one hand, it is subject to constant change and offers many opportunities for active participation, on the other hand, there are firmly anchored principles that seem irrevocable.

There are numerous challenges in terms of costs, funding, the transition between the different sectors – particularly the interlocking between in-patient and out-patient – and the structure of the hospital landscape.

To transfer the German healthcare system into the digital age, the regulatory framework is currently revised and reshaped.

The economic pressure, particularly on the hospitals, will not diminish and since 2020 more hospital closures – which is actually intended – are expected than before.

Hospitals compete for the patients in performance competitions. Therapies with an economic advantage are of special economic interest.

Overall, clinical evidence seems to increasingly gain importance but plays a minor role in concrete purchasing decisions in the hospital compared to economic considerations.

A special feature is the large proportion of patients with health insurance (97%), which makes it necessary that innovative medical devices are covered by health insurances (primary health care market). The willingness to pay out of pocket for treatment (secondary healthcare market) is rather low.

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1. History

For an understanding of structures, requirements and challenges, it is reasonable to deal with a short outline of the German healthcare system's history.

The German healthcare system is one of the oldest in the world and has grown continuously over the last centuries. Essential characteristics are e.g. structural characteristics of social protection. The resulting demands of society on healthcare and on the system have become culturally and politically anchored over the centuries.

The German market economy is a social market economy. The market is only free to a limited extent, as it is strongly regulated, particularly the healthcare market. The social welfare of the German state is stipulated in the Basic Law as well as in 13 other social law books and is thus regarded as one of the unchangeable requirements.

The grown and complex structures of the German healthcare system can represent barriers to the market entry for innovative and disruptive technologies. On the other hand, there are opportunities for innovative technologies having the potential to provide a solution to current challenges in healthcare.

2. Current challenges in the German healthcare system

Healthcare costs are continuously rising. This is the price for continuously improving medical care, higher age and satisfactory healthcare for the aging population.

As long as the costs can be financed by the likewise rising gross domestic product (GDP), this circumstance seems unproblematic. However, the healthcare costs per capita also increase in relation to the GDP. A bigger problem than the costs seems to be the funding of the statutory health insurance (Gesetzliche Krankenversicherung - GKV).

In Germany, a health insurance is compulsory, 97% of the population are insured with free access to out-patient and in-patient healthcare. Almost 90% of the insurants are insured in one of the 103 statutory health insurances (status 2021), the rest of the population is privately insured. The statutory health insurance is financed equally by employers and employees who both pay a percentage of the wage to the health insurance companies.

The general decline in the number of employees subject to social insurance contributions combined with a simultaneous increase of the elderly population and an increase in life expectancy is expected to further increase the discrepancy between health insurances‘ revenues and expenses in the next years. Due to the pay-as-you-go system, with which the funds of the insurants are used for current expenses – without the formation of significant savings – short-term budgeting of expenses plays a greater role for health insurance companies than precautionary measures and prevention. Savings through innovative medical products, which result from the avoidance of later treatments, play at an inferior role for health insurances at the moment.

Politicians are currently addressing the current challenges. In the last legislative period under Health Minister Jens Spahn, more than 100 laws were introduced to improve the situation. The equipment of hospitals as well as the lack of nursing staff are major challenges. He launched 18 healthcare laws in 18 months. The first of these laws alone, the „Nursing Staff Strengthening Act“ (Pflegepersonal-Stärkungsgesetz, PpSG), is considered the most significant change in hospital financing since since the introduction of the G-DRG system.

