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Working Paper

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Defining benefit catalogues and entitlements to health care in Germany – decision makers, decision criteria and taxonomy of catalogues

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Zusammenfassung

Während die Rahmenbedingungen für das deutsche Gesundheitssystem vom Gesetzgeber vorgegeben werden, obliegt die Bestimmung einzelner Leistungen bzw. Leistungsinhalte den Entscheidungsträgern der Selbstverwaltung. Dabei variiert die Genauigkeit der Leistungsdefinition zwischen verschiedenen Sektoren und Ausgabenträgern. Während die Leistungen einiger Ausgabenträger nur implizit definiert sind, ist der Leistungsumfang anderer Ausgabenträger bereits explizit als Leistungskatalog formuliert. Dabei orientiert sich die Mehrheit der Ausgabenträger an dem Leistungsumfang der gesetzlichen Krankenversicherung (GKV) und überträgt diesen in den eigenen Bereich. Im Rahmen der GKV, die ca. 88% der Bevölkerung versichert und 56,9% der Gesundheitsausgaben trägt, bestimmen verschiedene Kataloge zusammen mit den Richtlinien des Gemeinsamen Bundesausschusses den Leistungsumfang. Die Leistungen, der Aufbau und der Inhalt der Leistungskataloge, die an der Definition der Kataloge beteiligten Akteure, sowie die Entscheidungskriterien für die Aufnahme neuer Leistungen in die Leistungskataloge der Sozialversicherungen werden in diesem Zusammenhang ausführlich dargestellt und analysiert.

Abstract

While the general framework for the German health care system is laid down by the government, the definition of benefits is delegated to self-regulated organizations of payers and providers that are actually involved in financing and delivering health care covered by social insurance schemes. However, the explicitness of defined benefits varies largely by sector and among the different schemes. While some schemes rather have an implicitly defined benefit basket, benefits provided by other schemes are laid down explicitly in one or several catalogues. Most schemes determine their benefits following the Statutory Health Insurance Scheme which covers 88% of the population and accounts for 56.9% of Germany's total health expenditure. Under the Statutory Health Insurance Scheme entitlements of the insured are defined in different benefit catalogues and the directives of the Federal Joint Committee. The entitlements of the insured, the taxonomy of benefit catalogues, the actors involved in the decision making process and the decision criteria for the inclusion of new benefits are described and analyzed in this paper.

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I) Overall description of the organizational structure and the actors involved

A. Organizational structure of the health care system

A fundamental aspect of the German political system – and the health care system in particular – is the sharing of decision-making powers between the *Länder*, the federal government and legitimized self-governmental organizations. In health care, governments traditionally delegate responsibilities to membership-based, self-regulated organizations of payers and providers that are actually involved in financing and delivering health care covered by social insurance schemes. In the – for health care – most prominent scheme, the Statutory Health Insurance (SHI) covering 88% of the population, sickness funds, their associations and associations of SHI-affiliated physicians and dentists have assumed the status of quasi-public corporations. These corporatist bodies constitute the self-regulated structures that operate the financing and delivery of benefits covered by Statutory Health Insurance within the legal framework. They are based on mandatory membership and internal democratic legitimization. They may define and raise membership fees and finance or deliver services to their members. In joint committees of payers (associations of sickness funds) and providers (association of physicians' and/or dentists' and/or hospitals) legitimized actors have the duty and right to define benefits, prices and standards (federal level) and to negotiate horizontal contracts, to control and sanction their members (regional level). The vertical implementation of decisions taken by senior levels is combined with a strong horizontal decision-making and contracting among the legitimated actors involved in the various sectors of care.

Beyond the established decision-making corporatist organizations, other organizations have recently been given formal rights to contribute to decision-making bodies by consultation (e.g. nurses and allied health professions), participation and proposals (patient organizations) or becoming a deciding and financing partner at the table (private health insurance for case payments in hospitals). A separate group of actors are the social courts.

The constitution defines areas of exclusive federal legislation and concurrent legislation. Health is not an area exclusive to federal legislation – and in fact the constitution does not mention any entitlements to health care or any specific health services – but specific topics relevant to health are included in the concurrent legislation, for example, social protection and benefits, measures against diseases that threaten public safety, protection against ionizing radiation, certification of physicians and other health professions, pharmaceuticals and drugs,

and the economy of hospitals. However, federal law – where it exists in these areas – takes precedence over *Länder* law. In addition, parts of environmental policies fall into this category. Implicitly, all other aspects of (public) health are therefore the responsibility of the *Länder*.

Federal level

At the national level, the Federal Assembly, the Federal Council and the Federal Ministry for Health and Social Security are the key actors. The Ministry of Health and Social Security (in the following text called Ministry of Health) has been reorganized into eight areas with two or three sub-divisions each:

- administration
- European and international health and social policy
- planning, future of the social state, innovation and information
- pharmaceuticals and health protection
- health care, Statutory Health Insurance, securing long-term care
- prevention, combating disease and biomedicine
- Statutory retirement insurance, social compensation
- issues of disabled people, social welfare.

The Ministry of Health is assisted by subordinate authorities with respect to the execution of licensing and supervisory functions, scientific consultancy work and information services to the population or scientific community. Among them are:

- The Federal Institute for Pharmaceuticals and Medical Devices (BfArM) licenses pharmaceuticals and supervises the safety of pharmaceuticals and medical devices.
- The German Institute for Medical Documentation and Information (DIMDI) has the task of providing information to the public and professionals in all fields of the life sciences. After initially concentrating on health care and medicine, DIMDI now offers a broad collection of databases covering the entire spectrum of life sciences and social sciences. It has organized the prioritization, out-sourcing and publication of health technology assessment reports since 2000. It is also responsible for the development of German versions of the OPS and of the ICF.

Other federal institutions relevant to the health care system are the Federal Insurance Authority (for social insurance actors) and the Federal Authority for Financial Services Supervision, responsible for supervising private for-profit insurance.

Länder level

The federal structure is represented mainly by the 16 state governments and, to a very small extent, by the state legislatures. In 2003, 13 out of the 16 *Länder* governments had a ministry with "health" in its name. However, none has an exclusive health ministry. In most of these *Länder* it is most commonly combined with Labour and Social Policy (which is also the case in the remaining three *Länder*), less commonly with family or youth affairs, and only in one Land is it combined with environmental affairs.

Within a *Land*'s Labour Ministry, "health" is typically one of four or five divisions. In Lower Saxony for example, the health division is further sub-divided into units concerned with

- public health services and environmental hygiene
- health promotion, prevention and AIDS care
- state-owned hospitals
- hospital planning
- supervision of health professions and their professional institutions
- psychiatry and illegal drugs
- pharmaceuticals and supervision of pharmacists and their professional institutions.

Most other areas affecting health such as traffic, city planning or education are controlled by other ministries.

Corporatist level

For the Statutory Health Insurance scheme, corporatism is represented by the SHI-affiliated physicians' and dentists' associations on the provider side and the sickness funds and their associations on the purchasers' side. These bodies have assumed the status of a quasi-public corporation and are based on mandatory membership. Many decisions are taken in joint committees consisting of representatives from the sickness funds and the provider's side and presided by a neutral chairperson.

Providers

Physicians treating SHI-insured patients are organized in regional physicians' associations, based on obligatory membership and democratically elected representation. There is a physicians' association in each of the 16 *Länder*. In addition, the highly populated *Land* North Rhine-Westphalia has two physicians' associations. The Federal Association of SHI Physicians is responsible for cooperation within the corporatist institutions at the federal level.

SHI-accredited Dentists are organized in the same way as physicians, that is, through dentists' associations in the *Länder* and a Federal Association of SHI Dentists.

The German Hospital Association has increasingly been integrated into decision-making bodies of the Statutory Health Insurance structures. Formally it does not have the status of a quasi-public corporation but represents the interests of hospitals as an organization based on private law. It is, however, increasingly charged with legal responsibilities as well. The membership of the German Hospital Association consists of 16 *Länder* organizations and 12 associations of different types of hospitals, for example, university, public municipal, or private for-profit. Other provider organizations have gained consultative rights but no decision-making powers in recent years.

Payers

The payers' side is made up of autonomous sickness funds organized on a regional and/or federal basis. The total number of sickness funds has decreased steadily since the general regional funds and the substitute funds were legally opened to all those seeking insurance through the Health Care Structure Act of 1993. In January 2004 there were 292 statutory sickness funds with about 72 million insured people (about 50.7 million members plus their dependants). On 1 January 2004:

- 37% of all SHI members were insured by one of the 17 general regional funds (*Allgemeine Ortskrankenkassen*, AOK);
- 33% were insured by one of the 10 substitute funds (*Ersatzkassen*), formerly open to either white collars or to blue collars;
- 21% were insured by one of the 229 company-based sickness funds (*Betriebskankenkassen*, BKK) and
- 6% were insured by 20 guild funds (*Innungskrankenkassen*, IKK).

Special rules apply to the sickness funds for farmers (14), miners (1) and sailors (1) with "closed" and comparably small membership (4% in total).

All funds have non-profit status and are based on the principle of self-governance. By law, sickness funds have the obligation to raise contributions from their members, which includes the right to determine what contribution rate is necessary to cover expenditure. In most funds, the management is made up of an executive board of two full-time managers responsible for the day-to-day management of the fund, and an assembly of delegates deciding on bylaws and other regulations of the fund, passing the budget, setting the contribution rate and electing the

executive board. Usually, the assembly is composed of representatives of the insured and employers, whereas the assemblies of the substitute funds are entirely comprised of representatives of the insured population. Both the representatives of the employees and insured and of the employers are democratically elected every six years.

Corporatist institutions similar to the sickness funds exist in other health-related statutory insurance schemes as well:

- Statutory Accident Insurance scheme covering curative and rehabilitative care services for work-related accidents and diseases,
- Statutory retirement insurance schemes, responsible for most rehabilitative measures,
- since 1995, Statutory long-term care insurance scheme is administrated by the existing sickness funds and

B. Planning, regulation and management

Federal level

Issues of equity, comprehensiveness and the rules for providing and financing social services are regulated at the federal level. All social insurance schemes are regulated through the Social Code Book (SGB) – the cornerstone of social insurance legislation – but fall within the authority of different ministries. The Social Code Book has regulated the social insurance schemes in the new eastern *Länder* since 1 January 1991, in the same way as in the western *Länder*, except for certain special, mainly transitional regulations.

The entitlements, rights and duties of insured covered by social insurance schemes are defined in Social Code Book I and specified in subsequent social code books. Health-related social services are regulated through several social insurance schemes, most importantly Statutory Health Insurance which is dealt with in Social Code Book V (SGB V), amended and supplemented by various reform laws. In fact, it was modified 100 times between its inception in December 1988 and December 2003. SGB V falls under the authority of the Federal Ministry of Health since 1991. Other health-related social code books regulate accident insurance (SGB VII), Statutory retirement insurance (SGB VI, including responsibility for part of the rehabilitative measures which are regulated separately by SGB IX) and, since 1995, Long-Term Care Insurance (SGB XI). Books IV and X define responsibilities and administrative procedures common to all social insurance agencies.

Chapter 1 of SGB V defines the basic principles of the SHI. The remaining chapters regulate the following issues:

- mandatory and voluntary membership in sickness funds (chapter 2);
- contents of the sickness funds' benefit package (chapter 3);
- scope of negotiations between the sickness funds and providers of health care, most notably the physicians' associations (chapter 4);
- Advisory Council for Evaluating the Development in Health Care (chapter 5);
- organizational structure of sickness funds and their associations (chapters 6 and 7);
- financing mechanisms including the risk compensation scheme between funds (chapter 8);
- tasks and organization of the medical review boards (chapter 9);
- collection, storage, usage and protection of data (chapter 10);
- administrative fines and penalties (chapter 11), and finally
- special regulations for the eastern part of Germany (added through the Re-Unification Treaty as chapter 12).

Chapter 3 regulates the benefit package of the sickness funds. Section 1 (§ 11 SGB V) gives an overview on the benefits provided and refers to the corresponding articles in other sections. Section 2 (§§ 12-19 SGB V) defines general rules for the provision of all services, for example that the provision of services has to be a sufficient, appropriate and efficient (§ 12 SGB V). It also regulates the special terms for the provision of services abroad.
According to § 11 SGB V insurants are entitled to

- the prevention of diseases or their aggravation, contraception, sterilisation and abortion (section 3, §§ 20-24b SGB V),
- the most earliest detection of diseases (section 4, §§ 25-26 SGB V),
- and the treatment of diseases (section 5, §§ 27-52 SGB V).

Section 6 (§§ 53-54 SGB V) regulates special issues for insurants above a certain income that are voluntarily insured at the sickness funds. Section 7 (§§ 55-59 SGB V) defines the terms for the provision of dental prosthesis. Section 8 (§ 60 SGB V) identifies the conditions for travelling expenses to be covered by the SHI. Section 9 (§§ 61-62 SGB V) restricts the entitlements of the insurants: While § 61 SGB V defines co-payments for certain benefits, § 62 SGB V limits total amount of co-payments yearly paid. The last section, section 10 (§ 63-68 SGB V), addresses the development of the provision of services.

Chapter 4 is the core chapter regulating the corporatist – or self-regulated – structure of the SHI system. It defines what has to be and what may be self-regulated through joint committees of funds and providers (for example, the details of the benefit package or the

relative point values for services) or through direct negotiations (for example, the total remuneration for ambulatory or dental care); the level at which these negotiations have to take place; how the composition of the joint committees is decided; what happens if they cannot agree, etc.

While the rules are defined by the legislature through SGB V at the federal level, the Federal Ministry of Health is responsible for supervising compliance by the federal associations of physicians and sickness funds and the joint committees (see the respective sub-section below). The supervision of nationally operating sickness funds is the responsibility of the Federal Insurance Authority, which is also charged with calculating the risk-structure compensation mechanism among all sickness funds.

Long-term care is also regulated under the authority of the Federal Ministry of Health through Social Code Book XI (SGB XI), which is in most parts similar to SGB V in its main content. The benefit package is regulated in chapter 4 (§§ 28-45c SGB XI), especially in section 3 (§§ 36-43b SGB XI).

Länder level

The *Länder* governments are responsible for maintaining hospital infrastructure, which they do through "hospital plans" and their funding. The investments are paid for independently of the actual ownership of the hospitals and according to the priorities of the *Land* government. While the responsibility for major investments (buildings and large-scale medical technology) is undisputed, sickness funds are now responsible for financing building maintenance and repairs.

A second major responsibility of the *Länder* is public health services (subject to certain federal laws concerning diseases dangerous to public safety). Some *Länder* operate them themselves while the majority of the *Länder* devolve responsibility for community health services to local governments. The public health tasks comprise supervision of employees in health care institutions, prevention and monitoring of transmissible diseases, supervision of commercial activities involving food, pharmaceuticals and drugs, environmental hygiene, counselling, provision of community-based psychiatric services, health education and promotion and clinical examination of school children. Since the 1970s, most of the preventive measures, such as screening programmes and health check-ups for children and adults, were included in the sickness funds' benefits package and thus are carried out by office-based physicians.

Additionally, the *Länder* are responsible for undergraduate medical, dental and pharmaceutical education and the supervision of the regional physicians' chamber as well as the regional physicians' association(s) and the sickness funds operating in the *Land*.

Corporatist level

While the Federal Government, the Federal Assembly and the Federal Council have assumed increasing responsibility in reforming health care through legislation since the 1980s, the health care system is still characterized by a relatively strong degree of decentralized and autonomous decision-making. Of particular importance are corporatist actors of payers and providers which are operating the Statutory Health Insurance and other social insurance schemes. Governments and parliaments at federal or *Länder* level typically do not take part in the decision-making bodies of the Statutory Health Insurance, the Statutory Long-Term Care Insurance nor the Statutory Accident Insurance (while federal government has decisional powers and financial duties for example in the statutory unemployment insurance). The operations of the non-profit corporatist SHI actors are financed by their respective mandatory members and organized on the basis of internal representative democratic structures. Furthermore, a large part of decision-making is realized by horizontal negotiations in joint committees among provider organizations and payer organizations at federal level and regional level.

While the decision-making powers of SHI bodies have been reduced in most European countries in order to reach cost-containment targets, they have been increased in Germany. The federal governmental aim to exercise more control of the types and delivery of services included in the benefit basket has led to enhanced state supervision of decisions taken by the self-governing structures of SHI but has not led to a centralization of decision-making powers towards governmental authorities. It paradoxically led to the creation of new committees within the self-governance of the Statutory Health Insurance system which is charged with implementing those legal stipulations.

Within self-governing structures, federal legislation promoted competition at the level of sickness funds regarding the provision of services while centralizing decision-making powers on the benefit basket and quality assurance towards the federal level to secure uniform standards. The shift towards joint committees meant a relative decrease of physicians' autonomy in favour of increased powers for sickness funds.

Payers

The corporatist institutions on the payer side – the sickness funds – have a central position within the SHI system, as defined by the social code book. The sickness funds have the obligation to raise contributions from their members and to determine what contribution rate is necessary to cover expenditure. Their responsibilities include contracting, negotiating prices, quantities and quality assurance measures with providers on behalf of all sickness funds' members. Services covered by such contracts are usually accessible to all fund members without any prior approval by the fund. Approval is necessary, however, for preventive spa treatments, rehabilitative services and short-term nursing care at home. In cases where there is doubt, the sickness funds must obtain an expert opinion on the medical necessity of treatment from the Medical Review Board, a joint institution of the sickness funds.

Providers

The corporatist institutions on the provider side have to provide all personal acute health care services. The most prominent examples are the physicians' and dentists' associations, which have corporatist monopolies and missions to secure ambulatory care. The monopoly means that neither hospitals (with a few exceptions, such as university outpatient clinics), nor sickness funds, nor municipalities, nor non-medical health professionals have the right to provide ambulatory services medical care except for purposes mandated by legislation or by joint commissions of payers and providers. These exceptions have been gradually extended in recent years. The mission includes the obligation to meet the health needs of the population, to guarantee provision of state-wide services in all medical specialities and to obtain a total, prospectively negotiated budget from the sickness funds which the physicians' associations distribute among their members. Regional physicians' associations and regional dentists' associations are obliged to secure the provision of ambulatory care during practice hours and out-of-hour services. It also implies that regional physicians' associations negotiate collective contracts with the numerous sickness funds that operate in their region for ambulatory care. They distribute financial resources among their members according to nationally uniform but regionally adapted rules.

The physicians' associations must provide health services as defined by both the legislature and contracts with the sickness funds. The physicians' associations must guarantee the sickness funds that this provision meets the legal and contracted requirements.

Ambulatory medical care is therefore the classic sector in which the corporatist institutions have the greatest power. Social code book V concentrates mainly on regulating the framework, that is, generic categories of benefits and the scope of negotiations between the sickness funds and the physicians' and dentists' associations. These negotiations determine both the financing mechanisms and the details of the ambulatory benefit package. As a general rule, both the scope of services which can be reimbursed through the sickness funds and the financing mechanisms are tightly regulated, sometimes legally but usually through negotiations between providers and sickness funds.

Due to the absence of corporatist institutions in the hospital sector, hospitals contract individually with the sickness funds. Usually, all sickness funds with more than a 5% market share in a particular hospital negotiate the contract with that hospital. However, the conditions regarding both the range and number of services offered and the remuneration rates are valid for all sickness funds.

Joint institutions

An important aspect of self-regulation is termed "joint self-regulation" by at least two actors, and comes in two different forms: negotiations leading to contracts and decisions by joint committees. While some delegated tasks always require decisions by joint committees (for example, defining the benefits), others are only decided by joint committees if no agreement can be found in open negotiations (for example on the budget for ambulatory care). In still others, a joint committee is the first level of appeal against decisions of another joint committee (for example, in the case of claims review). On the federal level[1], joint self-regulatory institutions in the German system include the Federal Joint Committee, the Valuation Committee, the Extended Valuation Committee, the Dental Valuation Committee, the Extended Dental Valuation Committee and the Committee on Hospital Payment.

Since 2001, the federal associations of sickness funds and the German Hospital Association have been jointly running the independent Institute for the Development of the Hospital Payment System, which supports the continuous technical development of the diagnosis-related groups system.

[1] On the level of each of the 16 *Länder*, there are arbitration committees (if bilateral negotiations for example on reimbursement increases lead to no result), accreditation committees, accreditation arbitration committees, claims review committees and claims review arbitration committees.

The most important body for the benefit negotiations between sickness funds and physicians concerning the scope of benefits used to be the Federal Committee of Physicians and Sickness Funds, which was responsible for the ambulatory sector. During the last few decades, it issued around 20 directives to regulate the inclusion of new technologies and procedures into the ambulatory benefits package, the provision of screening services or family planning, the prescription of pharmaceuticals, medical aids and care by non-physicians such as physiotherapists, the quality-assurance of diagnostic imaging techniques, needs-based planning of the distribution of physicians in private practice, or the certification of sickness. The second SHI Restructuring Act gave the Federal Committee new competencies in July 1997, when it became responsible for assessing the existing benefits, for defining a positive list for care by non-physicians and for directives on providing rehabilitative entitlements. The Federal Committee had several sub-committees, one of which made proposals for decisions concerning the effectiveness of new diagnostic and therapeutic methods according to a set of criteria that were outlined in directives first passed in 1990. After the extension of the committee's mandate, this sub-committee was renamed the Medical Treatment Sub-committee and passed new evaluation directives.

In 2000, a joint committee was introduced for the hospital sector consisting of representatives of sickness funds and the German Hospital Association. The committee was charged with quality assurance functions and with decision-making on benefit exclusions but was not required to provide positive decisions on benefit coverage as was its ambulatory counterpart. In addition, a Coordinating Committee was introduced to connect the committees for ambulatory physician care and hospital care. It also was charged with identifying areas of over-utilization or under-utilization as well as with passing inter-sectoral treatment health care guidelines and disease management programmes.

Since the Statutory Health Insurance Modernization Act came into force in 2004, the various joint committees for the ambulatory sector, the hospital sector and the coordination committee have been unified into one common committee, the Federal Joint Committee. The main body of the Committee consists of nine representatives of the federal associations of sickness funds (three from general regional funds, two from substitute funds and one each from company-based funds, guild funds, farmers' funds and the miners' fund) and nine representatives from provider groups (four from the Federal Association of SHI Physicians, one from the Federal Association of SHI Dentists, and four from the German Hospital Association), two neutral members with one proposed by each side, and a neutral chairperson – accepted by both sides – who has the decisive vote if no agreement can be reached. In addition, nine non-voting

representatives of formally accredited patient organizations have been given the right to participate in consultations and to propose issues to be assessed and decided upon.

Based on the legislative framework of the Social Code Book, the Federal Joint Committee issues directives relating to all sectors of care. Some directives are passed by the Plenary, the central decision-making body of the Federal Joint Committee, e.g. the body's standing rules and the rules of procedures for assessing technologies for inclusion or exclusion from the SHI benefit catalogue.

Furthermore, the Federal Joint Committee is composed of 4 additional bodies, each of which passes directives for a distinct field of regulation. They consist of actors involved in the respective field. While federal associations of sickness funds (decision-making powers) and patient representatives (no vote) are represented in all of the four committees, the composition of providers varies, i.e. the Federal Association of SHI Physicians is represented in the Committee on Ambulatory Care, the Committee on "Physician Issues", but not the Committee on Dental Care where the Federal Association of SHI Dentists is represented. The German Hospital Association delegates representatives to the Committee on Hospital Care and the Committee on Physician Issues. These joint committees consist of various joint sub-committees that prepare recommendations, conclusions and directives, partly supported by working groups.

Their directives are legally binding for actors in Statutory Health Insurance although subject to complaints at social courts. They are mainly concerned with the coverage of benefits and assuring that SHI services are adequate, appropriate and efficient. They seek to clarify rules for patients' access and to steer accountable behaviour of all office-based physicians individually. The four Committees have the following functions:

1) The decision-making body with the broadest range of responsibilities is the Committee on Ambulatory Care, the successor of the Federal Committee of Physicians and Sickness Funds. It consists of sub-committees for medical procedures, psychotherapy, sickness certification, prevention, family planning, care provided by allied health professionals and medical aids, pharmaceuticals, prescription of hospital care and patient transport, home

nursing care, rehabilitation, socio-therapy, quality reporting and assurance as well as needs-based planning[2].

- The committee's directives on evaluating technologies sets the criteria for deciding upon benefit coverage in the ambulatory sector of Statutory Health Insurance, where a new method has to obtain a positive evaluation in order to be covered and reimbursed by SHI.
- Directives relating to care provided by allied health professionals are developed in consultation with the federal organizations of the providers concerned, for example physiotherapists, speech and language therapists, occupational therapists (the so-called partner model). In a similar mode, nursing associations are consulted when directives on home nursing care are amended by the committee.
- The directive on pharmaceuticals entails a broad range of decisions upon coverage, prescription recommendations for physicians and price determination for outpatient drugs covered by SHI. Decisions upon coverage include the listing of brands for substances which the ministry put on a negative list or exemptions from co-payments. Instead of excluding drugs from SHI coverage altogether the predecessors of the Committee preferred to inform about efficacy, safety and prices of substances by indication and to issue prescription recommendations based on relations of benefits and price. The committee is also responsible for selecting and grouping drugs to be subjected to the reference price scheme, which since 2004 relates not only to off-patent drugs but also again to patented drug.

2) The Committee on Dental Care the successor of the previous Federal Committee of Dentists and Sickness Funds and issues directives on dental treatment and orthodontic treatment, case-finding, individual prophylaxis, dentures, procedures to assess new and existing technologies, as well as needs-based planning.

3) The Committee on Hospital Care. It consists currently of the Sub-Committee for Methods to Evaluate Technologies which prepares directives for decisions upon the exclusion

[2] Apart from directives concerning the named fields of health care the Committee has e.g. issued a definition for chronically ill persons who are eligible to co-payment limitations or a directive about conditions for SHI-affiliated physicians to employ a physician colleague.

of technologies (in contrast to the ambulatory pendant which has to decide upon the inclusion of technologies), the Sub-Committee for External Quality Assurance in Hospitals and the Sub-Committee for Other Forms of Quality Assurance in Hospitals.

4) The Committee on Physician Issues is the successor of the previous Coordinating Committee and consists currently of the Sub-Committee for Ambulatory Treatment in Hospitals which issues for example a list of highly specialized conditions that may be treated in outpatient departments and the Sub-Committee for Disease Management Programmes. The Sub-Committee on Quality Assurance has to report on and evaluate quality assurance programmes and to issue recommendations for uniform standards quality assurance across professions and sectors.

All directives issued by the Federal Joint Committee are transferred to the Federal Ministry of Health. Unless the ministry objects to a directive for formal reasons within a period of two months the directive becomes binding for the concerned SHI actors at federal level, *Länder* level, and local level as well as for individual providers and insured patients.

Once a decision to include a technology into the benefit catalogue of ambulatory SHI-affiliated physician services has not been objected by the Ministry of Health, another joint committee at federal level determines reimbursement issues and requirements for physicians who want to want to claim reimbursement for the delivery of this technology from Statutory Health Insurance. This Valuation Committee consists of representatives from sickness fund associations and the Federal Association of SHI Physicians. In particular it determines the relative value of a technology compared to other technologies in the Uniform Value Scale.

Supervision

Supervision of corporatist decisions – whether those of single institutions or joint committees – is a multi-layered endeavour involving self-regulatory institutions themselves, the government and the social courts. “The government” is the Federal Ministry of Health in cases concerning federal associations of sickness funds and providers, joint institutions and their decisions and contracts. Nation-wide sickness funds are supervised by the Federal Insurance Authority. For actors, decisions and contracts on the *Länder* level, the government is the Statutory Health Insurance unit within the *Länder* ministry responsible for health.

Supervision and enforcement can be divided into several levels:

- formal governmental approval of (or lack of objection to) decisions taken by self-regulatory bodies, the latter relates for example to decisions of the Federal Joint Committee;
- governmental veto of self-regulatory decisions if these are not taken according to the law;
- the federal government's right to intervene where no decisions have been taken ("*Ersatzvornahme*") as for example applied during the introduction of diagnosis-related groups as a payment system in hospitals;
- legal action against institutions that do not fulfil their charge.

While the theoretical threat of closing sickness funds applies mainly to financial instability or incompetence, the ultimate threats to physicians' and dentists' associations are more related to their behaviour as corporatist institutions. As a first step, a state commissioner may be installed if no board is elected or if the elected board refuses to act according to its legal responsibilities (§ 79a SGB V). In the case of 50% or more members of an association refusing to treat sickness fund-insured patients, the association loses its legal monopoly to provide care which is then passed to the sickness funds (§ 72a SGB V).

Beyond this rare mode of state intervention, disputes are usually resolved during the joint negotiations. If the actors cannot resolve disputes over tasks that have been delegated to them by law, a sophisticated system of joint arbitration committees and regulations is applied to make sure that a regulatory vacuum is avoided and that contracts among the responsible actors are in place in time.

Social courts

Many corporatist decisions as well as parliamentary laws or governmental regulations may be challenged before the social courts, which exist at the local, state, and federal levels, constituting a separate court system. Within health care, cases resolved by social courts include, for example: patients suing their sickness fund for not granting a benefit; individual physicians disputing the calculations of the Claims Review Arbitration Committee at state level; or medical device companies objecting to the non-inclusion of their product in the ambulatory medical services benefits package.

II) Definitions of entitlements and benefits by sector and decision criteria

As already described before, the Statutory Health Insurance scheme is the most important benefit scheme in Germany. It covers 88% of the population and accounts for 56.9% of Germany's total health expenditure (table 1). Other benefit schemes such as the Statutory Retirement Insurance schemes, the Statutory Accident Insurance scheme, private health insurance schemes, the Statutory Long-Term Care Insurance scheme and the Government allowance scheme for civil servants cover much smaller parts of the population and contribute less to total health expenditure. This chapter mainly concentrates on benefit entitlements of the Statutory Health Insurance scheme and the Statutory Long-Term Care Insurance scheme (A), although part B at the end of the chapter roughly describes benefits of the other schemes.

Table 1: Benefit schemes according to their contribution to total health expenditure, 1992-2002

	1992	**1994**	**1996**	**1998**	**1999**	**2000**	**2001**	**2002**
Public sources	**77.7**	**77.0**	**77.2**	**75.3**	**74.8**	**75.5**	**74.9**	**75.2**
Taxes	13.0	12.9	10.8	8.1	8.0	7.9	7.8	7.8
Statutory Health Insurance scheme	60.7	59.7	57.4	56.7	56.8	56.9	57.0	56.9
Statutory retirement insurance scheme	2.3	2.4	2.4	1.7	1.7	1.8	1.8	1.7
Statutory Accident Insurance scheme	1.8	1.9	1.7	1.7	1.8	1.7	1.7	1.7
Statutory Long-Term Care Insurance scheme	n. a.	n. a.	4.9	7.0	7.1	7.2	7.0	7.0
Private sources	**22.3**	**23.0**	**22.8**	**24.7**	**25.2**	**24.5**	**25.1**	**24.7**
Out-of-pocket payments	10.7	11.1	11.3	12.6	12.3	12.2	12.3	12.2
Private health insurance schemes	7.3	7.6	7.3	7.8	8.3	8.2	8.2	8.4
Employer benefits	4.3	4.3	4.2	4.2	4.1	4.1	4.1	4.1

Source: Federal Statistical Office 2004.
Note: na: not applicable

A. Statutory Health Insurance and Long-Term Care Insurance schemes

There is no uniform benefit catalogue defining the benefits provided by the Statutory Health Insurance and the Statutory Long-Term Care insurance. Benefits are defined by a complex structure of explicit and implicit regulations regarding each health care sector. The Statutory Health Insurance (SHI) general benefit regulation defines the overall framework for provided benefits. However this framework only gives a broad definition and seldom mentions single benefits that have to be provided. The Federal Joint Committee has the function to interpret the general framework and issue general as well as special directives defining certain benefits for each health care sector. By taking the criteria of need, costs and sometimes cost-effectiveness into consideration directives can be positive as well as negative benefit decisions. Additionally there are remuneration schemes in several health care sectors being primarily designed to define provider remuneration (SHI-DRG, SHI-EBM, SHI-BEMA, SHI-BEL II). However these schemes also serve as a benefit catalogue as all listed services are covered by the SHI-scheme.

Table 2: Benefit-defining laws/decrees and catalogues as well as implicit regulation by sector.

	Statutory Health Insurance (SHI) - general benefit regulation	SHI - general directives of the Federal Joint Committee	SHI - special directives of the Federal Joint Committee (positive)	SHI – appendices to directives of the Federal Joint Committee (negative)	SHI - DRG	SHI - EBM	SHI - BEMA	SHI - BEL-II	Statutory long term care insurance - general benefit regulation
Catalogue: type of document, actors and contents									
HC.1.1	x	x		x (X)	x				
HC.1.2	x	x		x (X)		x			
HC.1.3.1	x	x		x (XI)		x			
HC.1.3.2	x	x	x (I)	x (XII)			x	x	
HC.1.3.3	x	x	x (II)	x (XI)		x			
HC.1.3.9	x	x	x (III)	x (XI)					
HC.2.1/2.2	x				x				
HC.2.3	x								
HC.3.1	x								x
HC.3.2	x								x
HC.3.3	x		x (IV)						x
HC.4.1	x	x				x			
HC.4.2	x	x				x	x		
HC.4.3	x		x (V)						
HC.5.1.1	x	x							
HC.5.1.2	x	x	x (VI)						
HC.5.2	x	x	x (VII)						
HC.6.1	x	x	x (VIII)						
HC.6.3	x								
HC.6.4	x	x	x (IX)			x	x		
HC.6.5	x								

I	Directive on the Provision of Prosthetic Services	VII	Directive on Medical Aids
II	Directive on Psychotherapy	VIII	Directive on Maternity Care
		IX	Directives on A. the Early Detection of Cancer, B. Dental Prophylaxis & C.
III	Directive on Care by Non-physicians		Medical Examinations for the Early Detection of Diseases
IV	Directive on Home Nursing Care	X	Appendix to Directive according to § 137c (to evaluate hospital procedures)
V	Directive on Patient Transport	XI	Appendix to Directive on Medical Procedures
VI	Directive on OTC	XII	Appendix to Directive on New Dental Procedures

	Statutory health insurance (SHI) - general benefit regulation	SHI - general directives of the Federal Joint Committee	SHI - special directives of the Federal Joint Committee (positive)	SHI – appendices to directives of the Federal Joint Committee (negative)	SHI - DRG	SHI - EBM	SHI - BEMA	SHI - BEL-II	Statutory long term care insurance - general benefit regulation
Catalogue: type of document, actors and contents									
Legal status	law	directive	Directive	directive	contract	contract	contract	contract	law
Decision-maker	parliament	Federal Joint Committee	Federal Joint Committee	Federal Joint Committee	Committee on Hospital Payment	Valuation Committee (Physicians)	Valuation Committee (Dentists)	Valuation Committee (Dentists)	parliament
(original) purpose	Entitle-ments	Entitle-ments	Entitle-ments	Entitle-ments	Reimburse-ment	Reimburse-ment	Reimburse-ment	Reimburse-ment	Entitle-ments
Positive/negative definition of benefits	P/N	P	P	N	P	P	P	P	P/N
Degree of explicitness: 1 "all necessary", 2 areas of care, 3 items	1/2	2	2/3	3	3	3	3	3	1
If itemised: goods/ procedures only; linked to indications			goods/ procedures/ indication	goods/ procedures/ indication	procedures	procedures	procedures	goods	
Updating	if necessary	if necessary	if necessary	if necessary	every year	if necessary	if necessary	if necessary	
Criteria used for defining benefits									
* need	x	x	X	x	x	x	x	x	
* costs		x	X	x	x	x	x	x	x
* effectiveness		x	X	x	x	x	x	x	
* cost-effectiveness		(x)*	(x)*	(x)*					
* budget									
* other…									

* although explicitly mentioned it is mainly done for medical devices

HC.1 Services of curative care

HC.1.1 In-patient curative care

When the aim of curative care, i.e. to detect, cure, prevent the worsening, or relieve the discomforts accompanying disease cannot be achieved by ambulatory treatment (§ 39 SGB V), the insured are entitled to inpatient treatment in accordance with § 27 SGB V. Inpatient treatment encompasses standard and optional hospital services. These can be provided as full-time, part-time, pre or post inpatient care. The health care entitlement is linked to a co-payment of 10 Euro per calendar day, to a maximum of 28 calendar days per year (§ 39 para. 4 s. 1 SGB V).

Standard hospital services are granted with regard to the ability of the hospital to provide the respective services and in accordance with the level of care assignment of each hospital. In each individual case the provision of services needs to be suitable and adequate for the insured. This includes medical treatment, nursing care, the provision of pharmaceuticals, cures and therapeutic appliances, as well as board and accommodation. Part-time inpatient care differs from full-time inpatient care in the way that patients stay in the hospital during the treatment itself but not throughout the whole duration of the treatment. Pre inpatient care is provided without board and accommodation in order to prepare or to verify the necessity of full-time inpatient care. It must not amount to more than three days of treatment within five days prior to the starting date of the full-time inpatient care. Post inpatient care is also without board and accommodation, and is provided after a full-time hospital stay in order to ensure or sustain the success of the treatment. Seven days of post inpatient treatment within a period of 14 days must not be exceeded. In the case of hospital stays for organ transplantations, the post inpatient care period is limited to seven days within three months after completion of the full-time hospital stay (Directive on Hospital Care § 2).

Hospital care may only be provided in hospitals included in the hospital plan of the respective state (*Länder* level), in university hospitals or in hospitals that have concluded a service provision contract with the SHI health funds (§ 108 SGB V). While the spectrum of services provided by the respective hospitals is indirectly determined by the hospital plan (which also determines governmental subsidies for investments), the reimbursement for the provided services is decided in negotiations between each hospital and the association of sickness funds. The fundamental basis for the legal relationships between the sickness funds and the hospitals is regulated in § 17 b Hospital Financing Act (KHG), in the Hospital Payment Act (KHEntgG) as well as in the corresponding legal decrees (§ 69 SGB V).

The exclusion of health care services and/or the evaluation of examination and treatment methods are carried out in response to the application of the federal associations of the sickness funds, the German Hospital Association or a federal association of the hospitals by the Federal Joint Committee. The method under examination will be scrutinized as to its suitability to provide adequate, expedient and economical care for the insured persons, under consideration of the general state-of-the-art of medical knowledge. Should the examination reveal that the method does not meet the aforementioned criteria, it may no longer be applied at the expense of the Statutory Health Insurance. The members of the Federal Joint Committee responsible for hospital treatment, comprising representatives of the German Hospitals Association, the sickness funds and three independent members, issue a corresponding directive according to § 137c para. 1 SGB V (see Figure 1). Health care services in the framework of clinical studies are not subject to the directive. The Ministry of Health is authorised to withhold approval to the directive under § 137c para. 2 SGB V. This means that all health care services that are not excluded by a directive of the Federal Joint Committee may be provided at the expense of the SHI.

In the Reform Act of SHI 2000, dated 22nd December, 1999, it was resolved to introduce a case fee system for reimbursement with effect from January 1st, 2003. Up to that point, reimbursement for hospital services had been reimbursed on the basis of day charges. The introduction of the new system was commissioned to the contracting partners at the federal level (§ 17b para. 2 Hospital Financing Act). On 27th June, 2000 they decided to agree on the Australian Diagnosis-Related Groups as the starting base for the development of a German DRG system. On 10th May, 2001, the federal associations of the sickness funds, the Association of Private Health Insurers and the German Hospitals Association founded the Institute for the Remuneration of Hospitals (InEK), which was to support the introduction and the continual further development of the DRG system on basis of § 17b Hospital Financing Act. Technically, the InEK is under the control and supervision of the Committee on Hospital Payment (KEA), in which nine representatives of the German Hospitals Organization sit face to face with nine representatives of the federal associations of the sickness funds and of the Association of Private Health Insurers (see Figure 1). The areas of work covered by the DRG Institute comprise the definition of the DRG case groups, the maintenance of the DRG-system and the severity classification system, the working out of a coding directive and proposals for adapting the German modifications to the International Classification of Diseases ICD- 10, the Operating Procedures System (OPS). The tasks of the Institute further include the calculation of the DRG cost weights and individual adjustments within the DRG system.

In spite of the work put in by the Institute, the contract partners were initially unable to agree on billing regulations for the new reimbursement system. The Ministry of Health was obliged to issue the first Case Fees Act dated 19th September 2002 on the basis of § 17b para. 7 Hospital Financing Act, which contained the billing regulations and the Case Fees Catalogue of the DRG system for 2003. Due to the fact that the contract partners also failed to reach an agreement for the year 2004, the Ministry of Health also laid down the billing regulations in the second Case Fees Act dated 10th October 2003 for the year 2004. On 16th September 2004, the contract partners reached for the first time consensus in their Case Fees Catalogue, which contains the billing regulations for services and benefits for the year 2005.

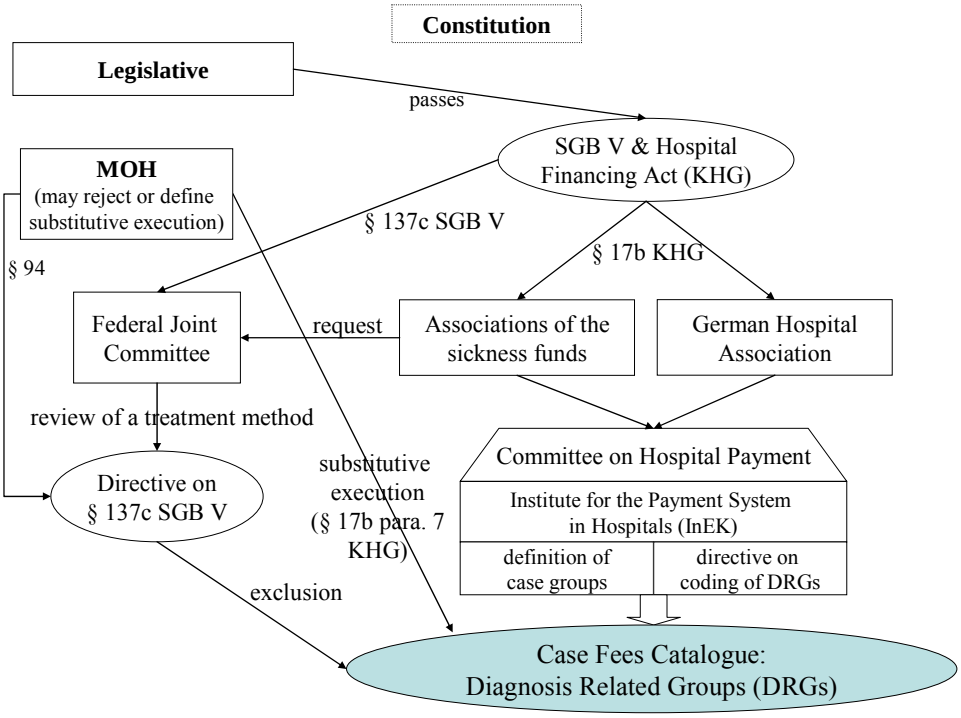


Figure 1: Description of the Case Fees Catalogue and the evaluation of examination and treatment methods.

As the basis for the new billing system, a uniform case fee catalogue with fixed payments for services and benefits, valid for the entire Federal Republic of Germany was developed, in which all services performed in the field of inpatient care are listed and grouped in accordance with the respective clinical diagnosis. The DRG system, laid out in more detail in Chapter III, constitutes, at the same time, the catalogue of services and benefits covered by the Statutory Health Insurance for inpatient care. However, the respective hospital itself is responsible for ensuring the quality of care provided to the patient and for the sensible and cost-effective provision services.

For inpatient services that cannot be covered by the DRG system (e.g. innovative methods of treatment), agreements are made with the hospitals concerned. The local contract partners have to inform the contract partners at federal level of such agreements, who may decide to initiate a procedure for the evaluation of the service provided in accordance with § 137c SGB V (§ 6 para. 2 Hospital Payment Act). In principle however, as already mentioned, all health care services that are not explicitly excluded by a directive of the Federal Joint Committee can be provided at the expense of the SHI.

HC.1.2 Day cases of curative care

Due to the separation of the hospital and the ambulatory care sectors in Germany, surgeons, ophthalmologists, orthopaedic surgeons and other specialists in private practice have performed minor surgeries for a long time.

Except for universities and emergency care, hospitals have traditionally provided inpatient care only. But their scope to provide ambulatory care has been extended increasingly in the past decade. Since 2003, hospitals may treat patients with diseases requiring highly specialized treatment on an ongoing basis. Since 2004, hospitals may also provide care in specialities for which underprovision of care is stated, as recommended in the Advisory Council's report on over-, under- and misuse in health care. Furthermore, ambulatory care for patients with certain rare diseases and special forms of disease progression as well as highly specialized services have been declared areas of hospital activity by the SHI Modernization Act. The Federal Joint Committee named a few genetic liver diseases and inborn metabolic disorders in children, and will present criteria on which the selection of hospital-based outpatient care is to be based by 2005. The list of disease conditions is reviewed every two years.

Since 1st January 2004 there is a three-party agreement in respect of day cases of surgical interventions between the federal associations of the sickness funds, the German Hospitals Organization and the Federal Association of SHI Physicians. This agreement regulates the conditions under which hospitals may render day cases of curative care. In Appendix 1 to this agreement, there is a 23-page catalogue of interventions in accordance with § 115b SGB V. However, this does not constitute an independent catalogue of services and benefits. It is just a possibility for hospitals to provide services belonging to the outpatient sector.

Because day care / ambulatory surgery belongs to the outpatient care sector, the benefit catalogue for day care / ambulatory surgery and the entitlements of the insured will be dealt with more detailed in HC.1.3.

HC.1.3 Outpatient care

Outpatient care is primarily regulated in Chapter 4 of the SGB V. In the second section "Relationships between physicians, dentists and psychotherapists", subsection "Assurance of medical and dental care by SHI physicians and dentists", § 72 SGB V stipulates that the provision of medical and dental care must be regulated and secured by agreements between the respective regional physicians' association/regional dentists' association and the regional associations of the sickness funds. These agreements are to secure adequate, expedient and economical care and a commensurate remuneration for the medical and dental services rendered. In § 73 SGB V, SHI outpatient curative care is sub-divided into the fields of general practitioners and medical specialists and the tasks comprised within each of the two respective fields are defined accordingly. According to this, the general practitioner shall primarily diagnose and coordinate the respective care and therapeutic measures required in the knowledge of the latter's domestic and family environment and. § 75 SGB V extends the scope of guaranteed care to be provided, also to the time outside of consulting hours.