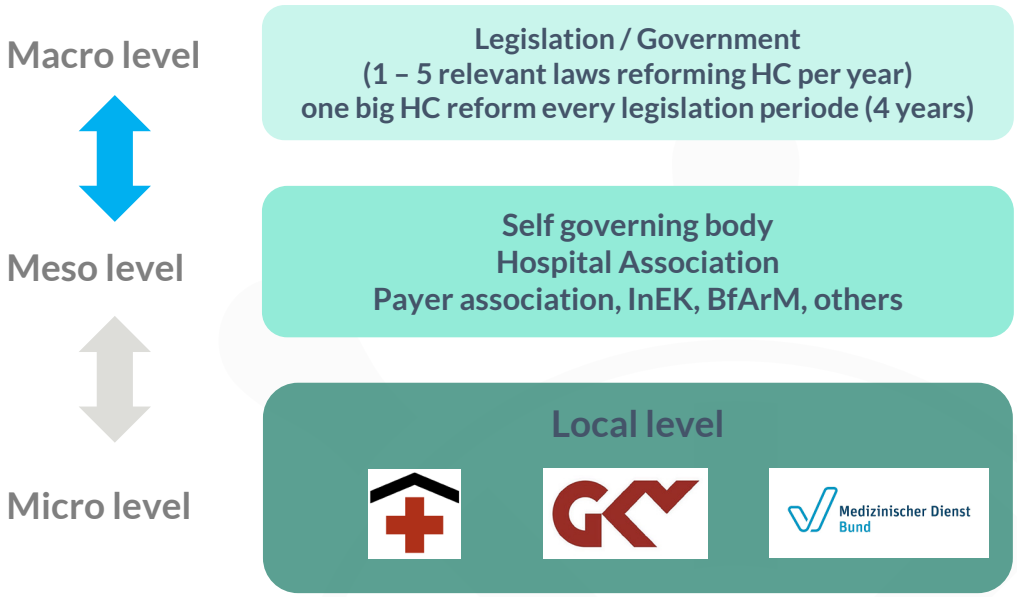
3. Numerous Stakeholders

The decision-makers in the healthcare sector can be divided into three hierarchically separated levels, the macro, meso and micro level.

At the macro level, the federal policy, regulatory framework conditions are created which are then prepared and finalized at the meso level.
In simplified terms, the meso level can be described as the level of a self-governmental body, where numerous different stakeholder groups from regional politics, associations of service providers and payers struggle to shape and fine-tune the framework conditions. The micro level can be regarded as the local level at which services and treatments are provided, negotiated and reimbursed.

The partners of the self-governmental body do not always act as the policy dictates and the contracting parties do not always act at the local level as decided by the self-governmental body. On the one hand, the network of relationships between the various stakeholder groups is complex, on the other hand there are numerous connecting factors with which influence can be gained.

Therefore, it is necessary to have a grown relationship to the different stakeholders for positioning an innovative or even disruptive technology.



4. Various sectors

The healthcare system in Germany is divided into four sectors, which are regulated differently and are subject to different Reimbursement systems. The most important of these are in the in-patient and out-patient sectors.

4.1 In-patient-sector

The in-patient treatment of patients in Germany takes place in one of 1,903 hospitals (2020). Hospitals in Germany are remunerated via a dual system. Dual hospital remuneration means that investment and operating costs are financed separately. The federal states responsible for ensuring healthcare are responsible for the investments.

The operating costs are financed by the health insurance funds in the form of a lump-sum Reimbursement via the G-DRG-system. Certain therapies, such as robotically assisted surgeries, are therefore financed by the federal states as well as via the G-DRG-system. The challenge is that the federal states (with a south – north and west – east decline) are increasingly failing to meet their financing obligations. This means that hospitals are forced to generate profits through the G-DRG-system in order to make the necessary investments. At the same time, however, the G-DRG-system has not been established for this purpose and the framework conditions only allow very small increases in the number of cases in order to enable hospitals to act economically.

For this reason, the economic results that can be achieved with therapies and products are particularly important for hospitals. Economic models and presentations of the medical industry in relation to the economic results of the various therapies are therefore in many cases helpful or even necessary for a successful Market Access.

Hospitals: In hospitals, all physicians (including the chief physician) are typically employed physicians. There is a strong hierarchical structure – especially in the surgical disciplines – with a consultant, registrar and (senior)house officer. Cooperative leadership models as in other countries are rather rare.

Which hospitals are required in a federal state and what kind of services can be offered is determined in the so-called federal state hospital plan. The level of care (basic/primary to maximum healthcare/university hospitals) plays an important role here. Hospitals may only provide their planned services.

Hospitals are typically distinguished by their sponsorship (in the sense of operators or owners of one or more hospitals). A distinction is made between public hospitals (run by municipalities, for example), non-profit hospitals (run by churches) and private hospitals (run by private groups). All groups have hospital associations or chains with the aim of strengthening market power. The funding of all hospitals is the same. There is basically no difference between private and other hospitals (e.g. only private patients or the like). Also the share in private patients does not differ between the different sponsorships.

G-DRG-system: The G-DRG-system as the basis for in-patient treatment Reimbursement is annually reviewed and further developed. Various proposal procedures can be used to influence the further development – also by the industry – which is desired and planned. As a rule, it is not necessary to provide evidence to finance a therapy. Detailed knowledge of the G-DRG-development process is necessary and advantageous for a successful proposal.