In the 3rd subsection of Chapter 4 "Agreements at Federal and State Level", § 87 SGB V stipulates that the Uniform Value Scale as a component of the Federal Framework Contract defines the services and benefits of the SHI in the sector of outpatient care. This is to be negotiated in the Evaluation Committee between representatives of the Federal Association of SHI Physicians and/or Dentists and the federal associations of the sickness funds.

Whereas, in accordance with § 137c SGB V, medical care in hospitals shall be, "adequate, expedient and cost-effective", for ambulatory care, in accordance with § 135 SGB V, the criteria to be applied shall comprise, "diagnostic and therapeutic expedience, medical necessity and cost-effectiveness". Thus, the inclusion and/or exclusion of health care services from the benefit catalogues differ in the two sectors. In the outpatient sector, the criteria, "expedience, necessity and cost-effectiveness" must be proofed by a service to be included into the catalogue of services and benefits. In contrast to that, health care services in the inpatient sector will only be excluded from the benefit catalogue of the sickness funds if the conditions are proofed unfulfilled. For this reason, it is possible that the health care services provided in the inpatient sector are not included in the benefit catalogue of the outpatient sector.

HC.1.3.1 Basic medical and diagnostic care and HC.1.3.3 all other specialised health care

The entitlement of the insured persons to medical care is regulated under § 28 para.1 SGB V. Insured persons are entitled to preventive care, the earliest detection and the treatment of diseases. This entitlement also embraces complementary services afforded by non-medical persons and practitioners, provided that they are prescribed by a physician. The legislative authority, however, does not define in detail the entitlements of the insured persons but rather regulates the procedures by which the institutions of self-governance and the contract partners determine the scope of SHI services.

In accordance with § 92 para. 1 SGB V, the Federal Joint Committee issues directives in respect of adequate, expedient and cost-effective medical care for the insured persons. These include, in addition to the Directive on Medical Procedures, also the Directive Concerning the Planning of the Medical Needs (§ 101 SGB V). The Ministry of Heath exercises legal supervision over the Federal Joint Committee and is entitled to raise objections to decisions made, and to put forward substitute proposals.

The concrete definition of the health care entitlements of the insured persons is effected by the Evaluation Committee (§ 87 SGB V), which is composed of seven representatives of the Federal Association of SHI Physicians and one representative from each of the federal associations of the sickness funds (AOK, BKK, IKK, LKK and sailors'), one each from the miners' sickness funds and one from the Association of the Substitute Funds. The Evaluation Committee decides over the in- or exclusion of health care services from the Uniform Value Scale (EBM). The EBM defines, as an integral component of the Federal Framework Contract – Physicians (BMV-Ä), the scope of medical care to be provided under the SHI throughout Germany. If the Evaluation Committee fails to reach consensus, at least two of its members or the Federal Ministry for Health and Social Security may demand that the extended Evaluation Committee in accordance with § 87 para. 4 SGB V is brought into action. Resolutions are to be submitted to the Ministry of Health, which, in the event of unresolved objection, may define substitute executions.

The Federal Framework Contract – Physicians, in accordance with § 82 SGB V, concluded between the Federal Association of SHI Physicians and the federal associations of sickness funds, which was last amended on January 1st, 2004, came into force on 1st January 1995. In addition to the scope of health care provided under the SHI, the BMV-Ä regulates participation in ambulatory care, the pertinent aspects of quality assurance, and entitlement to benefits on the part of insured persons. Thus, the Uniform Value Scale (EBM), as well as the

directives of the Federal Joint Committee are integral parts of this agreement. In § 2 of the Federal Framework Contract – Physicians, the description of a service in the EBM is stipulated as a condition for the provision of the respective service. Thus, the Uniform Value Scale (EBM), described in detail in part III, constitutes the catalogue of services and benefits covered by the Statutory Health Insurance. For the compilation of the EBM, the directives of the Federal Joint Committee in accordance with § 92 SGB V para. 8 are of mandatory character (see Figure 2).

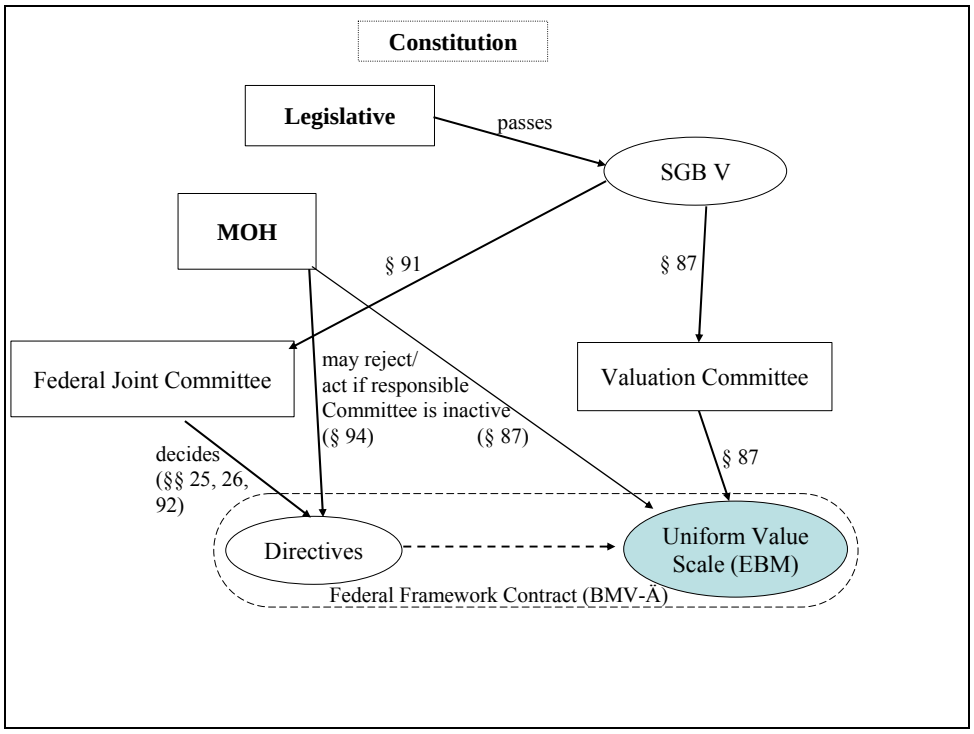


Figure 2: Definition of the Uniform Value Scale in the outpatient sector.

In addition, in § 87 SGB V, the broad structure and the contents of the EBM are stipulated:

- The EBM shall show the health care services covered under the SHI and their value in relation to one another in the form of a points system,
- health care services shall be grouped as far as possible in accordance with related service packages or case-related fixed payments,
- a basic scale of remuneration for general practitioners shall be determined,
- differentiation shall be made between the health care services to be rendered exclusively by the general practitioner and those to be rendered exclusively by the specialist physician and
- the respective health care services shall be assigned exclusively to the individual groups of specialist physicians that are allowed to provide them.

As an appendix to the Federal Framework Contract – Physicians, there is an agreement that applies to care to be provided by general practitioners under § 73 SGB V. This came into

force on 1st January 1994 and is to enable the further structural development of outpatient care. In accordance with this, the tasks of general medical practitioners are stipulated as the provision of medical treatment and the early detection of diseases. The definition of individual services to be provided is included in the EBM. In addition to these central agreements, which are uniform for all SHI health funds, there exist numerous „small" contracts that determine the scope of the health care services covered by the Statutory Health Insurance in Germany.

HC.1.3.2 Out-patient dental care

The basic entitlements of the insured to dental care are defined in § 28 para. 2 SGB V. The insured are entitled to the prevention, the early detection and the treatment of diseases of the teeth, the mouth and the jaw. Therefore prophylaxis treatments and basic dental care are covered by the sickness funds.

While benefits for ambulatory physician services are legally defined in generic terms only, the legislator has regulated issues of dental care much more specific in the SGB V. One reason was the dysfunction of the Federal Committee of Dentists and Sickness Funds, until 2003 in charge of decision making on ambulatory dental care concerning benefits, accreditation and quality.

After the beginning of 2004 the Federal Joint Committee began its work. So far, the Federal Joint Committee has issued eight directives to ensure a sufficient, appropriate and efficient dental treatment according to § 12 SGB V Abs 1 (§ 92 SGB V para. 1):

1. a directive for sufficient, appropriate and cost-effective dental care,
2. a directive for orthodontic care,
3. a directive for sufficient, appropriate and cost-effective dental prosthesis,
4. a directive that defines a prosthetic standard treatment for 52 findings,
5. a directive on dental prophylaxis (children aged 3 to 6),
6. a directive on dental prophylaxis (children aged 6 to 18),
7. a directive for the definition of appropriate, under- and overprovision of dental care (manpower planning) and
8. a directive that defines rules for the implementation of new services and for the evaluation of dental care.

The directives consist of a general part that explains their aim, their users and names the corresponding paragraph in the SGB V. After the initial section the directives become more detailed. For example, the directive for sufficient, appropriate and cost-effective dental

prosthesis describes at first the general requirements to a dental benefit. Thereafter the basic principles and requirements to a prosthetic benefit are described. The last section defines the requirements for specific prosthetic treatments (crowns, bridges, removable prosthetics, combination of prosthetics, implantable prosthetics).

While the directives broadly define when the patient is entitled to a benefit, they do not define the benefit catalogue explicitly. Therefore the Dental Valuation Committee defines the Uniform Value Scale for Dentists (BEMA) (see figure 3). The BEMA lists services that are reimbursed by the sickness funds and thus explicitly defines the SHI benefit catalogue. The services of dental technicians, producing the material needed for orthodontic or prosthetic services, are listed in a similar framework, the Uniform Value Scale for Dental Technicians (BEL-II). The content of the BEL-II is also negotiated in an Valuation Committee between the federal sickness fund association and the Federal Association of SHI Dentists (for details of both cf. part III).

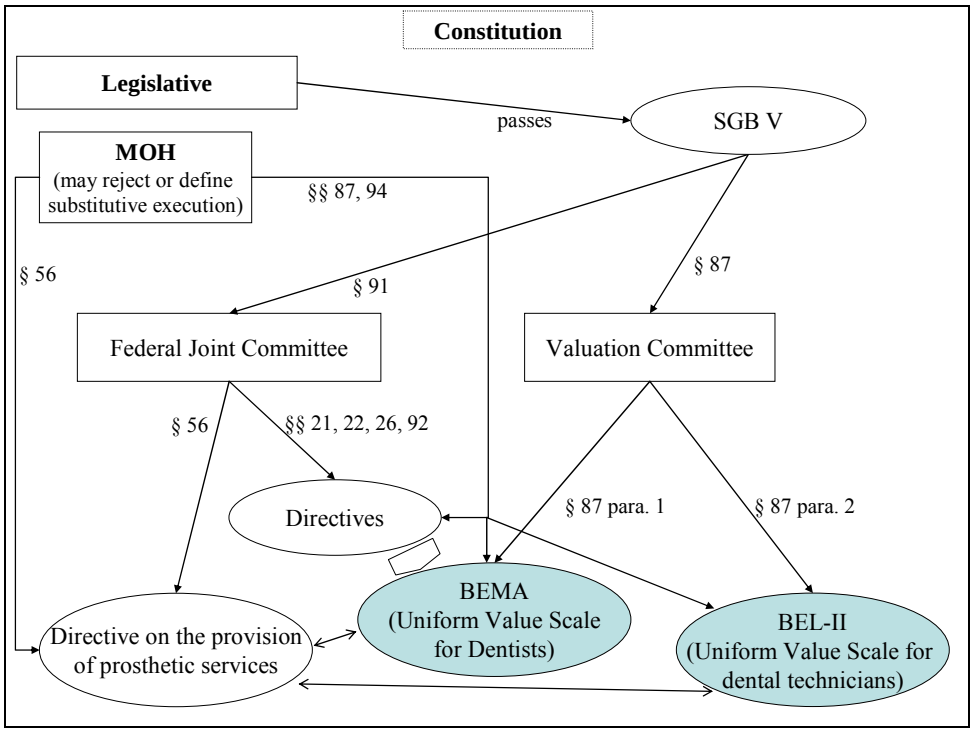


Figure 3: Implicit and explicit definition of the SHI benefit catalogue for dental care.

Orthodontic treatments, except for the treatment of abnormalities, are to begin during childhood and are excluded for insured aged above 18 years (§ 29 SGB V). A co-payment of 20 % of the orthodontic treatment cost is paid by the parents. The co-payment for another simultaneous orthodontic treatment of another child in the same family is reduced to 10% of the treatment costs. In order to prevent the overprovision of services, dentists have to prepare a cost schedule that is reviewed by the sickness funds.

Dental prosthesis services are only partly covered by the sickness funds and therefore defined more detailed. The insured receive a so called 'subsidy' as a percentage of a "standard" treatment, defined by the Federal Joint Committee in a directive according to § 56 SGB V. The directive currently available defines a standard treatment for 52 findings. For each standard treatment all reimbursable services of the dentists and the dental technicians are listed separately. For a detailed description of the service, it is referred to the BEMA and the BEL-II.

The subsidy of the sickness funds is normally 50% of the standard treatment costs. An increased level of subsidy of 70% is granted, if the patient can prove yearly preventive medical checkups for the past five years. The dentist also needs to certify that patient's efforts for dental hygiene are observable. If the patient can prove yearly medical checkups for the past ten years, a subsidy of 80% of the standard treatment costs is allowed (see figure 4). Higher subsidy levels, up to full coverage of the costs of the standard treatment, are only provided for people with a very low income.

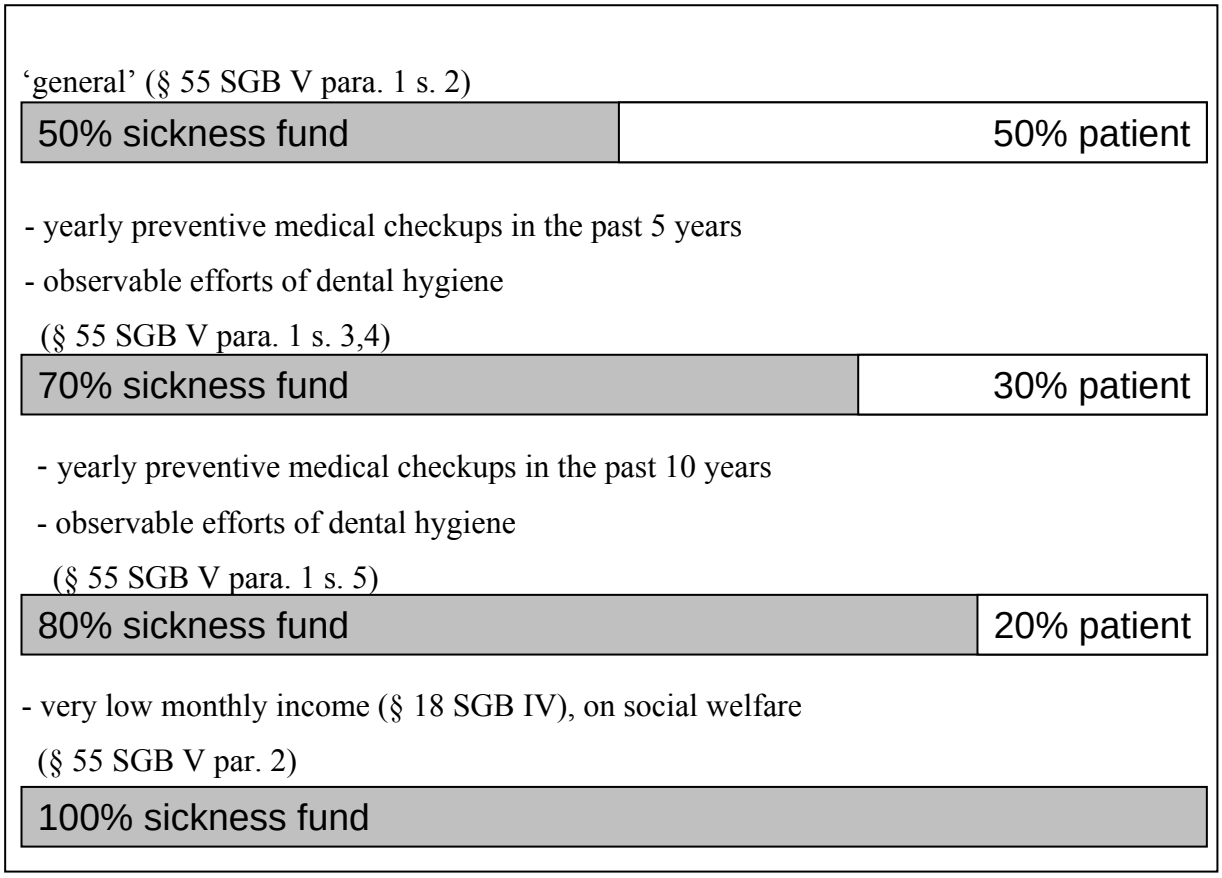


Figure 4: Subsidy and co-payment for dental prosthesis in percent of the standard treatment costs.

Although the amount of subsidy and the amount of co-payment are defined by the subsidy level and the costs of the standard treatment, the patient is free to choose non-standard treatments (§ 55 para. 5 SGB V) or include additional services (§ 55 para. 4 SGB V). In both

cases the amount of subsidy remains unchanged. The sickness funds do not take a share in the additional costs.

HC.1.3.9 All other outpatient curative care

The term "Cures" subsumes health services in Germany that are provided by non-medical practitioners, which include professional, recognized therapists, such as physiotherapists, occupational therapists etc. The entitlement to cures of insured persons can be found in the fifth section "Benefits in the Event of Disease" under Chapter III of the SGB V. This stipulates, under § 32 SGB V, that insured persons have an entitlement to cures, that is limited by a co-payments for insured over the age of 18 under § 61 para. 3 SGB V.

A further limitation on the entitlements is imposed under § 34 para. 4 SGB V, "Excluded Pharmaceuticals, Cures and Medical Aids". The Ministry of Health is entitled to exclude cures from the catalogue of services and benefits covered by the SHI by legal prescription, with the approval of the Federal Council (Upper Chamber of Parliament). However, a corresponding legal decree, in accordance with § 34 para. 4, SGB V, does not exist at the present time.

The scope of services covered by the Statutory Health Insurance is explicitly described and regulated by the Directive on Care by Non-physicians issued by the Federal Joint Committee under § 92 SGB V, which is described in part III. The prescription of more cost-effective measures with equal efficacy, e.g. drugs or other therapeutic appliances that achieve the same therapeutic objective is to be given precedence (precept of cost-effectiveness of the SGB V). The prescription of several cures at the same time is only possible if this gives rise to necessary therapeutic synergies. The inclusion of new cures in the benefit catalogue has been linked by the legislative authority, under § 138 SGB V in section 9 "Quality Assurance in the Provision of Care", to their inclusion in the aforementioned directive.

The federal associations of sickness funds and representatives of the interests of the cure providers conclude a Catalogue of Care by Non-physicians for the implementation of the directive issued by the Federal Joint Committee (see figure 5), in accordance with § 125 SGB V, which regulates

- the content, scope and frequency of cures,
- further training measures and quality assurance,
- the content and scope of collaboration between cure providers and the prescribing SHI physician,

- measures to meet the precept of cost-effectiveness and
- specifications for remuneration structures.

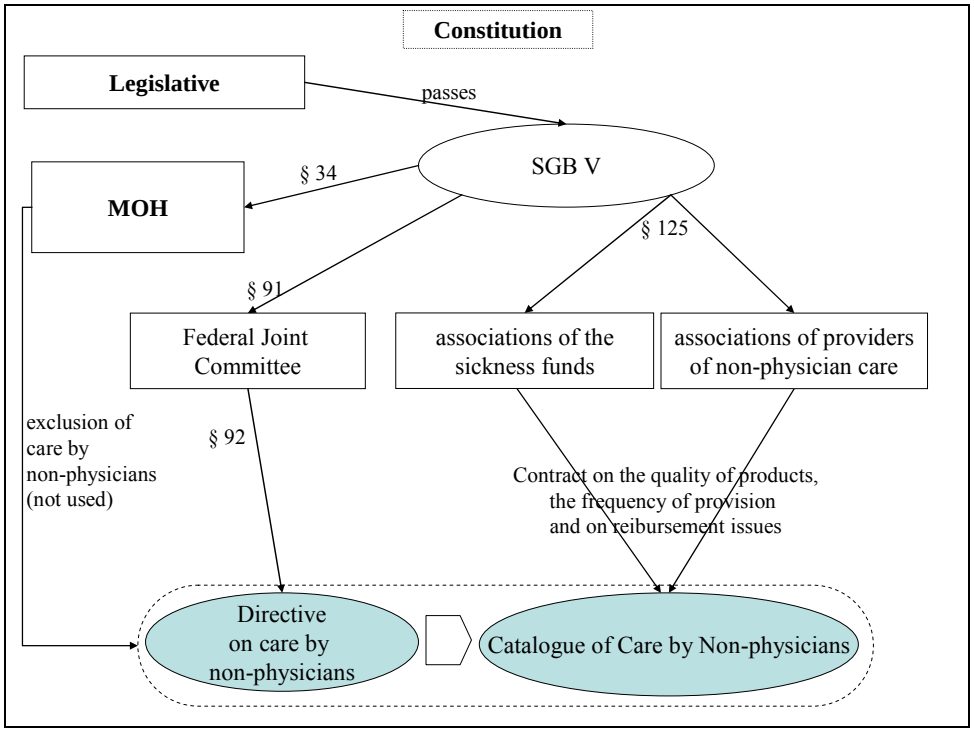


Figure 5: Definition of the SHI-benefit catalogue of care by non-physicians.

HC.2 Services of rehabilitative care

Medical rehabilitation services belong to the health care services to which persons insured by sickness funds, in accordance with § 27 SGB V, are entitled. The objective of rehabilitation measures is to avert, eliminate, alleviate, counterbalance and prevent the worsening or relieve the consequences of disablement or the need for constant care (§ 11 SGB V). The entitlement of insured persons is limited by a co-payment of 10 Euro per day, to a maximum of 28 calendar days per year (§ 40 para. 5 SGB V). Should outpatient care be insufficient to achieve the objectives described above, insured persons may receive inpatient rehabilitation services (§ 40 SGB V). In § 40 para. 1 SGB V, however, the entitlement of the insured persons is relativized, since the sickness funds itself are authorised to determine the legal consequence of a state of disease. In addition, the SHI only provides subsidiary rehabilitation services, i.e. if no other social insurance is responsible (§ 40 para. 4 SGB V).

In addition to the fifth book of the SGB, the ninth book of the SGB is applicable, which regulates rehabilitation and the participation of disabled persons, and which came into force as from 1st January, 2001. The Statutory Health Insurance, in accordance with §§ 5 and 6 SGB IX is the payer for medical rehabilitation as well as financial maintenance and other complementary benefits. Medical rehabilitation services incorporate medical treatment by

physicians, dentists and, subject to medical prescription, members of other non-medical professions, the provision of pharmaceuticals, bandages and dressing materials, cures, which include physiotherapy, speech therapy, occupational therapy and psychotherapy, the provision of therapeutic appliances, as well as early support for disabled children or children threatened with disablement (§ 26 para. 2 and § 30 SGB IX). Financial maintenance and other complementary benefits include cash benefits, such as health allowance, injury allowance, bridging allowance or maintenance allowance (§ 44, SGB IX).

Two steps are necessary to receive rehabilitative services, in accordance with a directive issued by the Federal Joint Committee, which came into force on 1st April, 2004. With the consent of the patient, the SHI physician informs the sickness fund by means of a short written form that curative care is not sufficient and that rehabilitation services are indicated. The sickness fund checks whether it is responsible and examines the existing health care entitlements of the insured person concerned and duly informs the SHI physician. In the second step, the SHI physician prescribes the rehabilitation measure. The rehabilitation prescription, in addition to a social and clinical anamnesis, includes information on the need for rehabilitation, the rehabilitation capacity, the aims of the rehabilitation and the rehabilitation prognosis in respect of the insured person concerned. Following this, the SHI Medical Review Board examines the rehabilitation indication and the rehabilitation prescription. This examination is conducted in accordance with § 275 SGB V. If the corresponding conditions are met, the rehabilitation service is approved and can be carried out in an institution offering rehabilitative services.

The responsible sickness fund determines the type, duration, scope, starting date and execution of the provided service (§ 40 para. 3 SGB V). In this, the fund orientates itself to the Framework Recommendations with respect to the content of a service and to the normally required duration, which are determined by the Federal Association for Rehabilitation Services, comprising the joint representation of all sickness funds, health service providers and self-help groups. In the event that there is no existing benchmark for a particular rehabilitation measure, the provision of ambulatory care must not exceed a duration of 20 treatment days or three weeks, in the case of inpatient care, respectively, and may only be repeated every four years (§ 40 para. 3 s. 2 SGB V).

The sickness funds may only allow rehabilitation services to be performed at institutions offering rehabilitation services with whom a service provision contract exists in accordance with § 111 SGB V and which can prove, in accordance with § 107 para. 2 SGB V, that they are under constant medical supervision, that they have qualified personnel and that they

proceed in accordance with a medical treatment plan. Adherence to the Framework Recommendations for outpatient rehabilitation is likewise a precondition for the sending of patients to a particular institution on the part of the sickness funds. Convalescent care for mothers or fathers together with a child is provided in accordance with § 41 SGB V at an institution belonging to the Convalescent Care Centre for Mothers and is not to be confused with preventive care services of the same name, which fall under the prevention of diseases and are subject to different legal regulations.

According to §§ 42 and 43 SGB V insured persons are entitled to a test of their resistance to physical exertion, work therapy, complementary rehabilitation services, such as training measures, rehabilitative sport and specific functional training and, in accordance with § 43 SGB V, to non-medical, socio-paediatric care for children in the form of psychological, curative pedagogical and psycho-social care services that may be required in order to detect and rectify possible defects at the earliest possible moment in time.

The composition of rehabilitation services is based on scientific knowledge in respect of rehabilitation measures and the definitions of objectives, methods and procedures. The fundamental basis for the services offered depends on the conditions under which diseases arise, on their consequences and the possibilities that exist to influence their course by suitable measures. Derived from this, a system of rehabilitation measures, consisting of several steps is developed, which forms the four pillars of modern rehabilitation (figure 6).

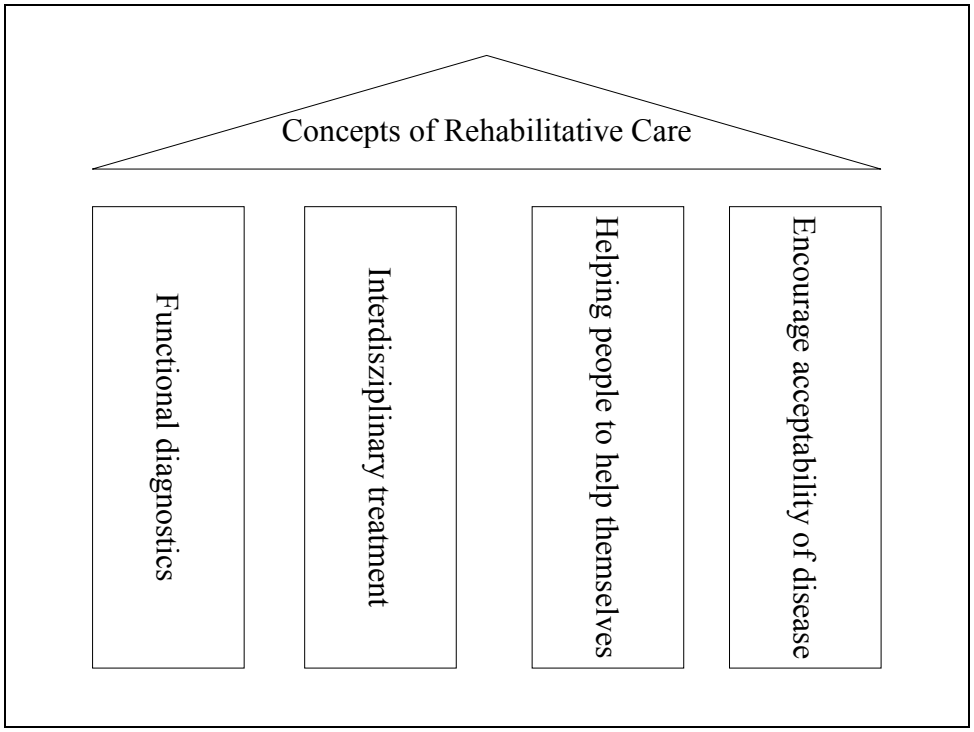


Figure 6: The four pillars of modern medical rehabilitation.

The integral components of rehabilitative care, which, in each individual case, are referred to as general services, are

a. initial, on-going and final examinations under consideration of socio-medical preconditions,
b. agreement on the setting of the rehabilitation aims and their verification in collaboration with the patient,
c. the planning and coordination of the therapy with the involvement of the patient in the conception of the therapy,
d. medical examinations and consultations with the patient in respect of the patient's disease and its effects on his private, professional and social sphere,
e. medical documentation at the sickbed, final release report, socio-medical assessment and
f. the review of the rehabilitation results.

These general services constitute the lowest common denominator of the Catalogue of Services and Benefits in the field of rehabilitation. However, neither in the sector of outpatient care, nor in the inpatient sector there is an explicit list of individual services. Explicit regulations governing the exclusion or inclusion of services are therefore not stipulated for the field of rehabilitation.

HC.2.1/2.2 In-patient rehabilitative care and day cases of rehabilitative care

In addition, to the general services offered, the services and benefits include board and accommodation, special features that are dependent upon the equipment and spatial amenities of the particular institution in question. Thus, care may be provided including cure treatments, such as salt-water, sulphur or mud baths, thermal and exercise baths, fango packs, inhalations, cures involving drinking healing waters or climatic cures in so far as the respective inpatient establishment has these possibilities at its disposal. Medico-physical treatments based on the Kneipp method, massages, radiation and electrotherapy may also be included. Furthermore, indication-related leisure and recreation activities may be performed. The exact composition of the measures is neither legally determined nor is it laid down in the Framework Recommendations. Instead, they consist of the services offered by the respective, individual provider, in the implementation of the care directives of the respective sickness fund and in the implementation of directives issued by the respective special association for certain indications.

The structural quality components, newly added in 2004 to the Operational Procedures Schedule OPS in the services documentation of the rehabilitative fixed payments complex lead to an explicit definition of the services to be provided for inpatient rehabilitation provided in a hospital. For an explicit explanation of the classifications of inpatient services provided in hospitals in the field of rehabilitative care, reference can be made to the respective chapter on DRGs in part III.

HC.2.3 Out-patient rehabilitative care

Framework Recommendations of the Federal Alliance for Rehabilitation (BAR) exist for the provision of outpatient rehabilitative care. The BAR was founded in 1969 to represent the sickness funds, the rehabilitation providers (rehabilitation clinics, Federal Association of SHI Physicians) and self-help organisations. In accordance with §§ 13 SGB IX and 111b SGB V it has the task of coordinating the contents and the course of individual therapeutic measures among the rehabilitation providers. Amendments to the recommendations are effected by the rehabilitation providers at the request of the Federal Ministry of Economics and Labour in consultation and agreement with the Ministry of Health and Federal Council, by the Federal Alliance for Rehabilitation or by the rehabilitation providers themselves (§ 13 para. 3-7 SGB IX).

The Framework Recommendations for ambulatory rehabilitation are conceived as a directive for the creation and expansion of an outpatient rehabilitative care structure to meet existing needs. It consists of a general part covering all areas and a special part comprising specific indication concepts. In addition to the concepts for neurological, cardiological rehabilitation and rehabilitation in the case of muscular skeletal diseases, the special part, since April 1, 2004, contains recommendations for dermatological and oncological care and for the rehabilitative care of psychiatric and psychosomatic diseases.

In the general part of the Framework Recommendations, general requirements in respect to providers of rehabilitative care are explained. The concept of the special part focuses on allocating the respective clinical picture to the pertinent international classification of the functional capacity, disablement and state of health and the differentiation between rehabilitation objectives, in order to determine in this way the treatment frequency and the rehabilitation duration. Furthermore, stipulations are laid down in respect of personnel and medico-technical requirements to be met by the providers of ambulatory rehabilitative services.

HC.3 Services of long-term nursing care

Statutory Long-Term Care insurance was introduced in 1994 – as Book XI of the Social Code Book – following a 20 year debate about how to secure financing and access to Long-Term Care in an ageing society with an increasing burden on municipalities to support elderly care. The Statutory Long-Term Care Insurance typically consists of the mandatory Long-Term Care Insurance and the mandatory private Long-Term Care Insurance. Before the introduction of the Statutory Long-Term Care Insurance there were certain benefits in the SHI package for ambulatory long-term care (these were cancelled after the introduction of the new scheme).

In contrast to most sectors covered by Statutory Health Insurance (with the notable exception of rehabilitation), benefits are available upon application only. The Medical Review Boards (operated jointly by sickness funds and long-term care funds) evaluate the applicants and place them into one of the three categories (or deny care). Entitlement to insurance benefits is given when care is expected to be necessary for at least 6 months (hence "long-term" care), while short-term nursing care continues to be a benefit of the sickness funds. Beneficiaries with a care dependency then have a choice of receiving monetary benefits or professional nursing care while staying at home or to receive professional nursing services in nursing homes.

The benefits of Long-Term Care Insurance are graded according to type, frequency and duration of the need for nursing care:

- grade I: support is necessary for at least two activities in the areas of body care, eating and mobility (at least once daily) as well as housekeeping (at least several times a week) with an overall average duration of at least 90 minutes daily;
- grade II: support is necessary at least three times daily with an overall average duration of at least 3 hours daily;
- grade III: support is necessary around the clock including nights with an overall average duration of at least 5 hours daily.

The inpatient and outpatient long term care benefits are legally limited according to grade (§§ 36, 37 SGB IX). The nominal level of these amounts has not been changed since the introduction of the Statutory Long-Term Care Insurance, which in fact means a real decrease in cash-benefits and the amounts of provided benefits-in-kind.

The duty to guarantee access to professional ambulatory long-term care has been legally entrusted to sickness funds that are responsible for administering the Statutory Long-Term Care scheme, while the *Länder* guarantee access to institutionalized care. The prices are

negotiated at *Länder* level between long-term care funds and associations of providers delivering nursing care (§ 89 SGB XI). The federal government is authorised to define the services included into the benefits covered by LTC insurance and their reimbursement (§ 90 SGB XI), but, so far this possibility has not been used. In the case of nursing care the principle of "dual financing" means that the *Länder* have to cover investment costs fully for institutions and partly for ambulatory suppliers. The *Länder* are also responsible for planning but they are legally not allowed to limit the number of providers in the ambulatory care sector so that competition is enhanced.

HC.3.1 In-patient long-term nursing care

For people choosing institutionalized nursing care, benefits of the Statutory Long-Term Care Insurance are available for day or night clinics as well as old age or special nursing care homes. Monthly benefits are limited to € 1023 (Grade I), € 1279 (Grade II) and € 1432 (Grade III) Higher benefits may be provided in exceptional cases.

The SHI pays a subsidy to the provision of services (palliative treatments) for insured that are not in need of an inpatient curative treatment according to § 39a SGB V. Therefore the federal association of sickness funds contracts with the provider associations for details of care provision.

HC.3.2 Day cases of long-term nursing care and HC.3.3 Long-term nursing care: home care

The Statutory Long-Term Care Insurance supports the delivery of home care by family members with € 205 (Grade I), € 410 (Grade II) € 665 (Grade III) plus a professional substitute for up to €1,432 a year to cover holidays. In addition, family members serving as care-givers at home can attend training courses free of charge. The care-giver is also covered by Statutory Accident Insurance and Statutory Retirement Insurance, financed by the sickness fund administering the Statutory Long-Term Care Insurance of the person in need. The limits for professional ambulatory services delivered on an in-kind basis are €384, €921, and €1,432, respectively.

A new development is the option of personal budgets for recipients of professional ambulatory long-term care. From July 2004, they may apply for a personal budget, which is lower than the normal home care budget, and which can be spend on the provider and service of their choice (e.g. non-qualified nurses).

SHI home nursing care is regulated separately. The Federal Committee has passed guidelines to clarify responsibilities and improve cooperation between the sickness funds, responsible for acute home nursing care, and the long-term care funds. However, organisational responsibilities and financing obligations are still subject of debate. Recently the Federal Social Court decided that medical aids for recipients of statutory Long-Term Care Insurance have to be paid by their Statutory Health Insurance.

The insured are entitled to acute home care according to § 37 SGB V, if an inpatient treatment is necessary but not feasible or if the duration of an inpatient treatment can be reduced by home care. The entitlement is limited to 4 weeks per case of illness, except the SHI Medical Review Board has approved a longer period. If the patient is graded a need for nursing care according to SGB XI, the benefits of the SHI are only granted in connection with the treatment of a disease (§ 37 SGB V Abs. 2). A co-payment of 10 Euro for the insured older than 18 years for the first 28 days receiving home care within a year restricts the SHI benefits further. Outpatient hospice services are encouraged by the sickness funds according to § 39a SGB V.

HC.4 Ancillary services to health care

HC.4.1 Clinical laboratory

Benefits belonging to this category are included in the benefit catalogues of the affected sector and therefore dealt with in the corresponding section.

HC.4.2 Diagnostic imaging

Benefits belonging to this category are included in the benefit catalogues of the affected sector and therefore dealt with in the corresponding section.

HC.4.3 Patient transport and emergency rescue

There are substantial regional variations among the 16 *Länder* with respect to legislation, regulation, organization, purchasing, financing and delivery of rescue care and emergency care. Emergency rescue and non-emergency rescue are integrated with other types of rescue services. Often non-rescue patient transport is also part of the rescue package. There are about 360 control and coordination centres for rescue care in Germany, with uniform telephone numbers and criteria to differentiate between the need for rescue care or emergency physician care.

Since the second SHI Restructuring Act (1997), planning for emergency physician service capacities has been clearly allocated to the *Länder*, unless state legislation explicitly delegates the duty to regional physicians' association (as in Bavaria). Non-emergency after-hour care is still delegated to the regional physicians' associations and is thus supervised by the state ministries responsible for health.

Most *Länder* delegate the organization and delivery of rescue care to the municipalities. Within the framework of the state rescue law, local communities may accredit, regulate and plan for capacities of integrated public providers (mostly integrated with fire protection) as well as contracted private rescue providers.

While capital financing is mainly a task of the Länder, the recurrent expenditure are financed by the SHI or – to a lesser extent – by private health insurance. Nevertheless, direct contracting between SHI and providers outside the hospital is still rare. This is because contracting is only required for SHI, if there are no regulations imposed by the *Länder* or the municipalities (§ 133 SGB V). Co-payments have traditionally applied to non-emergency transport services, but since 2004, they also relate to emergency transport and services at the hospital. A fee of € 10 is charged for emergency transport. In addition, non-rescue patient transports have been excluded from SHI. A few exceptions have been outlined by the Federal Joint Committee, including the transport of patients with certain severe disabilities or in need of special ambulatory treatments, for example chemotherapy and haemodialysis. Time standards for reaching patients are established in all states; however, they are only specified in the legislative text in Brandenburg (arrival within 15 minutes).

HC.5 Medical goods dispensed to out-patients

HC.5.1 Pharmaceuticals and other medical non-durables

HC.5.1.1 Prescribed medicines

The provision of prescribed medicines is part of the benefit catalogue of the sickness funds. The paragraphs regulating pharmaceutical care are spread within the fifth chapter of the SGB V (benefits due to disease). §§ 31, 34, 35, 35a regulate the entitlements to pharmaceutical care. § 91 and § 92 identify the tasks of the Federal Joint Committee. In §§ 129, 129a, 130, 130a and 131 pharmacies, hospital pharmacies and manufacturers of pharmaceuticals are regulated. Additionally, the admission of pharmaceuticals to the market is defined in the Pharmaceutical Act.

There is no explicit benefit catalogue for pharmaceuticals. A so called positive list that should have included all pharmaceuticals covered by the sickness funds, was planned, but never implemented. Therefore every drug, which has received admission to the market and is not an OTC is covered by the sickness funds and thus included in the benefit package of the insured (§§ 31, 34 SGB V). The entitlements of the insured aged above 18 years are limited through cost-sharing (§§ 61, 62 SGB V). The insured pay a share of 10% for all prescribed drugs with a minimum of 5 Euro and a maximum of 10 Euro per package.

However, § 34 SGB V states some exemptions from universal coverage. Insured aged over 18 years are excluded from drugs generally used for minor conditions, e.g. cough and cold remedies, laxatives, travel sickness products and mouth and throat infections (§ 34 para. 1 SGB V). The Federal Joint Committee can issue indication based exemptions if those drugs are standard therapy for severe diseases. As part of the SHI Modernization Act (2004), "lifestyle drugs" are being legally excluded from reimbursement. Therefore, drugs for erectile dysfunction as well as anti-smoking drugs and others are no longer reimbursed by the sickness funds (§ 34 para. 1 SGB V). In addition the Social Code Book allows the Minister of Health to exclude "inefficient" drugs (i.e. they are not effective for the desired purpose) or drugs with combinations which cannot be evaluated with certainty (§§ 2, 12, 34 para. 3 and 70 SGB V). The evaluation of these drugs has to take into account the peculiarities of homeopathic, anthroposophic (drugs generated from natural sources based on a philosophy about the affinity of humans to nature) and phytotherapeutic drugs. A negative list according to these principles came into effect on 1st October, 1991. It was revised in 1993 and in 2000 and contains currently about 2,200 drugs. Additionally, drugs for "trivial" diseases which can usually be treated by treatments other than drugs may be excluded (§ 34 para. 2 SGB V). But so far a list of this type has not yet been worked out.

The entitlement of the insured to a pharmaceutical benefits are further restricted by the German reference pricing system according to § 35 SGB V. It defines a reimbursement limit for groups of comparable pharmaceuticals. The grouping procedure is done by the Federal Joint Committee. Subsequently the federal associations of the sickness funds set reference prices. The difference between the drug price and reference price is paid for by the insured in addition to the "regular" co-payment according to § 33 SGB V, but that is rarely the case, as only for 4.3% of the pharmaceuticals available on the market were priced above the reference price in 2003.

HC.5.1.2 Over-the-counter medicines

Until the beginning of the year 2004, there was a difference in reimbursement between OTX (prescribed OTC) and self-medication (OTC). While self-medication was paid by the patients, prescribed OTC were covered by the sickness funds under the conditions described above. The Statutory Health Insurance Modernization Act removed that difference with some exemptions. Now, OTC are basically excluded from the SHI benefit catalogue. However, there are three legally defined exemptions in § 34 SGB V:

1) for children below the age of 12 years,
2) for children with developmental disabilities below the age of 18 years, and
3) for OTC prescribed because of a severe illness, if the Federal Joint Committee lists that indication as an exemption within its directive according to § 34 para. 1 s. 2 SGB V.

The directive of the Federal Joint Committee described in section III thus explicitly defines the benefit catalogue for OTCs (see figure 7). The regulatory instruments described in the section for non-OTC are also valid for OTC covered by the sickness funds. OTC paid by the patient are not subject to pharmaceutical price regulation. Pharmaceuticals are in price competition with each other.

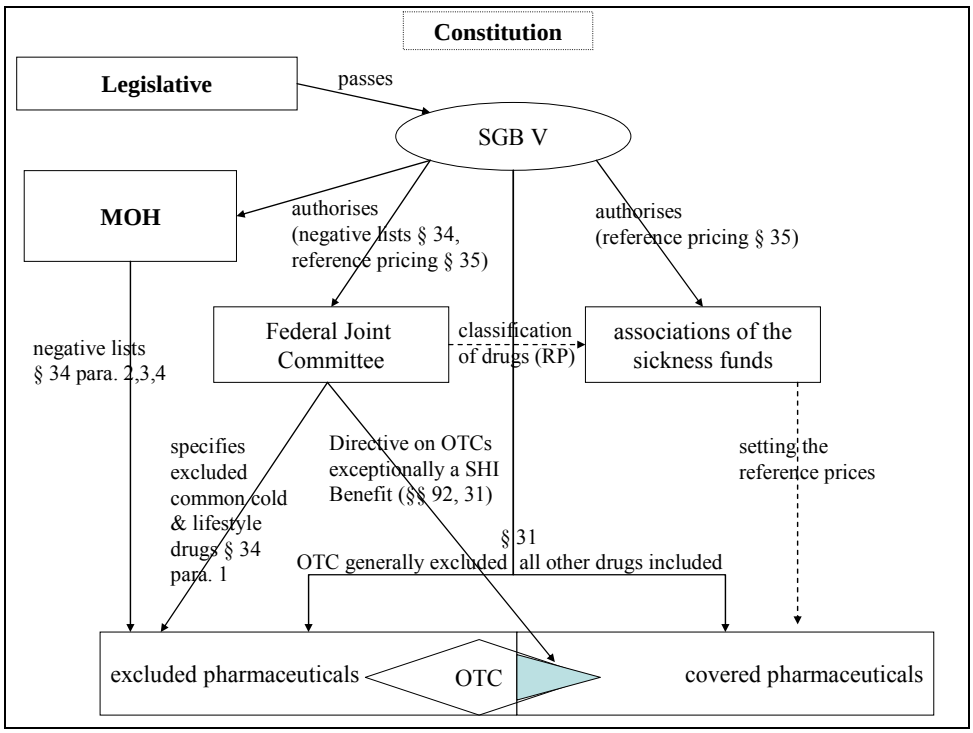


Figure 7: Regulation of pharmaceutical benefits.

HC.5.2 Therapeutic appliances and other medical durables

According to § 33 SGB V and § 31 SGB IX, insured persons are entitled to the provision of therapeutic appliances. Therapeutic appliances are medical products that are complemented by medical services. The genus of the therapeutic appliance comprises items prescribed by a physician for a medical aim and, as such, to effect the success of the medical treatment of disease and/or the compensation of physical disablement, i.e. they are immediately aimed at combating the disease or disablement (§ 33 SGB V). Therapeutic appliances are required in individual cases to assure the success of the treatment of disease and facilitate the participation in normal, every-day life. The entitlement also includes any necessary modifications, repair and replacement of the therapeutic appliance. According to § 33 para. 5 s. 5 SGB V the entitlement of the patient is restricted by a co-payment of 10% of the prescription value up to a maximum of 10 Euro for monthly needs for each indication. In addition, the legislative authority has imposed a limitation on the care entitlement of the insured persons in the form of a reference pricing system. Sickness funds are only obliged to bear the costs incurred for a therapeutic appliance prescribed by a physician up to the reference price of the product, which is determined by the Federal Associations of the Sickness Funds. Cost for therapeutic appliances over and above the reference price, irrespective of the co-payment in accordance with § 33 SGB V are borne by the insured persons themselves.