Other forms of Reimbursement: In addition to the Reimbursement via DRGs, hospitals also have the opportunity of negotiating integrated care contratcs (iGV) with the payers, performing out-patient surgeries within a certain framework or setting up to a medical care center.

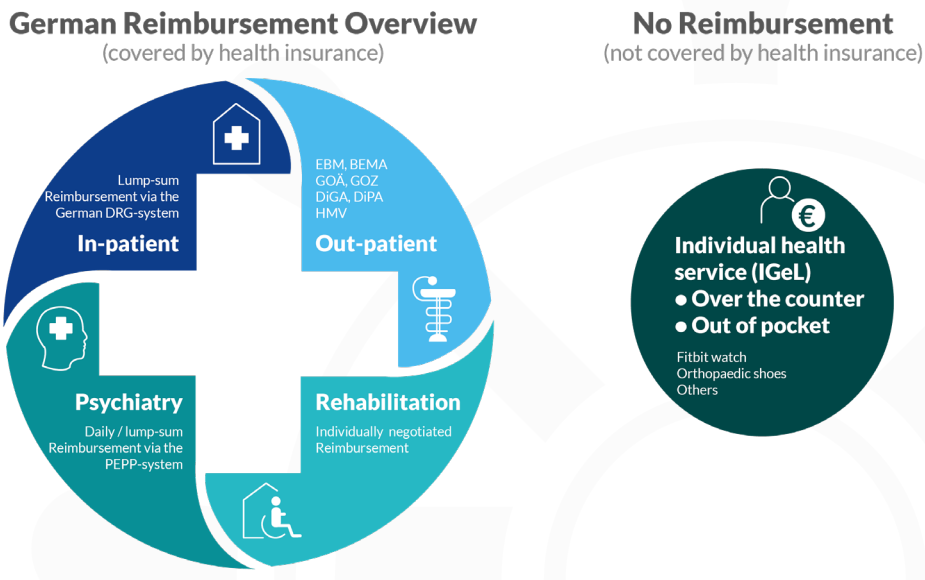
4.2 Out-patient sector

Out-patient treatment of patients is typically performed outside hospitals. In Germany, there are the so-called "Vertragsärzte", general practitioners or specialists, who typically have a contract with the Association of statutory health insurances registered physicians (KV).

Patients with a statutory health insurance have free access to physicians having a contract with the KV. Free access to hospitals is only available for emergency treatment and privately insured persons. Patients with statutory health insurance have a free choice of physician but must first consult a "Vertragsarzt" before receiving in-patient treatment. For this, the patient will receive an assignment.

For patients with statutory health insurance, billing is based on the EBM ("Einheitlicher Bewertungsmaßstab") and for patients with private health insurance, on the GOÄ ("Gebührenordnung für Ärzte"). Since evidence is generally required for the introduction of new therapies in the out-patient sector, the further development process of the out-patient billing system is more complex and takes more time than the in-patient process. In addition, the entire process is less standardised and structured and is often complicated due to conflicting interests of the stakeholder's involvement.

The out-patient emergency treatment is performed in hospitals as well as in the out-patient emergency of the physicians with an own practice.
In some hospitals, individual physicians are authorized to provide out-patient treatments.



5. Evidence

Clinical evidence is basically the scientifically proof of benefit for therapies and products and is especially important in Germany regarding the support of market entry.

However, the importance of evidence and the type of evidence required depend heavily on the sector in which the medical device is to be used.

In the out-patient market, the so-called „prohibition with permission reservation“ is valid. New examination and treatment methods may not be provided here at the expense of the statutory health insurance if they have not been permitted. Evidence and benefit assessments are necessary for permission. This is a rather time-consuming and complex process.

In the in-patient sector, the so-called “permission with prohibition reservation” is valid. This means that a therapy with a medical device can be performed and invoiced on the statutory health insurance, as long as it is not forbidden.

Nevertheless, it should be noted that for the in-patient sector – e.g. within the framework of various proposal procedures – stakeholder groups are necessary to support the projects, which in turn insist on evidence. The required form of evidence can be different. In many cases, it is enough to prepare the available evidence for the different therapy options in the form of a dossier.

Evidence as proof of quality for therapies and products is important but less important than economic requirements when it comes to purchasing decisions in the in-patient sector. The process of evidence generation is complex, long and time-consuming. Early strategic planning of the Market Access path and the relevant stakeholder groups and their requirements therefore seems relevant.

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