Therapeutic appliances may only be applied by authorised service providers (§ 126 SGB V). To be authorised, the provider must be able to guarantee the adequate, expedient, functionally suitable and cost-effective manufacture, supply and modification of a therapeutic appliance. The quality of therapeutic appliances is indirectly regulated by European law on medical products and by the state regulations pertaining to the qualifications of persons employed in the supply of therapeutic appliances. The regional associations of the sickness funds as well as the regional associations of the substitute funds conclude contracts with the Associations of the Providers of Therapeutic Appliances or with individual providers of therapeutic appliances in respect of the provision of products for the insured persons (§ 127 SGB V).

The legislative authority charges the federal associations of the sickness funds in accordance with § 128 SGB V with the task of compiling an index (Catalogue of Medical Aids) in which all therapeutic appliances that are a SHI benefit are listed. This Catalogue of Medical Aids is explained in detail Chapter III. During the compilation and on-going completion of the index, the federal associations of the providers of therapeutical appliances and the manufacturers themselves are given the opportunity to submit their comments and opinions.

The precondition for the inclusion of new therapeutic appliances in the Catalogue of Medical Aids is proof supplied by the manufacturers of the appliances in respect of the functional effectiveness and the therapeutic utility and quality (§ 139 SGB V). On written application submitted by the manufacturer, the SHI Medical Review Board verifies whether the preconditions are fulfilled for the inclusion of a therapeutic appliance in the Catalogue of Medical Aids on the basis of the standards fixed by the federal associations of the sickness funds. Thus, accordingly, the federal associations of the sickness funds jointly decide on the inclusion of new therapeutic appliances in Catalogue of Medical Aids (see figure 8).

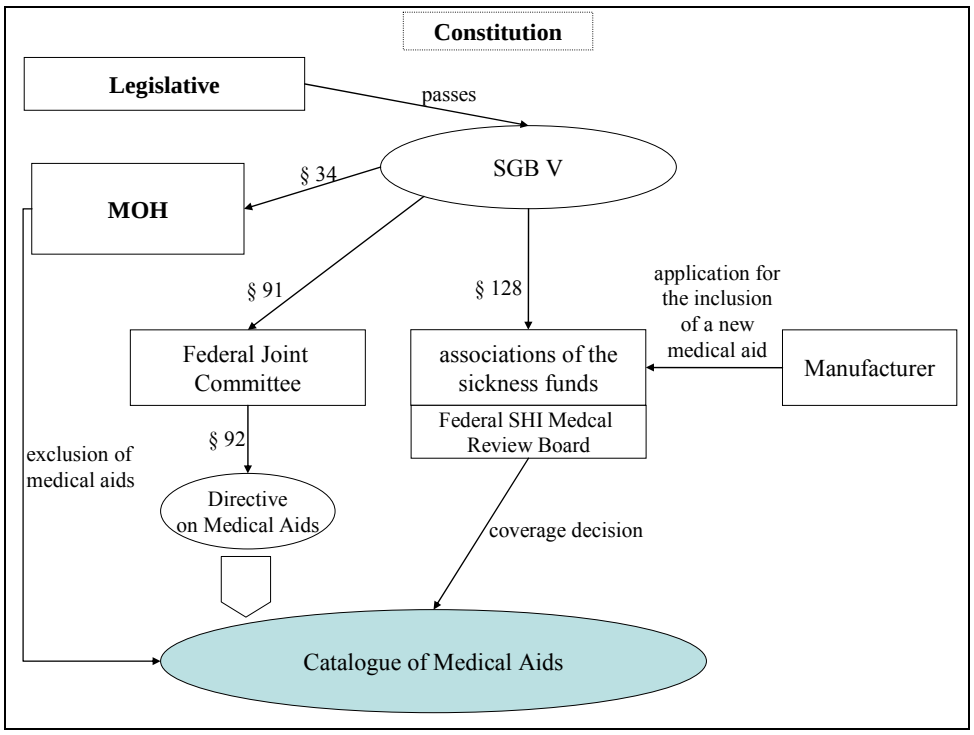


Figure 8: Inclusion and exclusion of therapeutic appliances in the Catalogue of Medical Aids.

In addition, in accordance with § 34 para. 4 SGB V the Ministry of Health can determine by lawful decree, with the approval of the Federal Council, therapeutic appliances of little or disputable therapeutic value or with a low selling price, which are not reimbursed by the sickness funds. Hearing aids for children below the age of 10 are not to be excluded from the Catalogue of Medical Aids.

The entitlements of the insured to seeing aids are already described in SGB V in respect of indication and scope. Up to completion of the 18th year of age, insured persons have a general entitlement to the provision of seeing aids; insured persons over the age of 18, however, only have an entitlement in the case of serious eyesight impairment (the precondition is an eyesight impairment of at least stage 1 of the WHO- classification) or for the treatment of eye injuries or diseases (§ 33 para. 1 s. 2 SGB V). The prescription of contact lenses shall only be undertaken in exceptional cases of absolute medical necessity (§ 33 para. 3 SGB V). The Federal Joint Committee laid down in a directive in accordance with § 92 SGB V for which indications spectacle lenses, contact lenses and other seeing aids, such as magnifying lenses, magnifying spectacles, telescope spectacles, etc. may be prescribed.

HC.6 Prevention and public health services

In the field of prevention, the scope of services and benefits covered by the Statutory Health Insurance is already laid down, in principle, by the SGB V. The entitlements of the insured persons are primarily regulated under Section 3, “Health care services for the promotion of

health and prevention of diseases" (§§ 20–24b) and section 4 of Chapter III, "Health care services for the early detection of diseases" (§§ 25-26).

According to § 20 SGB V, the sickness funds should define services for primary prevention in their statutes. To this end, the federal associations of sickness funds determine, with the aid of independent expertise, high priority fields of action and criteria for health care services that improve the general state of health. In addition, preventive care services should prevent deterioration of the state of health, which, in the foreseeable future, would lead to disease, and/or be able to avert the worsening of a disease or the need for constant care. The entitlements of the insured persons to preventive care services include, in accordance with § 23 SGB V pharmaceuticals, bandages and dressing materials, cures and therapeutic appliances, in so far as they are necessary to meet the aim. § 21 and § 22 SGB V describe preventive measures to be provided in the field of dental care, stipulated in detail in the directive issued by the Federal Joint Committee.

In § 24 SGB V, the entitlement to mother-and-child and/or father-and-child measures is regulated. §§ 24a and 24b SGB V regulate the entitlements in respect of contraception, termination of pregnancy and sterilisation. § 25 SGB V stipulates the legal entitlement to preventive medical check-ups. Preventive medical check-ups are only performed for diseases that can be treated effectively and are possible to detect with certainty already beforehand or in early stages. The provision of preventive medical check-ups is additionally coordinated with the responsible regional physicians' association and are then carried out in accordance with the pertinent directive issued by the Federal Joint Committee in accordance with § 92 SGB V. In § 26 SGB V, the legal entitlement is defined in respect of preventive medical check-ups for children up to the sixth year of age and so-called youth health examinations. Here, too, the scope of services and benefits are stipulated in detail in the directive issued by the Federal Joint Committee.

The directives in the field of prevention are structured according to the respective subject fields. However, they are focussed on the detection of certain diseases and lay down corresponding stipulations concerning the application of examination methods. In addition, regulations are issued concerning the documentation and the evaluation of examination results for the respective competent health service providers. The individual services or service packages contained in the directive - as also in the case of other outpatient services – can be remunerated in accordance with the Uniform Evaluation Scale (EBM) described in chapter III. Thus, in the field of prevention, the EBM is not to be regarded primarily as a catalogue of services and benefits but merely as a fee scale.

HC.6.1 Maternal and child health; family planning and counselling

Insured persons are entitled to counselling on questions relating to contraception and the necessary examinations involved. The costs for prescribed contraceptives, however, are covered by the Statutory Health Insurance only up to the end of the twentieth year of age (§ 24a).

The Directive on Maternity care issued by the Federal Joint Committee regulate medical care during pregnancy and after confinement, so as to avert risks for life and health of mother and child in good time as well as to enable the early recognition and treatment of health disorders. The directive, last amended on 24th March, 2004, came into force on 10th December, 1985. The examination and counselling procedures belonging to the tasks assigned to the physician are described therein. The individual sections of the directive prescribe measures for the early recognition and monitoring of endangered pregnancies (Ultrasonic diagnosis), serological examinations to detect infections, medicinal measures and the prescription of bandages and dressing materials and remedies.

Medical preventive care services for mothers and fathers that are necessary to prevent a foreseeable impairment of health and/or disease in time (§ 23 SGB V Section 1), can be provided, in accordance with § 24 SGB V, in the form of mother-and-child and/or father-and-child measures in institutions suitable for this purpose.

In addition, § 24b SGB V regulates comprehensively the payment of the costs for the termination of pregnancy and sterilisation. The individual medical services and the necessary conditions under which the services are covered by the SHI are explicitly specified therein. A directive issued by the Federal Joint Committee further regulates the procedures in the case of a termination of pregnancy.

The entitlement to preventive medical check-ups for children and medical examinations for young people (§ 26 SGB V), are also laid down in two directives issued by the Federal Joint Committee:

The Directive concerning the early Detection of Diseases in Children up to Completion of the 6th Year of Age ("children directive"), last amended on 22nd March, 2000, came into force on 1st January, 1977. It is subdivided into the sections A. – E. and comprises, together with 3 appendices, 17 pages:

A. The general section specifies the diseases that shall be detected by the examination. Subsequently, the measures to be undertaken by the health care providers in the case of suspicion are specified.

B. In Section B, the time intervals for the examination steps (U1 – U9) and the findings to be sought therein are stipulated.
C. Section C regulates the fundamental basis of the documentation (examination record) and prescribes that the findings shall be recorded both by the sickness funds and by the regional physicians' association.
D. Section D clarifies how to proof eligibility for benefits: proof is to be established by presentation of the insurance card.
E. Section E regulates the coming into force of the directive.

The examination booklet, the recommendations for the execution of TSH Screening examinations for the early detection of a hypothyreosis and the recommendations for sonographic examinations of the hips in newborn babies are printed in the appendices.

The Directive on the Medical Examination of Young People stipulates the specifications for the early detection of diseases in young people over the age of 10. It came into force on 1st October, 1998. The last amendment was effected on 27th January, 1999. The directive comprises four pages and is subdivided into six sections:

1. The objective of the examination is the early detection of diseases that are a significant threat to physical, mental or social development.
2. Insured persons between the beginning of their 13th and the end of their 15th year of age are eligible for entitlement.
3. To begin with, a differentiated anamnesis is compiled by means of a clinical-physical examination. Laboratory tests are only to be conducted on suspicion of hypercholesterinaemia in the family.
4. The directive stipulates the health service providers responsible for conducting the examinations.
5. The procedure for the documentation and the evaluation of the results of the measure is determined.
6. The coming into force of the directive is regulated.

HC.6.3 Prevention of communicable diseases

As a matter of principle, the entitlement to vaccinations exists only if these are specified in the statutes of the respective sickness fund. In accordance with § 23 para. 9 SGB V they constitute a so-called "optional service" of the SHI. For the provision of these services, the sickness funds and/or the associations of the sickness funds must conclude contracts with the health service providers responsible. Thus, for example, the "Agreement over the execution of vaccinations against communicable diseases" between the Federal Association of SHI

Physicians and the Association of Substitute Funds stipulates which vaccinations may be performed at the expense of the substitute funds.

HC.6.4 Prevention of non-communicable diseases

After reaching the age of 35, insured persons are entitled to preventive medical check-ups (§ 25 SGB V). These preventive medical check-ups are to be focussed on diseases that can be treated effectively and are detectable with certainty beforehand and/or in early stages. In particular, these include cardiovascular diseases, kidney diseases, diabetes mellitus and cancer.

The composition of SHI – benefits is left to the Federal Joint Committee that passes a directive. Additionally, the provision of preventive medical check-ups is coordinated with the regional physicians' associations and subsequently carried out according to the pertinent directive issued by the Federal Joint Committee in accordance with § 92 SGB V.

In this way, for example, the Directive on Medical Examinations for the Early Detection of Diseases ("Medical Examinations Directive") dated 1st October, 1989, last amended on 23rd March, 2001, regulates the entitlement of women and men from the age of 36, in accordance with § 25 SGB V. It specifies the contents and frequency of the examinations and regulates matters relating to documentation. For the early detection of cancer there is a separate directive, the so-called Directive for the Early Detection of Cancer dated 1st July, 1977, last amended on 1st January, 2004. Women above the age of 20, are entitled to examinations for the early detection of cervical cancer; above the age of 30, they are entitled to early detection examinations of the breast and skin and from the age of 50, they have an additional entitlement to early detection examinations of the rectum and of the colon. After the age of 45, men are entitled to examinations for the detection of cancer of the prostate, the external genitals and the skin. After the age of 50, they are entitled to early detection examinations of the rectum and the colon. Since 2003, the existing SHI cancer-screening benefits have been extended to cover colonoscopy (two tests, at age 65 and 75), as an alternative to stool-testing, and a systematic mammography screening programme for women aged 45–64. The precise procedure for the examination, as well as the examination methods are specified in the directive.

Continuous prophylactic treatments are also considered very important for the prevention of dental diseases. Dental prophylaxis is defined very detailed in § 21, § 22 and § 26 SGB V. In addition, the Federal Joint Committee issued two directives to define which diagnostic tests and procedures should be included for the beneficiary.

For children below the age of twelve years the legislator has obligated the sickness funds to encourage and finance prophylaxis for groups (§ 21 SGB V). Therefore the sickness funds cooperate with dentists and local authorities at the *Länder*-level, schools and nursery schools. In practice, children visit the local dentists in attendance of their teacher for regular dental check-ups. The examinations emphasise dental hygiene, dental enamel and advises on eating habits (§ 21 SGB V para. 1). In areas with an above average danger of caries, group prophylaxis measures are continued on up to the age of sixteen years.

Additionally, children aged three to six years are entitled to a yearly preventive medical check-up of the mouth, the teeth and the jaw (§ 26 SGB V). The dentist should asses the risk of caries and advice on dental hygiene. He should also consider a treatment with florid taking into account treatments during the group prophylaxis. Children between the age of six and eighteen are entitled to a prophylaxis examination beside the group prophylaxis twice a year (§ 22 SGB V).

Adults are supposed to visit the dentist at least once a year for a dental check-up. Visits to the dentists for prophylactic treatments are twice a year free of the 10 Euro co-payment usually paid for the first quarterly visit of a physician. The participation in a yearly dental check-up has also direct impact on the entitlement to dental prosthesis at a later stage (see for example HC.1.3.2).

HC.6.5 Occupational health care

In § 20 para. 2 SGB V the sickness funds are given the opportunity to become active in the field of occupational health and safety in cooperation with the accident funds. The sickness funds shall promote self-help groups and points of contact that are engaged in the field of prevention and rehabilitation (§ 20 para. 4 SGB V).

B. Other benefit schemes

Governmental Allowance Scheme for Civil Servants and Judges (GAS)

While most of the population are covered by SHI, the government, which is as an employer obliged to assure health care to its employees (§ 79 Civil Servant Act), has not included its irredeemable civil servants and judges and their entitled relatives (wife/husband, children) in the SHI scheme. Instead of the liability to pay the employer's contribution to the SHI, the government directly pays for the treatment costs of the beneficiary.

The Government pays a fixed percentage of the costs for the provision of provided benefits. The level of allowance varies according to the status of the beneficiary and its profession.

Civil servants and judges receive an amount of 50% of their treatment costs. Retired civil servants and judges receive 70%. The wife or the husband of a civil servant also receives 70%, if their income in the preceding year has been lower than € 18,000. Children are entitled to an amount of 80%. Single civil servants with two or more children receive an additional amount of 20% for themselves (see figure 9).

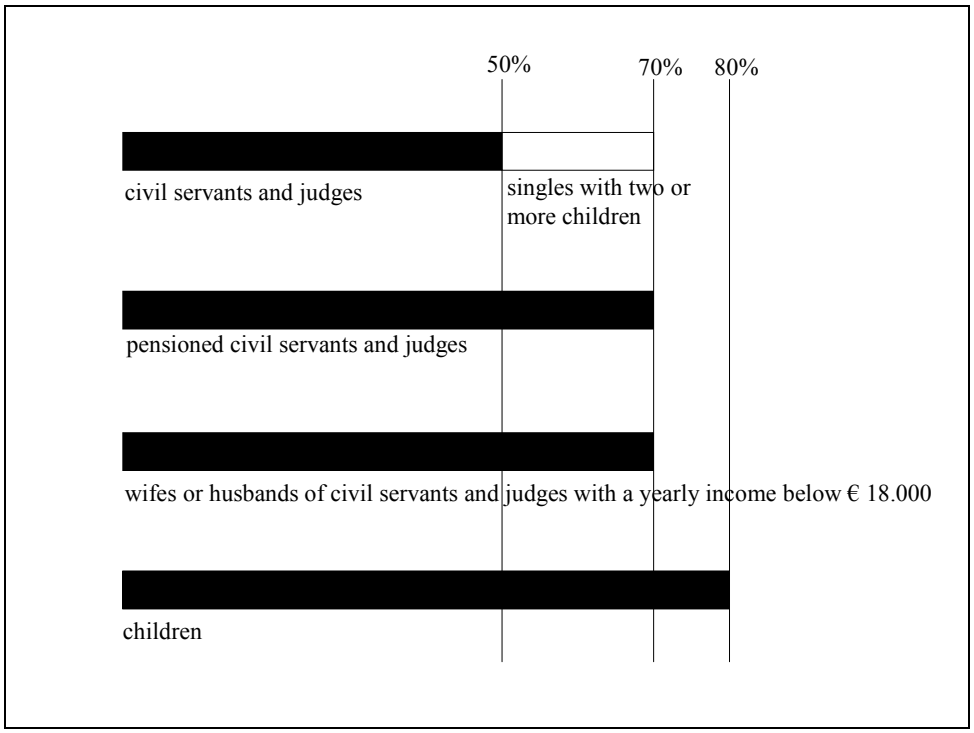


Figure 9: Level of allowance for civil servants and judges.

The allowance is not paid if other schemes cover the full treatment costs. A combined coverage is limited to 100% of the respective costs. Most civil servants and judges take up complementary private health insurance plans paying the amount which is not covered by the allowance and thus ensuring coverage of 100%.

For the Government it has been cheaper to finance health care costs of its civil servants and judges as to pay half of the contribution rate to the SHI, as the risk structure among civil servants and judges has traditionally been better than of SHI members. To anticipate the increased health care costs of its employees in 2014 – 2030, the government has reduced the annually wage increase of its employees by 0.2% since 1999 and allocated it into a special reserve fund.

In general, the benefit regulation in the Governmental Allowance Scheme is less explicit than in the SHI. It concentrates on defining the share of payments for the demanded benefits. For an explicit definition of benefits, it is mostly referred to the SHI benefit catalogues or the

benefit catalogues of private health insurance schemes. The benefit catalogues differ slightly by the respective employee (federal government, Länder governments), but the benefit catalogue of each federal state mostly complies with the catalogue of the federal government.

Benefits provided for the GAS have to be necessary, appropriate and not explicitly excluded by the Federal Allowance Decree (FAD). A civil servant or a judge is entitled to the treatment of a disease by physicians, dentists and psychotherapists (§ 6 FAD). This also includes pharmaceutical care (to the same extent as they are SHI benefits), medical aids and care provided by non-physicians. Inpatient treatment encompasses standard and optional hospital services. These can be provided as full-time, part-time, pre or post inpatient care. First aid, patient transport, accommodation for a necessary treatment that is provided apart from the residence, treatment in a sanatorium, cures and ancillary services to health care are covered at the respective level of the allowance, as well. Long-term care benefits are graded according to type, frequency and duration of the need for nursing care (see HC.3). The share for the allowance is the same as the benefits of the Statutory Long-Term Care Insurance scheme (see HC.3.1, HC.3.2 and HC.3.3). For the entitlement to prevention it is referred to the directives Federal Joint Committee (§ 10 FAD) which have been described in detail in HC.6.3 and HC.6.4. Medical treatments in EU member states are also subsidised. If the expenses arise on an official journey, the share of payments is not limited. In all other cases, it is limited up to the costs of the same medical treatment in Germany.

All areas of care are subject to co-payments that reduce the allowance according to § 12 FAD. Basically, cost-sharing for civil servants and judges follows the same rules as cost-sharing for SHI patients. Pharmaceutical care and medical aids are, as well as in the SHI, subject to reference pricing, as described in HC.5.1.1 and HC.5.2.

According to § 5 FAD the Catalogue of Tariffs for Physicians and the Catalogue of Tariffs for Care by Non-physicians, that are similar to the EBM and are also used accounting for private health insurance, are the framework for the allowance for outpatient care (HC 1.3.1 and HC 1.3.3) and for care by non-physicians (HC 1.3.9). Psychotherapy is further regulated in appendix 1 of the FAD.

The allowance for dental care (HC 1.3.2) is a part of the Catalogue of Tariffs for Dental Care and appendix 2 of the FAD. For dental prosthetics the allowance is 65% of the cost of the respective SHI standard treatments (HC 1.3.2).

Medical Aids available, as well as Medical Aids excluded, are listed in appendix 3 of the FAD. The list only consists of generic terms which aggregate numerous single products. Only the allowance for spectacles is regulated in detail.

The entitlements according to GAS and according to SHI do not differ substantially. Therefore, the benefit catalogues of the GAS will not be described in detail.

Statutory Accident Insurance scheme (SAI)

Statutory Accident Insurance (SAI) is responsible for the prevention of work-related accidents and for the provision of health care due to work-related accidents or an occupational disease (§ 1 SGB VII). The Statutory Health Insurance explicitly excludes benefits for these purposes. The beneficiary encompasses employees, people in work-related training/education, students, pupils and people doing community services (§ 2 SGB VII).

The prevention of work-related accidents is organised in cooperation with the employers. The employers are advised on how to prevent accidents and occupational diseases. In addition, special safety regulations are applied to each industry.

In case of work-related diseases, the insured are entitled to its treatment, encompassing first aid, care by physicians, dentists and hospital treatment. This also includes – if prescribed by a physician – pharmaceutical care, care by non-physicians, rehabilitative care, medical aids and home-nursing-care (§ 26 SGB VII). Despite the coverage of treatment costs, the SAI is responsible to assist the employee if work-related accidents lead to disability. Thus, the SAI provides assistance for the handicapped to manage their live, incurring costs of a home-help or of childcare if needed. Long term care is either provided in kind or by payments according to the need of the beneficiary between € 295 and € 1,180 (former BRD) and between € 256 and € 1,023 (former GDR).

Although the provision of outpatient care is performed by the same physicians providing care for the SHI, a special contract between the associations of the accident funds and the Federal Association of SHI Physicians/Dentists determines the benefits and the scope of health care provided. A modified Catalogue of Tariffs for Physicians/Dentists, which is similar to the EBM, is used for provider remuneration. Hospital treatments are reimbursed on the basis of daily care rates. As the exposure to work-related accidents is not considered to be influencable by the individuals, there are no co-payments for SAI-benefits. Pharmaceutical care and medical aids, however, are subject to SHI reference pricing, as described in HC.5.1.1 and HC.5.2. Additionally, special areas of care are regulated by directives of the associations of the accident funds. Nevertheless, the SAI benefit catalogues do not differ substantially from the SHI benefit catalogues and will not be described in detail.

Statutory Retirement Insurance scheme (SRI)

The Statutory Retirement Insurance (SRI) is responsible for the payment of pensions to the people eligible. In order to avoid that a person is unable to work and thus receives a pension before the legal retirement age of 63 for women and 65 for men, the SRI finances rehabilitative measures. For already retired insured rehabilitative services are covered by the SHI.

Benefits of SRI are provided upon application only. A social and clinical anamnesis by a physician is needed, as well (see HC 2.). Measures are limited to a maximum of three weeks and may only be repeated every four years. Beside the treatment costs, the SRI benefits include travelling expenses, a compensation for the loss of salary during the measures (after 6 weeks of sickness days the salary will not be covered by the employer anymore), help at home and the costs of child care if necessary.

Co-payment – depending on monthly income – limit the SRI benefit: The surcharge varies from € 8 (monthly income above € 967) to € 10 (monthly income above € 1,200). For a detailed description of possible measures it is referred to the description of the SHI benefit catalogue in HC.2.

Public assistance scheme

Unemployed persons receive either benefits from SHI (if insured) or they receive benefits from the communal governments under the public assistance scheme. The public assistance scheme covers the same benefits which are provided by the SHI.

III) Description of benefit catalogues

A. Case Fees Catalogue: Diagnosis Related Groups (DRGs) (HC.1.1, HC.2.1)

The German DRGs are listed in a Case Fees Catalogue, which is an appendix to the Case Fees Act 2004 and/or to the Case Fees Agreement 2005. This Case Fee Catalogue can be referred to as a SHI benefit catalogue for inpatient care, with the limitation that the inpatient services provided are not all listed individually but summarised under general headings. The Case Fees Catalogue of 2004 consists of a table with 786 remunerable DRGs and two additional lists with 26 extra remunerations to be agreed negotiated separately as well as 18 DRG services that are not remunerable with a case fee. Thus, in the year 2004, there were a total of 804 (786+18) DRGs. In the year 2005, the total number of DRGs increased to 876, of which 33 are not remunerable with a case fee The number of extra remunerations to be negotiated separately has increased to 71.

The Case Fees Catalogue primarily serves as an instrument for the calculation of revenues in Germany. Therefore the Institute for the Remuneration of Hospitals (InEK) with the assistance of the Committee on Hospital Payment endeavours to provide a clear and accurate picture of the scope of all hospital services provided in order to enable remuneration on a per case basis. The exclusion of health care services is effected by the Federal Joint Committee, in response to application made by the federal associations of the sickness funds, the German Hospitals Association or one of the federal associations of hospitals by means of an evaluation of examination and treatment methods. Health care services that are not excluded by a pertinent directive under § 137c para. 1 SGB V may be provided. More detailed information regarding the scope of services and benefits within a DRG can be obtained indirectly from the definition handbooks 1-5 belonging to the DRG system. The definition handbooks are published annually by the Institute for the Remuneration of Hospitals (InEK) and explain the assignment of case to a respective DRG, and/or explicitly specify all care procedures and treatments that may qualify for remuneration according to a certain DRG. The following elaborations are based on the definition handbooks of the German Diagnosis Related Groups, version 2004. Amendments effected in 2005 are shown in brackets.

The German DRG system is subdivided into 23 Major Diagnosis Categories, or MDCs, which refer, in principle, to a body system or a disease aetiology and are associated with a specialist field of medicine (see table 3). Treatments assigned to the MDCs 15 (newborn babies), 18 (HIV) and 21 (polytrauma) may, however, show major diagnoses that also belong to other categories. Exceptional cases are assigned, irrespective of the major diagnosis, to so-called

pre-MDCs. Such cases include long-term respiration and transplantation. Cases that cannot be grouped under a specific category are assigned to Error DRGs.

Table 3: Overview of the MDCs with the number of DRGs 2004(2005) contained

Nr.	Code	MDC	Number of G-DRGs 2004 (2005)	Nr.	Code	MDC	Number of G-DRGs 2004 (2005)
0	A	Special Cases (Pre-MDC)	37 (54)	14	O	Pregnancy and childbirth	17 (18)
01	B	Diseases and disorders of the nervous system	69 (71)	15	P	Newbornes	38 (38)
02	C	Diseases and disorders of the eye	21 (24)	16	Q	Diseases and disorders of the blood and blood forming organs	12 (9)
03	D	Diseases and disorders of the ear, nose, mouth and throat	35 (41)	17	R	Myoproliferative diseases and disorders	20 (41)
04	E	Diseases and disorders of the respiratory system	45 (49)	18 A	S	Infectious and parasitic diseases, HIV	6 (6)
05	F	Diseases and disorders of the circulatory system	91 (102)	18 B	T	Infectious and parasitic diseases	16 (15)
06	G	Diseases and disorders of the digestive system	60 (59)	19	U	Mental diseases and disorders	11 (10)
07	H	Diseases and disorders of the hepatobiliary system and pancreas	31 (33)	20	V	Alcohol/drug use and alcoholdrug use induced organic mental disorders	8 (8)
08	I	Diseases and disorders of the musculoskeletal system and connective tissue	86 (88)	21 A	W	Injuries, poisoning and toxic effects of drugs, multiple trauma	11 (10)
09	J	Diseases and disorders of the skin, subcutaneous tissue and breast	38 (41)	21 B	X	Injuries, poisoning and toxic effects of drugs	18 (14)
10	K	Endocrine, nutritional and metabolic diseases and disorders	29 (27)	22	Y	Burns	8 (8)
11	L	Diseases and disorders of the kidney and urinary tract	42 (41)	23	Z	Factors influencing health status	13 (11)
12	M	Diseases and disorders of the male reproductive system	22 (20)	◊	9	Error DRGs	7 (9)
13	N	Diseases and disorders of the female reproductive system	33 (31)			Total	824 (878)

The format of a DRG is an alphanumerical code with 4 digits. The first digit represents the major diagnosis group. The letters A- Z directly identify the major diagnosis and/or with the number 9 an Error DRG. The second and third digits are numerical and indicate the respective partition of the DRG. The partition differentiates between surgical procedures (01- 39), other procedures (40- 59) and medical (conservative) procedures (60- 99) carried out during the hospital stay. For the assignment of a treatment episode to an operative partition, at least one OR procedure must have been carried out in the OR (operating room). If no OR procedure, but at least one non-OR procedure is carried out, the hospital case is assigned to “other

procedures". If, during the period of hospital care, neither an OR procedure nor a locally significant non-OR procedure is carried out, the treatment episode is assigned to one of the medical (conservative) procedures. The codification of the procedures is effected on the basis of the Operations and Procedures Codification Index (OPS), developed by the German Institute for Medical Documentation and Information (DIMDI) and explained further below.

The combination of a letter and two numerical digits represents a so-called Basic DRG. The Basic DRGs are made up of several DRGs, which, in principle, are defined by the same list of diagnosis and procedure codes. DRGs within a Basic DRG are structured on the basis of recourse consumption and are further subdivided according to various factors, such as complicating diagnoses/ interventions, reason for release, age and/or patient clinical complexity level (PCCL). The patient clinical complexity level is the absolute measure for the cumulative effect of complications and/or co-morbidities (CCL) per treatment episode and is calculated with the help of an algorithm on the basis of the coded CCL values. This is shown in the codification of the DRGs in fourth place by the capital letters A- E and/or Z (see figure 10). These letters represent the following: A highest consumption of recourses, B second highest consumption of resources, C third highest consumption of recourses, D low consumption of recourses and/or transfer, E very low consumption of recourses and/or day-cases and Z, the determination of severity codes is not possible for the DRG.

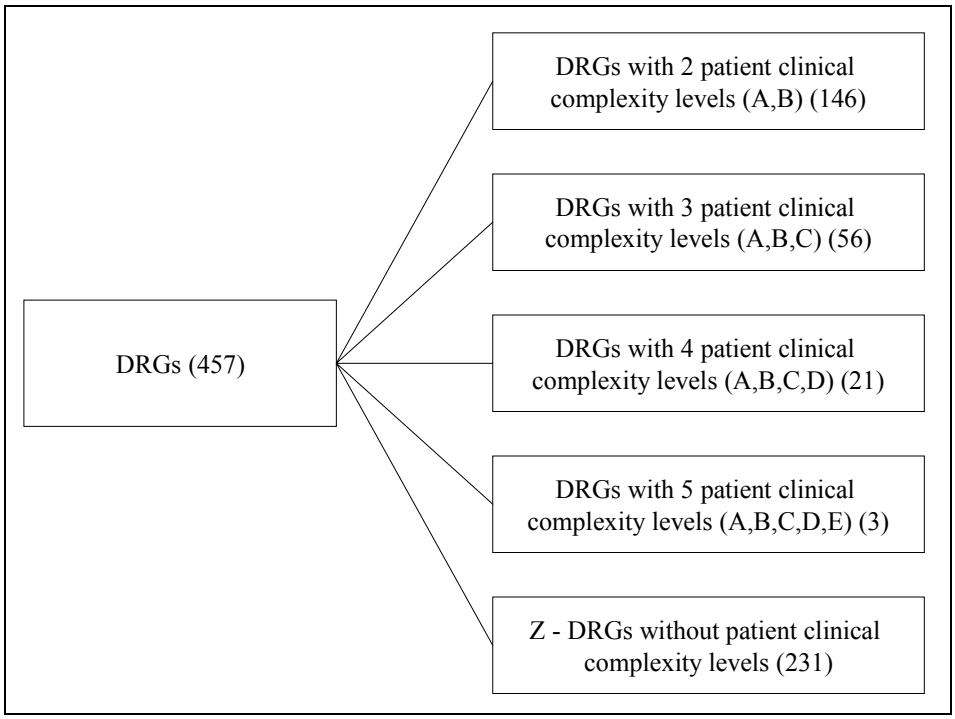


Figure 10: Partitioning of the Basic DRGs according to patient clinical complexity levels with the number of DRGs 2004.

In general, both the DRGs within a Basic DRG as well as the Basic DRGs are ordered hierarchically within the partitions “surgical procedures” and “other procedures“ on the basis of resource consumption. This hierarchical order is found again in the logical ordering of the DRG. Thus, for example, the DRG E01A signifies a higher consumption of recourses than DRG E01B, but also in relation to E02A, etc.

As an example, an excerpt is taken from the Case Fees Catalogue 2004:

B70A *Apoplexy with extremely serious CC*
B70B *Apoplexy with serious CC*
B70C *Apoplexy without extremely serious or serious CC*
B70D *Apoplexy, deceased < 4 days after admittance*
B70E *Apoplexy, one day of care*

The Basic DRG is B70. B identifies the treatment case as a patient with a disorder of the nervous system. The numerical digits 70 signify the assignment of the case to the partition „medical procedures“. The further subdivision of the Basic DRG B70 into B70A, B70B, B70C, B70D and B70E reflects the respective patient clinical complexity levels.

In addition to the number and the partition of the DRG, the tables contained in the appendix to the Case Fees Act/Agreement also indicate the clinical designation for the treatment episode as well as further specifications. For billing purposes each DRG was assigned with a DRG cost weight, an average catalogue retention period and an upper and lower limit retention period with corresponding modifications for the DRG cost weight as well as deductions in the case of a transfer of the patient.

Treatment cases are assigned to DRGs in three steps. Initially all relevant diagnoses and procedures of a hospital stay are codified according to the German modification of the international classification of diseases (ICD-10-GM and OPS). Subsequently the treatment cases are assigned to a DRG by an algorithm. A plausibility check covers the validity of the classifications assigned in respect of the calendar year, date of admittance of the patient, and verifies the concordance of the age and sex of the patient with the given diagnoses and procedures. On the level of the pre-MDC processing, cost-intensive exceptional cases are detected and a corresponding amendment is made to the MDC assignment, unless this is done on the basis of the major diagnosis itself. This is the case with MDC 15 (newborn babies), MDC 18A (HIV) and MDC 21A (polytrauma). In the third step, each treatment episode is assigned to a major diagnosis category. Thereafter the assignment of a partition and of the patient clinical complexity level is effected in the manner already explained above.

The actual assignment to a DRG is effected via the procedures code of the respective service in the OPS. The German Operations and Procedures Code (OPS) goes back on the 'International Procedure of Medicine' of the WHO in 1978. It attempts to show all services in health care that can be provided on the highest level of aggregation. Not every service provided by hand can be coded, but to this end, the OPS is subject to continuous development by the German Institute for Medical Documentation and Information (DIMDI). In this process the DIMDI receives advice from the Federal Board for Questions Relating to the Classification of Health Care Services comprising 4 representatives of the federal associations of the sickness funds and one representative from the German Hospitals Association, the Federal Board of Physicians, the Federal Association of SHI Physicians, the Working Committee of the Specialised Medical Scientific Institutions, the Federal Association of Statutory Accident Insurance, the Association of German Retirement Insurers, the Institute for the Remuneration of Hospitals, the Federal Office for Quality Assurance plc. and the Associations of the Private Health Insurers. The inclusion of new health care services in the OPS classification system is effected at the beginning of each year. Amendment proposals, however, must be submitted at least nine months before.

The OPS is basically is divided into five Chapters:

- Chapter 1: diagnostic procedures (for example biobsy, examinations with catheters, endoscopy),
- Chapter 3: diagnostic imaging (for example computer tomography, magnetic resonance imaging),
- Chapter 5: surgical procedures (surgery, mostly conducted in operating rooms),
- Chapter 8: non-surgical procedures (for example nuclear medicine) and
- Chapter 9: other procedures (for example psychotherapy, procedures relating to childbirth)

Within chapter 5, containing more than 80% of all procedures, the procedures are ordered anatomically. Therefore, services provided by different medical specialist are found in each organ subchapter. The procedures of the chapters 1, 3, 8 and 9 are ordered according to medical treatments.

An entity within the OPS generally possesses a five digit code structure (A – BBB.C). The first digit (A) is determined by the chapter that contains the procedure. The digits two, three and four (BBB) specify the kind of procedure and the organ or the part of the body the procedure is employed. The last digit (C) further specifies the instances of the procedure. C can be a numbers or a letter. If the instances of a procedure are not specified in the OPS but

known, the digit C will be coded as ’x’. If the instances are not known (for example if information was lost and circumstances can not be identified) C is coded as ‘y’. A sixth digit is added to the code if a procedure can be performed twice on the same part of the body (eyes, ears, kidneys, etc.). ‘R’ stands for right, ‘L’ for left and ‘B’ for a procedure that has been provided ambilateral.

As an example 5-183.0L is described in detail:

‘5’ stands for a procedure from the chapter 5 ‘surgical procedures’.

‘18’ stands for a surgical procedure performed at the ears

‘183’ stands for a surgical procedure performed at the appearance of the ears

‘183.0’ stands for a surgical dressing that has been provided at the appearance of the ears

‘L’ stands for the left ear.

Next to the procedure code, the entity is named and very close related work steps, that are included in the procedure code, are described. Work steps that are close related to the procedure, but covered by a different procedure or are an own procedure are listed with their code. Sometimes references to other related procedures are made additionally.

To display a hospital treatment all procedures performed, need to be coded according to OPS. Sometimes the treatment of an illness can be displayed by two codes, sometimes a lot of procedures need to be coded to display the services provided during the hospital treatment. The grouper software will, however, as explained above, check the coded procedures according to OPS and the coded diagnosis according to ICD-10-GM for plausibility and assign the corresponding DRG to the case.

Therefore a DRG serves as the description of all health care services provided in respect of medical diagnoses or procedures during hospital stay and is the basis for remuneration from the Statutory Health Insurance. It is also used to proof the quality of care delivered to the patients. In this way, the DRG system is designed as a price system, which exactly describes the products to be evaluated in order to enable commensurate remuneration. The procedure for assigning a specific type of care to a particular DRG is shown in figure 11.

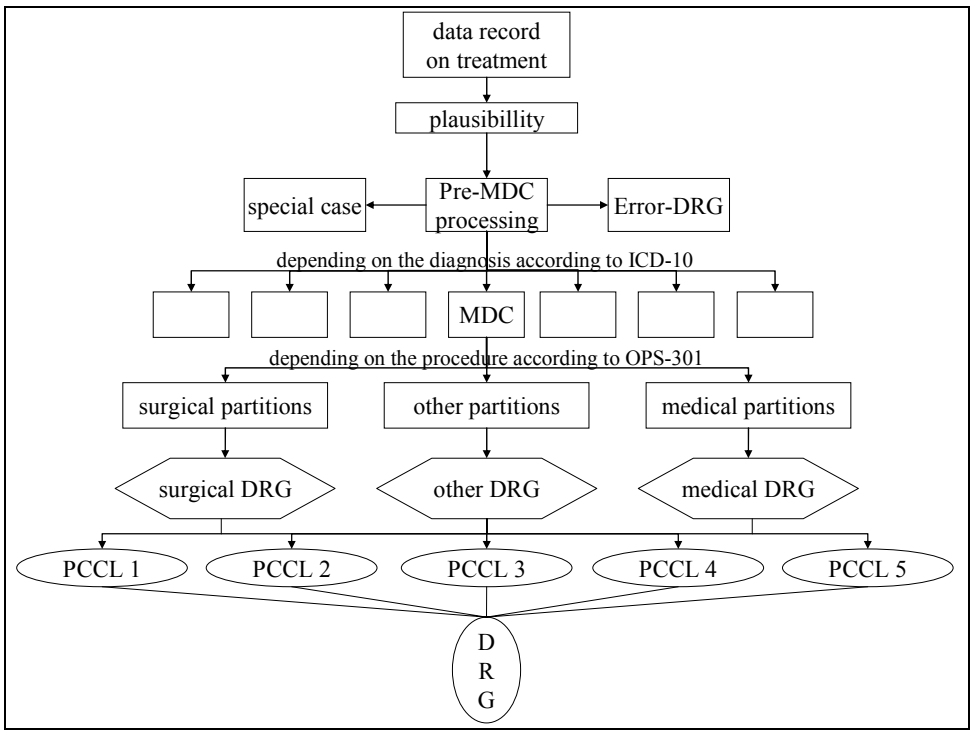


Figure 11: Composition and assignment algorithms of the German DRGs.

Due to insufficient data being available for the calculation of the DRG cost weight, 26 extra remunerations and 18 services, paid for but not listed in the Case Fees Catalogue had to be defined in 2004. The remunerations have to be agreed upon as fixed payments or daily care rates with each individual hospital concerned, in accordance with § 6 para. 1 Hospital Payment Act. In the year 2005 there will be 71 extra remunerations and 33 health care services, paid for, but not covered by the Case Fees Catalogue.

Health care services, paid for, but not covered by the Case Fees Catalogue, are for example, transplantations of intestinal or pancreatic tissue, the treatment of acute diseases and injuries to the bone marrow, tuberculosis, sex-change operations and serious burns. For these diagnoses and procedures DRGs were defined, but the number of cases was not sufficient to assign a DRG cost weight, an average retention period or a lower und upper retention period limit with the corresponding modifications of the DRG cost weight, since the treatments are rare diseases or highly specialised treatments.

Since the first Case Fees Amendment Act from 2003, health care services for early rehabilitation have been explicitly included in the hospital care services. Thus the Case Fees Catalogue 2004 contains a total of 21 early rehabilitation DRGs. Of these, 17 DRGs are contained within six major diagnosis categories (MDC 01 (3), 04 (1), 05 (1), 06 (1), 08 (9); 10 (2)), whereas four DRGs are extra remunerations to be negotiated in accordance with § 6 para. 1 Hospital Payment Act (KHEntgG). In the Case Fees Catalogue 2005, there are 24 early rehabilitation DRGs in eight major diagnosis categories (pre-MDC (1), MDC 01 (6), 04 (2),

05 (3), 06 (3), 08 (3); 10 (3); 21A (3)). The DRGs are coupled with the procedures code of the rehabilitative care packages. This code is divided into two sub-codes, the geriatric early rehabilitative care packages and the actual early rehabilitation. In the explanations to the codes, the required minimum characteristics of the care are explicitly specified. This includes a standardised procedure for geriatric assessment, covering at least five areas (state of consciousness, communication, mobility, capability for self-help, cognition, emotion, behaviour, social care), a written treatment plan, up-dated weekly, therapeutic care by qualified personnel, skilled in early rehabilitative care and the engagement of therapists from at least four different fields (physiotherapy, logaoedics, occupational therapy, swallow therapy, physical therapy, neuropsychology, music therapy, art therapy and psychotherapy).

B. Uniform Value Scale (EBM) (HC.1.3.1 and HC.1.3.3)

The explicit definition of inpatient medical care services is effected on the basis of the Uniform Value Scale (EBM). The EBM is laid down by the Evaluation Committee, consisting of the 7 members of the Federal Association of SHI Physicians and the 7 representatives of the federal associations of the sickness funds (§ 87 para. 1 and para. 3), and/or, if these fail to reach consensus, by the Extended Evaluation Committee (§ 87 para. 4 and para. 5). The Extended Evaluation Committee can be brought into action at the request of at least two members of the Evaluation Committee. To this end, the Evaluation Committee is complemented by four independent members and one independent chairman. Two of the independent members are nominated by the sickness funds and two by the physicians. To appoint the chairman of the Extended Evaluation Committee, which decides on the basis of a simple majority, the institutions involved must reach common consensus. The described version of the so-called EBM 2000Plus was presented on April 14, 2004, passed with minor amendments on May 14, 2004 and came into force on April 1, 2005.

The EBM is not a SHI benefit catalogue in the true sense. However, it contains the conditions under which the provision of basic medical outpatient care is a benefit of the Statutory Health Insurance. The EBM is basically a reimbursement catalogue that lists diagnostic and therapeutic health care services. To each service a five-digit reimbursement or service code and a points value is assigned. The individual health care services or care packages listed contain obligatory service contents, but also optional services. At certain time intervals, the descriptions and the corresponding points value are examined and brought up to date with the current medical and technical state-of-the-art.

The regulation of access to interventions and technologies in the ambulatory sector is delegated to the Federal Joint Committee and its Committee on Ambulatory Care. This

Committee has several sub-committees, one of which is responsible for assessing reimbursable medical technologies. New technologies can only be proposed when they were perceived to be "necessary" from a physician's point of view and when enough data were available for their evaluation. The right to propose was confined to the regional physicians' associations, the Federal Association of SHI Physicians and the federal associations of sickness funds.

The Sub-Committee on Medical Procedures of the Federal Joint Committee now performs an explicit prioritization of technologies to be evaluated. The results are announced publicly and medical associations and possibly individual experts are invited to submit evidence concerning the three mentioned criteria. The Sub-Committee then examines the quality of the evidence presented by the applicant, the medical association(s) and individual experts as well as the results of its own (literature) searches.

Based on the more or less evidence-based assessment, the Federal Joint Committee's Sub-Committee on Medical Procedures recommends whether the technology should be included in the SHI benefit package. In addition, its predecessor took another type of decision in 2001, when it concluded that evidence for the efficacy, safety and everyday effectiveness of acupuncture was not sufficient to decide on SHI coverage, but that a comprehensive evaluation of these in relation to chronic low back pain, chronic headache and chronic painful arthrosis of large joints was required. While SHI may not finance clinical efficacy research, many sickness funds consecutively launched three major acupuncture pilot projects to evaluate the three indications on an ongoing basis.

Once a positive decision has been taken to include a technology into the benefit catalogue of ambulatory physician care the Valuation Committee determines reimbursement issues and requirements for physicians who want to claim reimbursement for the delivery of this technology from Statutory Health Insurance. Thus the benefit is included into the EBM.

The EBM is composed of 518 pages and is subdivided into 6 main chapters (see figure 12):

- Chapter I, with 7 sub-chapters, comprises general regulations regarding the provision and reimbursement of health care services.
- Chapter II comprises general health care services which can be provided and accounted for by every SHI physician.
- Chapter III contains health care services relating to specific physician groups, which may only be provided by those physicians specified in the relevant chapter. A differentiation is made between services provided by general practitioners (III.a) and medical specialists (III.b).

- Chapter IV contains special health care services that are not related to specific physician groups but to special criteria be provided.
- Chapter V contains only one sub-chapter with 75 case fees for material costs (e.g. mailing material, x-ray contrastive agents, etc.) with billing codes and the case fee in Euro.
- Chapter VI contains the appendices to the EBM with a 4-page sub-chapter, in which individual health care services are contained without reimbursement code and points value.

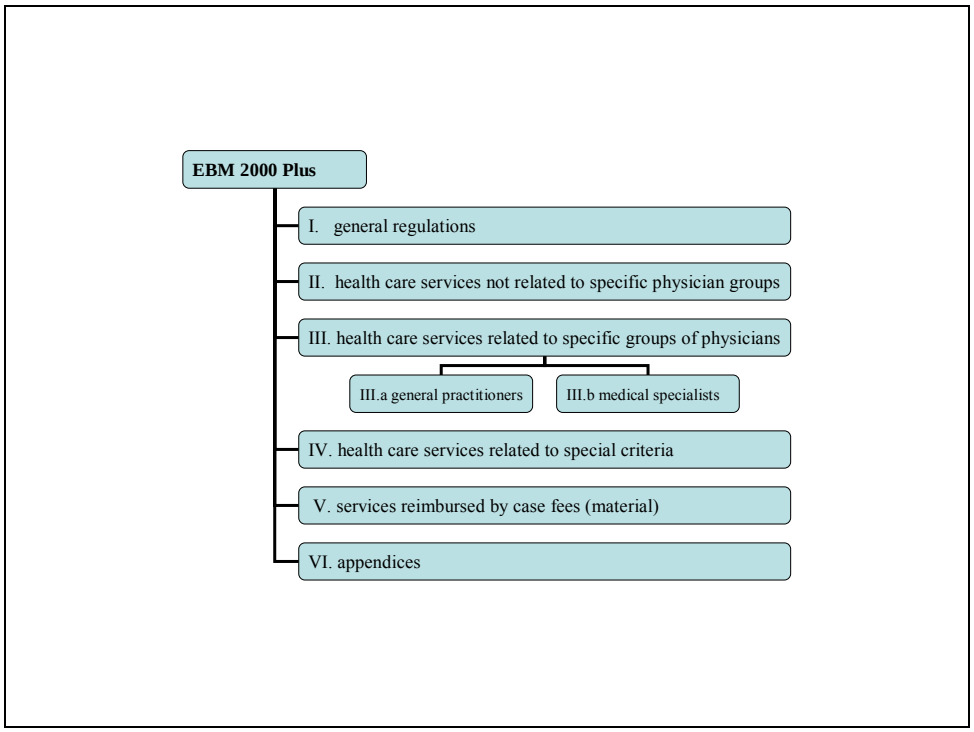


Figure 12: Overview of the chapters of the Uniform Value Scale (EBM).

The main chapters are further subdivided into sub-chapters. As from chapter II, the sub-chapters are numbered in ascending order, i.e. the first sub-chapter in chapter III does not begin with number 1, but with number 3. After chapter III.b, however, this system is interrupted. chapter III.b ends with the sub-chapter number 27. Chapter IV begins, however, with the sub-chapter 30 and ends with the sub-chapter number 35. The only sub-chapter of chapters V bears the number 40. In order to facilitate understanding of the system of subdividing the chapters down to the level of the individual service, which, in part, is not effected until after the fourth level of sub-chapters, chapter II, chapter III and chapter IV of the Uniform Value Scale (EBM) shall be explained in detail.

Chapter II “health care services not related to specific physician groups” is initially subdivided into the sub-chapters 1 “General health care services” and 2 “General diagnostic and therapeutic health care services” (see figure 13). The sub-chapter II 1 is subdivided into 8

further sub-chapters, one of which regulates the "Special claims on the services of the SHI physician". Here, for example – according to the time of day – the "Emergency health care services" are assigned with different weightings. In sub-chapter II 2, which contains 5 further sub-chapters, health care services such as infusions, transfusions, H2-breath tests, minor surgical health care services or physical-therapeutic health care services are contained. Some of the health care services listed here may only be provided, however, by specialist physician groups with the relevant qualifications.

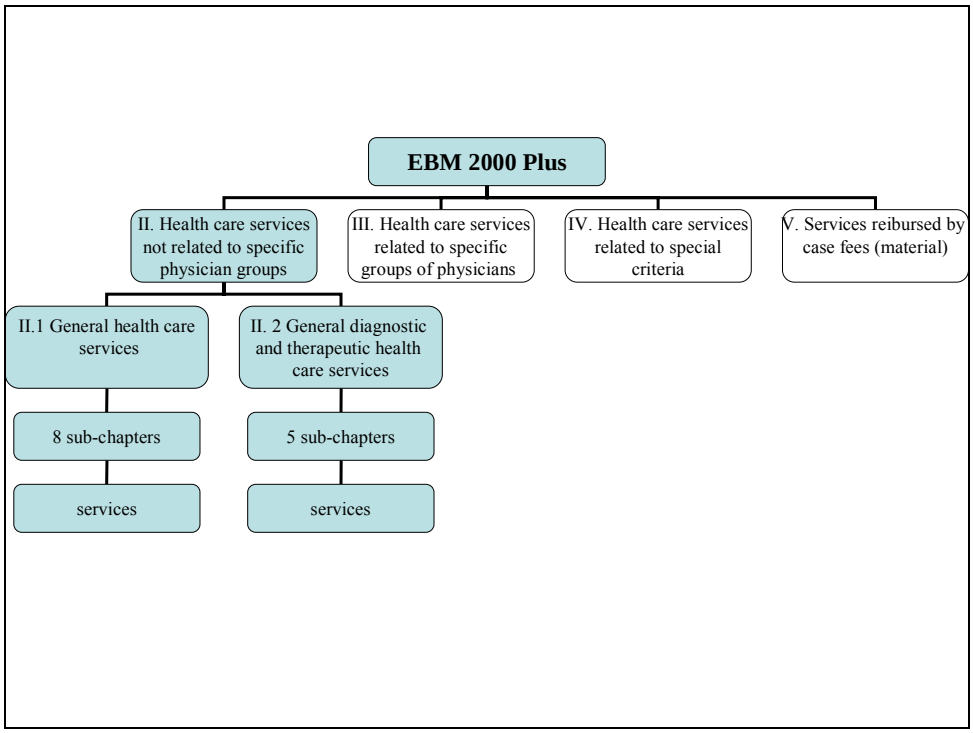


Figure 13: Overview of chapter II of the Uniform Value Scale (EBM).

Chapter III lists the "Health care services related to specific physician groups". It is subdivided into two care areas, "General Practitioners" (III.a) and "Medical Specialists" (III.b). On the level of the areas of care, but not until then, further subdivisions are made. In the scope of III.a differentiation is made between "GP care" (III.a 3) and "GP care for Children and Young People" (III.a 4). In the sub-chapter III.a 3, further differentiation is made between "Structural Services" (III.a 3.2) and "General Services" (III.a 3.3). Under "General Services" a final subdivision is effected into "Basic Services" (III.a 3.3.1), "Nursing Services" (III.a 3.3.2) and "Diagnostic and Therapeutic Services" (III.a 3.3.3). Then, on the next level, but not before, the individual services are assigned to the sub-chapters. All in all, in chapter III.a 3 "GP care", there are 29 reimbursement codes for the different services (see figure 14). Chapter III.a 4 "GP care for Children and Young People", with a total of 34 reibursement codes is subdivided similarly.

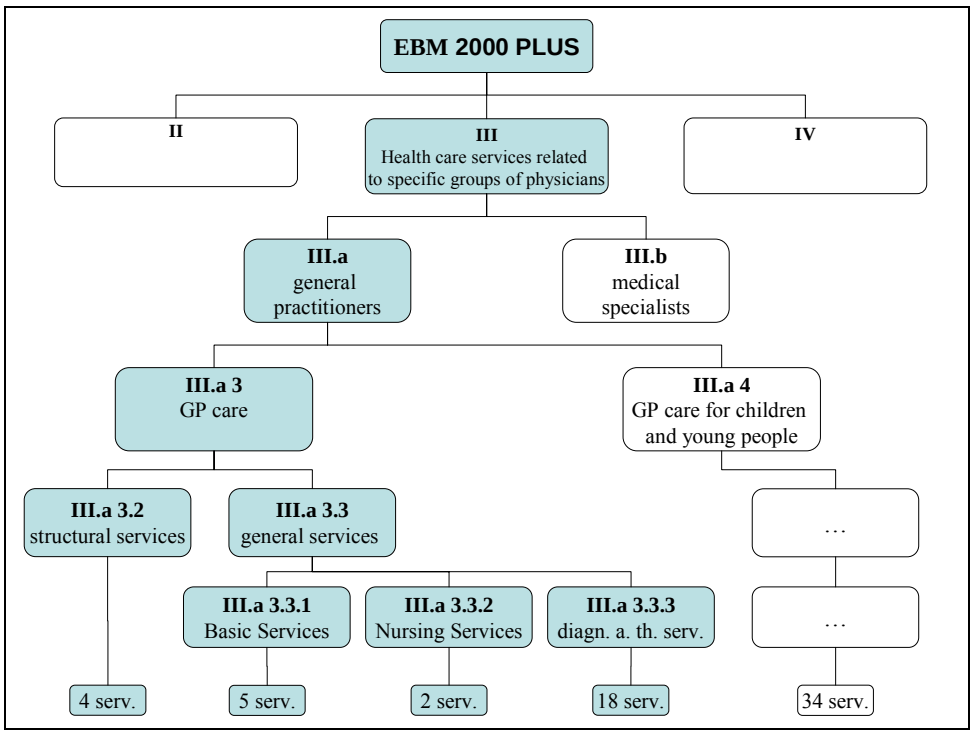


Figure 14: Chapter III.a 3 of the Uniform Value Scale (EBM).

Section III.b "Medical Specialists" is composed of a total of 153 pages and assigns specific reimbursement codes to 23 different groups of specialised physicians (see table 4).

Table 4: Different groups of specialised physicians in chapter III.b

Facharztgebiet	**Kapitel-nummer**	**Facharztgebiet**	**Kapitel-nummer**
Anaesthesiological services	5	Services in nuclear medicine	17
Ophtalmological services	6	Orthopedical services	18
Services in general surgery, paediatric surgery, plastic surgery and heart surgery	7	Services in pathology	19
Services in gynecology, obstetrics and reproductive medicine	8	Phoniatrics and child audiology	20
Otorhinolaryngological services	9	Psychological and psychotherapeutical services	21
Dermatological services	10	Psychotherapeutic medicine	22
Humangenetische Leistungen Services in human genetics	11	Psychotherapy-based services	23
Services in clinical pathology	12	Radiological services	24
Services in internal medicine	13	Radiotherapeutic services	25
Services in child psychiatry and child psychotherapy	14	Urological services	26
Services in oral and maxillofacial surgery	15	Physiotherapeutic and rehabilitation medicine	27
Neurological and neurosurgical services	16		

As an example of the subdivision of the chapter on medical specialists, figure 15 shows in detail the health care services provided by eye specialists (III.b 6). The sub-chapter of medical specialists is normally subdivided into the "Preamble" (III.b 6.1), "Basic Services" (III.b 6.2)

and “Diagnostic and Therapeutic Services” (III.b 6.3). Only the specialist fields “Internal Medicine” (III.b 13), “Medical Care for Women, Obstetretics and Reproductive Medicine” (III.b 8) and “Radiation Therapy” (III.b 23) are more specifically subdivided.

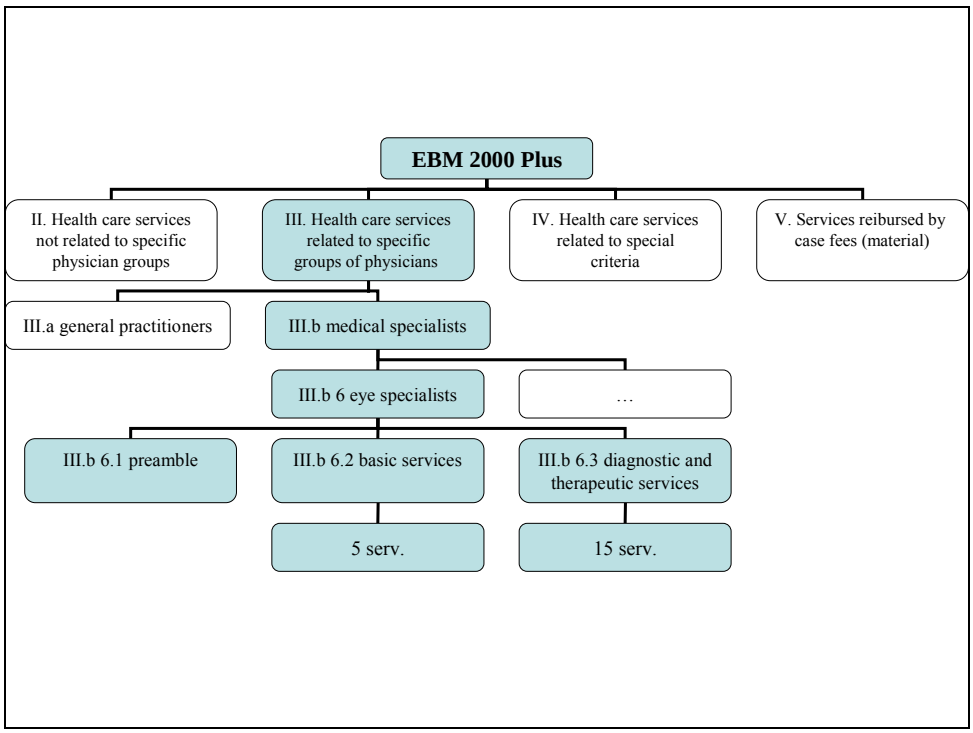


Figure 15: Subdivision of the chapter on medical specialists in (III.b) of the Uniform Value Scale (EBM) by the example of eye specialists.

Chapter IV, “Health Care Services related to special criteria” is subdivided into six sub-chapters (see figure 16):

- 30 special areas of care (8 sub-chapters, e.g. osteopathy, allergology and socio-therapy)
- 31 outpatient and day cases of surgical operation services and conservative surgical orthopaedics (5 sub-chapters, e.g. pre-operative examination complexes and post-operative care complexes)
- 32 laboratory medicine, molecular genetics and molecular pathology (3 sub-chapters: Basic services, general laboratory examinations, special laboratory examinations)
- 33 ultrasonic diagnostics (no further subdivisions, 36 individual services)
- 34 diagnostic and interventional radiology, computer tomography and magnetic resonance tomography (5 sub-chapters, e.g. osteodensitometry)
- 35 health care services in accordance with the Psychotherapy Directive.

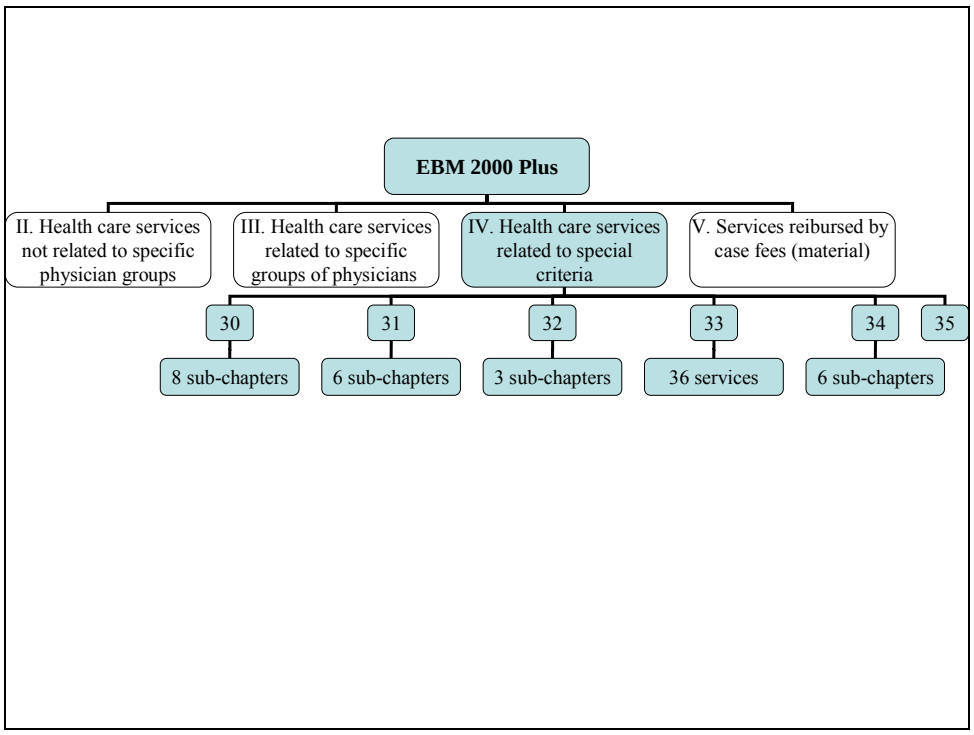


Figure 16: Overview of chapter IV of the Uniform Value Scale (EBM).

Outpatient surgery or day cases of care (IV 31) may also be performed in hospitals in accordance with § 115b SGB V. To this end, since 1st January, 2004, there has been a three-sided contract between the federal associations of the sickness funds, the German Hospital Association and the Federal Association of SHI Physicians, which regulates the conditions under which these services – although belonging to the outpatient sector – may be provided in hospitals. This contract contains an appendice with a 23-page catalogue that specifies in detail the respective interventions in accordance with § 115b SGB V. This, however, does not constitute another benefit catalogue, because the services are listed within the EBM.

C. Uniform Value Scale for Dentists (BEMA) (HC.1.3.2)

While the directives of the Federal Joint Committee broadly define when the patient is entitled to a benefit, they do not define the benefit catalogue explicitly. Therefore the Dental Valuation Committee with 7 members of the federal associations of sickness funds and 7 members of the Federal Association of SHI Dentists defines the Uniform Value Scale for Dentists (BEMA) (§ 87 para. 1 and para. 3). The BEMA lists services that are reimbursed by the sickness funds and thus implies a definition of the SHI benefit catalogue. It is a fee schedule for dental treatments, but it also contains detailed instructions for each service. Possible findings to be reported are listed. Restrictions in the frequency of provision or in the combination of services with each other are defined. As the BEMA has been set up with adherence to the directives of the Federal Joint Committee, the dentists act according to the

directives and the SGB V when choosing their treatments from the BEMA. If the Valuation Committee does agree on the BEMA, the Extended Valuation Committee decides.

Compared to the EBM, the BEMA is much smaller. It is divided into 5 basic categories of services only:

1) teeth preserving services, surgical services and x-ray diagnosis
   (Most of the 62 services listed are used for diagnosis or for prophylactic treatments. Therefore services in this category will be provided by all dentists. Eight services are subdivided due to a different number of pictures taken (x-ray) or different methods of the same treatment applied.)
2) services for jaw fractures and disorders of the temporo-mandibular joint
   (The 10 services cover procedures for treatment and procedures for aftercare. One service is subdivided.)
3) orthodontic services
   (The 27 services cover the planning of the treatment and the procedures of the treatments itself. Three services are subdivided due to different levels of severity.)
4) periodontal services
   (The 7 services cover the procedures of periodontal treatments within the SHI benefit catalogue. These services are only reimbursable for patients with a Periodontal Screening Index (PSI) of 3 and 4 or if the depth of the gum pockets around the teeth is more than 3.5 mm.)
5) prosthetic services
   (The 31 services cover all procedures for prosthetic treatments. 11 are subdivided due to different levels of severity or due to different methods of treatment applied.)

The BEMA had multiple predecessors and thus merged multiple enumerating systems. Basically each service is labelled with a number or with a combination of numbers and letters. Some services even have an additional abbreviation in adherence with its corresponding name. For example, Service ‘Ä1’ in category one is followed by service ‘01’, service ‘01k’ and service ‘02’. There is another service labelled ‘2’ and a service labelled ‘K2’ in category two, again. Others services are subdivided with ‘a’, ‘b’ and ‘c’ due to different levels of severity. The combination of numbers and letters does therefore not always follow a systematic approach, although numbers are mostly increased by one from a service to another. Additionally each service is assigned a point value for reimbursement reasons. It reflects the labour and resource consumption by the provision of the service. It does not include costs for

pharmaceuticals, one-off costs for handed over appliances and the costs of material supplied by dental technicians.

The BEMA and its structure are visualized figure 17. As an example category four (periodontal services) is dealt with more explicitly. It contains 7 services for periodontal treatments. The first service, labelled "4", consists of a periodontal examination and the preparation of a cost schedule. The services 'P200', 'P201', 'P202' and 'P203' contain the cleaning of the gum pockets around the teeth from inflamed tissue or foreign material (curettage). When providing service 'P200' or service 'P201', a non-invasive treatment method is used for the cleaning of the gum pockets. The two services each contain the same treatment, but they differ in the point value assigned to them. Service 'P200' is accounted for when cleaning a one rooted tooth, while service 'P201' is accounted for when cleaning a multiple rooted tooth. Services "P202" and "P203" are accounted for an invasive treatment to clean the gum pockets. The next service, service '108', is provided when teeth are uneven or a single tooth protrudes. The grinding-in treatment of service '108' is to improve the occlusion. The last service available for SHI patients in this category is described as an aftercare treatment. This includes the examination of the outcomes and, for example advice on future dental hygiene.

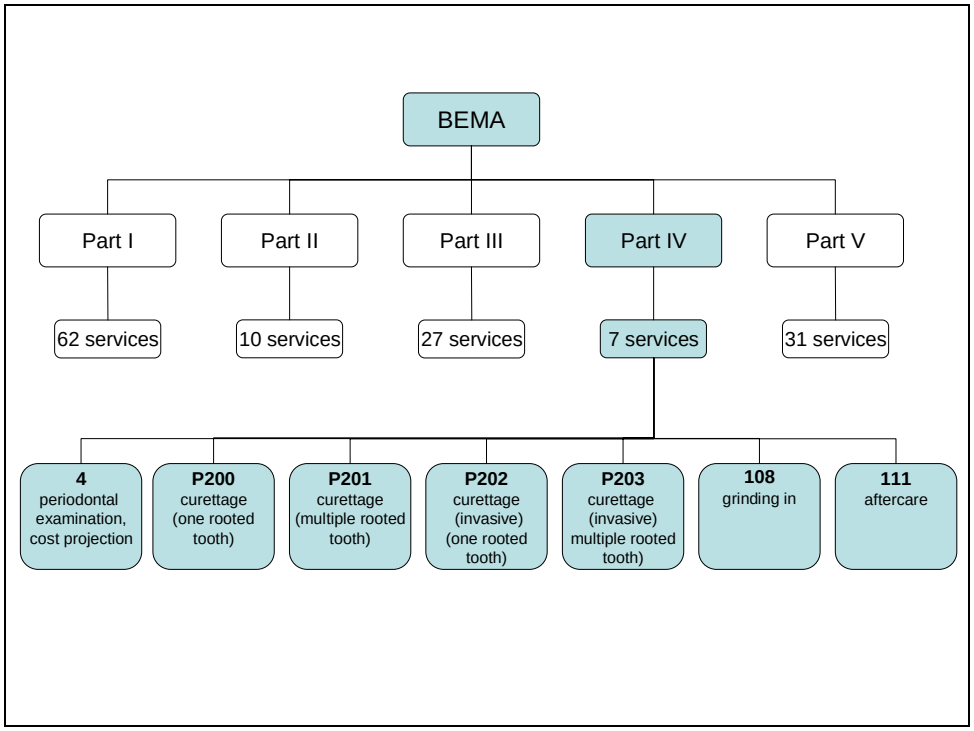


Figure 17: Structure of the BEMA, especially category four (periodontal services).

In addition to the five categories of the BEMA described above, an initial section defines conditions for the reimbursement of services not listed in the catalogue that are nonetheless

covered by the sickness funds. For these minor exemptions it is referred to the governmental reimbursement schedule from 1982, the Catalogue of Tariffs for Physicians (GOÄ).

D. Uniform Value Scale for Dental Technicians (BEL-II) (HC.1.3.2)

The services of a dental technician are listed in a similar framework, the Uniform Value Scale for Dental Technicians (BEL-II). The content of the BEL-II is negotiated in the Dental Valuation Committee between the Federal Association of Sickness Funds and the Federal Association of SHI Dentists. The Federal Guild of Dental Technicians is allowed to express its concerns at hearings, but is not further involved in the decision making.

While the BEMA assigned a point value to each service, the BEL-II includes maximum prices for its services. The maximum prices are negotiated at the Länder level between the sickness funds and the regional guild of dental technicians. For taxation reasons, they differ for commercial dental laboratories and dental laboratories belonging to the dentists by five percent. This is due to the fact that commercial laboratories pay excise taxes, while dentists do not.

In the BEL-II the services are labelled with a 4-digit-code. The first number is due to the category, the second and the third number are given due to the subcategory and the fourth is attributed directly to the individual service. The BEL-II is divided into 8 basic categories (see figure 18):

0) preparations
   (The 16 subcategories with its 19 services cover the production of an impression.)
1) fixed prosthetics
   (The 19 subcategories and its 33 services cover the production of crowns and bridges.)
2) removable prosthetics (permanent)
   (The 9 subcategories and its 28 services cover the production of a permanent removable prosthetic and its brackets.)
3) removable prosthetics (provisional)
   (The 11 subcategories and its 20 services cover the production of a provisional removable prosthetic and its brackets.)
4) occlusion appliances
   (The 5 subcategories and its 9 services cover different sorts of occlusion appliances.)
7) orthodontics
   (The 26 subcategories with one service each cover basically parts that are needed to produce braces or other orthodontic appliances.)

8) enhancement and repair

   (The 12 subcategories with its 18 services cover the repair of broken parts or the enhancement of an appliance.)

9) shipping and handling costs / metal surcharge

   (There are only 2 subcategories with one service each. The metal surcharge is granted for additional efforts with non-metal compositions.)

Categories 5 and 6 are left empty for future classifications and are thus not in use today. It is planned that category 5 will be used for implantable prosthetics, but the self-governmental institutions have not finished the decision-making on this issue yet.

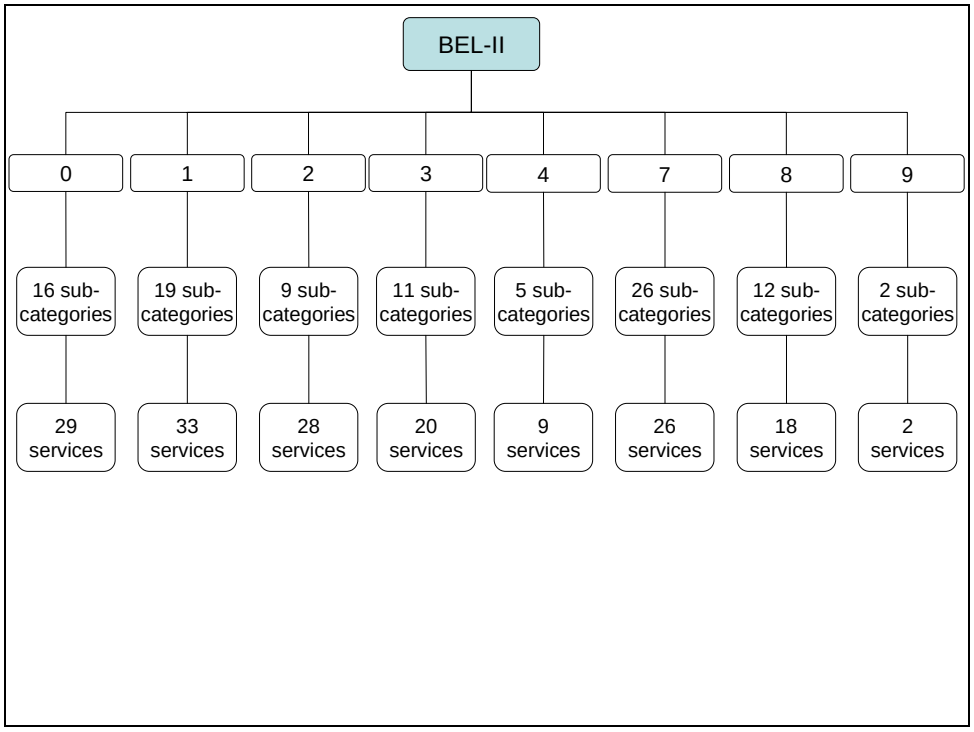


Figure 18: The structure of the BEL-II.

Category 4, occlusion appliances, is displayed in detail in figure 19. Occlusion appliances are used to prevent the clenching or grinding of the teeth at night (bruxism) or to improve the occlusion by changing position of the teeth. The category is divided into 5 subcategories: subcategory 401 for appliances with an adjusted surface, subcategory 402 for appliances without an adjusted surface, subcategory 403 for a rework of a prosthetic to an occlusion appliance, subcategory 404 for synthetic braces and subcategory 406 for metal braces. Each of the subcategories contains one or multiple services. For example the subcategory 401, appliance with an adjusted surface, contains three services: service 4011 ‘acrylic byte guard’, service 4012 ‘grinding appliance’ and service 4013 ‘occlusion plate’.

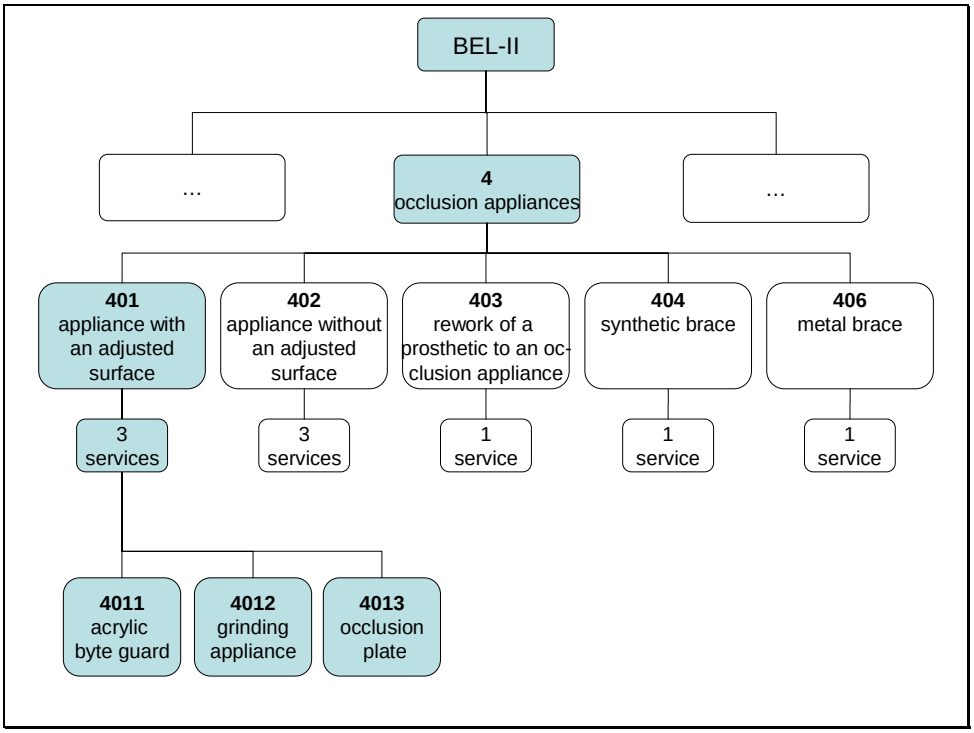


Figure 19: BEL-II, category 4, occlusion appliances.

E. Directive on Care by Non-physicians (HC.1.3.9)

The Directive on Care by Non-physicians of the Federal Joint Committee, last amended on 1st July, 2004, came into force on 1st July, 2001. It regulates the prescription of cures under the SHI. The cures listed in the directive in connection with the stipulated indications are services and benefits of the Statutory Health Insurance. New cures and/or the extension of the indications for a cure may only be prescribed after the Federal Joint Committee has recognised their therapeutic value and included them into the directive. The procedures necessary for the inclusion of new cures and/or indications is described in another directive, the Directive for the Evaluation of Medical Examinations and Treatment Methods.

The Directive on Care by Non-physicians is divided into two parts. The first part (sections I – X) contains general principles, for example, the admission of health cure providers, the principles of the prescription of cures and the cures themselves. In the section III-V of the first part all prescribable cures are specified. The subdivision is effected in four groups: III A Physical therapy, III B Podological therapy (only in the case of diabetic foot syndrome), IV Voice, language and speech therapy and V occupational therapy. The execution of the individual therapy methods is described and the medical diagnoses required for initial and subsequent prescription are specified.

As an example, the Physical Therapy measures (III A) are shown in detail. Here, a distinction is made between seven forms of therapy (see figure 20):

- Massage therapy (Distinction is made between seven types of massage: classical massage therapy, massage of the connective tissue, segmental massage, periostic massage, massage of the colon, under-water pressure-jet massage and manual lymph drainage. In the case of manual lymph drainage 30, 45 and 60 minutes may be prescribed depending on the degree of severity.)
- Exercise therapy (Seven therapy methods are distinguished: exercise treatment, chirogymnastics, physiotherapy, apparatus-assisted physiotherapy, CNS physiotherapy for children, CNS physiotherapy and manual therapy.)
- Traction treatment
- Electrotherapy/-Stimulation
- Aerated baths and carbon gas baths
- Inhalation therapy
- Thermotherapy (Here, 6 procedures using different therapeutic appliances are distinguished)

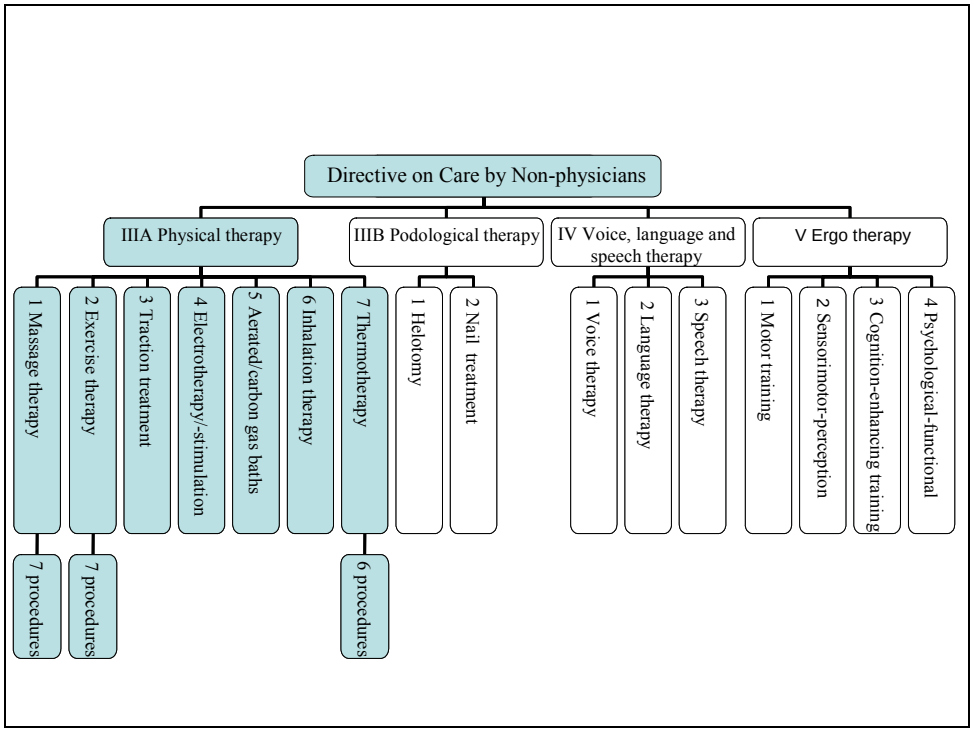


Figure 20: Directive on Care by Non-physicians, part 1, Section IIIa-V.

In the second part, in the so-called Catalogue of Care by Non-physicians, the cures are assigned to diagnoses and/or diagnosis groups in accordance with § 92 para. 6 SGB V. The indication for the prescription of a cure is specified not only on the basis of diagnosis, but also in respect of the degree of health damage, functional disorder and/or impairment of the faculties. The choice of a cure shall be made in accordance with the primary aim of the treatment and is divided into four categories A – D: A. high priority, B. optional, C.

complementary and D. standardised cure combinations. All indications and cures prescribable in the regular case are specified in a table. The regular case is conceived in the manner that, by means of the overall combination of the prescribed cures indicated for a respective diagnosis, the aim of the therapy can be achieved. It is pointed out, however, that the overall composition of the cures prescribed shall be in line with the requirements of the individual case, since the maximum prescribable composition is not always necessary. A new regular case, in the event of a recurrent or a new phase of a disease, only arises after an interval of at least twelve months without treatment. The prescription of longer cures requires special justification and the approval of the respective sickness fund.

The Catalogue of Care by Non-physicians is subdivided into four chapter in accordance with the above mentioned therapy groups. Within these chapters divisions are made for the various diseased organ systems. The lowest level is composed of the diagnosis or diagnosis groups. According to the type of health damage or the functional disorder the prescribable cures are then assigned to the categories A to D and possible cure combinations are specified. The structure of the categories is shown in figure 21.

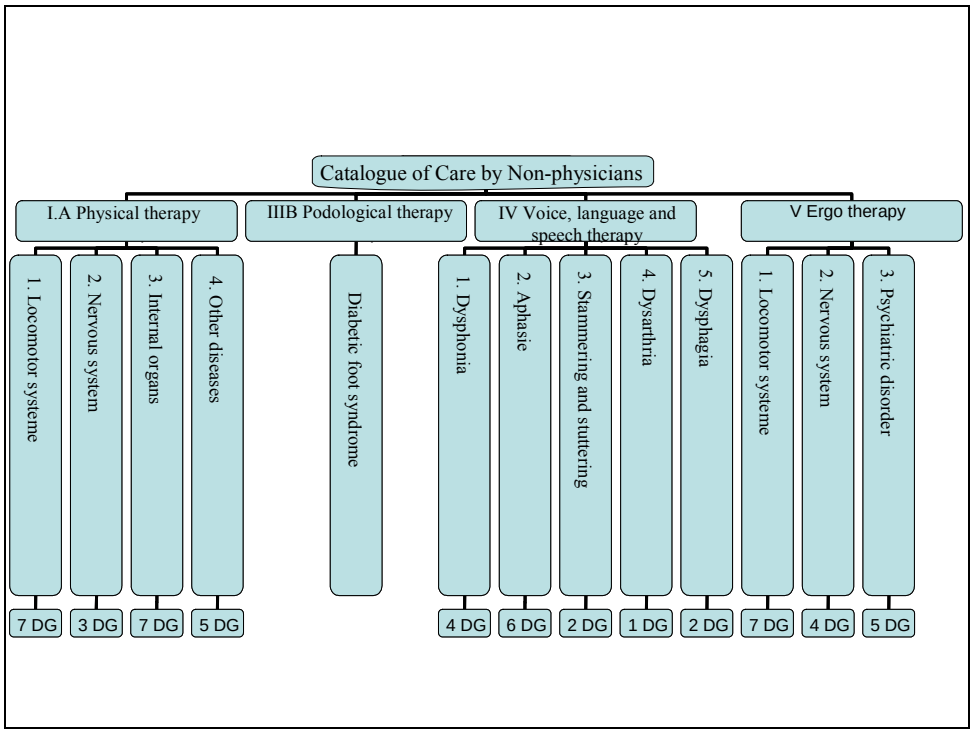


Figure 21: Catalogue of Care by Non-physicians, DG=diagnosis group.

The appendix to the Directive on Care by Non-physicians specifies cures that are not considered useful according to the Directive for the Evaluation of Medical Examinations and Treatment methods. Furthermore, certain cures are assigned to personal lifestyle. Thus, the appendix constitutes a list of non-prescribable cures (negative list).

F. Directive on OTCs (HC.5.1.2)

The definition of OTCs that are exceptionally a SHI benefit is a part of the Directive on the Provision of Pharmaceutical Care of the Federal Joint Committee. The directive was adopted on the 31st August, 1993 and was modified at last on the 16th November, 2004. Besides general rules for the provision of pharmaceutical care, it provides in part F a list of 41 active ingredients linked to a certain indication for that they are therapy standard (for example acetylsalicylic acid for the after-treatment of stokes or quinine for the treatment of malaria). The ingredients are listed in alphabetic order. Only if the OTC is prescribed for that purpose, it is reimbursed by the sickness funds.

G. Directive on Medical Aids (HC.5.2)

The prescription of therapeutic appliances under the SHI is regulated by the Directive on Medical Aids issued by the Federal Joint Committee (in accordance with § 92 SGB V). The currently valid version, last amended on 1st December, 2004, came into force on 17th June, 1992. In addition to the definition of the term therapeutic appliances contained in the introduction, the directive contains information in respect of prescription principles and medical information to be provided to the patient. The entitlements to seeing and hearing aids are specified by certain indications in accordance with § 33 SGB V. This is explained by the desire to distinguish necessary therapeutic appliances from objects of normal use.

The Directive on Medical Aids furthermore contains instructions regarding the conditions for the prescription of therapeutic appliances and the Catalogue of Medical Aids. According the directive itself (No. 8.1) only those therapeutic appliances may be prescribed at the expense of the sickness funds that are included in the catalogue. However, the Federal Social Court, in its decision dated 31st August, 2000 (B 3 KR 21/99R) expressed a different view. He argues that the Catalogue of Medical Aids is merely a guideline, i.e. that the physician might also prescribe therapeutic appliances that are not listed in the catalogue. However, since the Catalogue of Medical Aids is part of the Directive on Medical Aids and is passed by the Federal Joint Committee, the SHI physician must assume a generally normative significance of the directive in accordance with § 92 SGB V. The SHI physician will therefore have to prescribe the therapeutic appliances specified in the catalogue despite the decision of the court.

The Directive on Medical Aids accordingly constitutes a written, explicit catalogue of services and benefits of the SHI. The catalogue is jointly compiled and further developed by the federal associations of the sickness funds. The conditions for the inclusion and exclusion

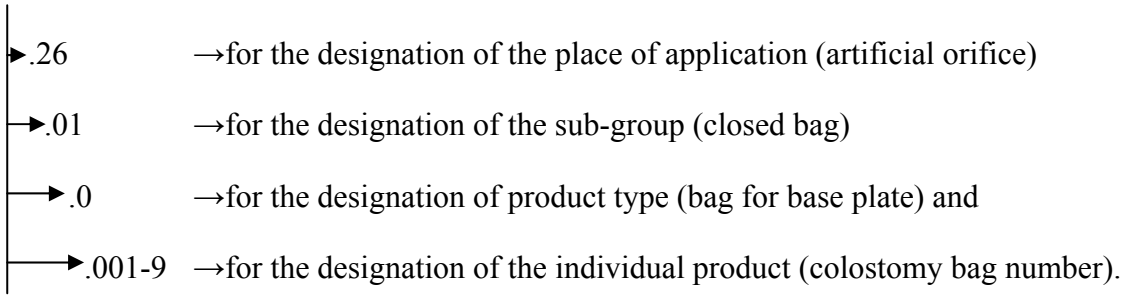
of therapeutic appliances in the catalogue are defined by the same institution. Currently the catalogue comprises 18,000 therapeutic appliances, which are subdivided into 34 product groups. A product group may consist of several sub-groups. Individual products that cannot be assigned to one of the product groups designated by name are assigned to product group 99 ‘Miscellaneous’. In table 5, the product groups are specified with their title and respective product group number.

Table 5: Overview of the 34 product groups specified in the Catalogue for Medical Aids

Titel	**Nr. der Produkt-gruppe**	**Titel**	**Nr. der Produkt-gruppe**
suction devices	01	transportation	18
adaptors	02	nursing care aids	19
applicators	03	storage aids	20
aquatic therapy aids	04	measuring instruments	21
bandages	05	mobilzing aids	22
radiation units	06	orthotic devices	23
appliances for amaurotics	07	artificial limb	24
arch-supports	08	spectacles	25
electrical stimulation devices	09	sitting aid	26
crutches	10	speaking aid	27
medical aids against decubituss	11	standing aid	28
aids for persons without larynx	12	stoma products	29
hearing aids	13	splints	30
inhalators	14	shoes	31
medical aids for incontinence	15	therapeutical motion device	32
communication appliances	16	toilet aids	33
elastic compression	17	miscellaneous	99

A seven-digit item number serves as the criterion for sorting each individual product. These item numbers are composed of digits indicating the product group, a digit for the area of application, the sub-group and the type of product. The digit for the individual product is given in fifth position, in the case of individually prescribable products. An example from the product group stoma products shows the labelling.

The item number 29.26.01.0.001-999 stands for:



IV) Discussion

The German health care system is characterized by a complex system of implicit as well as explicit benefit definitions. Definitions are stipulated on different decision levels as well for different health care sectors.

Each benefit scheme defines an overall framework for benefit entitlements. The Statutory Health Insurance is the most important benefit scheme in Germany since it covers 88% of the population and accounts for 56.9% of Germany's total health expenditure. Benefit entitlements for this scheme are stipulated in the fifth social code book. Other benefit schemes such as the Statutory Retirement Insurance scheme, the Statutory Accident Insurance scheme, private health insurance schemes, the Statutory Long-Term Care Insurance scheme, the Government Allowance Scheme for civil servants (under taxes), the Public Assistance Scheme and many very small schemes cover a much smaller part of the population and contribute less to total health expenditure.

The explicitness of defined benefits varies largely between these schemes. While for instance the Statutory Retirement Insurance scheme has a rather implicitly defined benefit catalogue, the Statutory Accident Insurance scheme has a rather explicit benefit catalogue laid down in the social code book. Most other schemes such as the public assistance scheme or the Governmental Allowance Scheme provide benefits according to the Statutory Health Insurance scheme.

Apart from the overall framework for each benefit scheme in the social code books, there are certain catalogues with definitions of items for remuneration. For the Statutory Health Insurance scheme there are four catalogues for different health care sectors: SHI-DRG, SHI-EBM, SHI-BEMA, SHI-BEL-II. These catalogues also serve to a certain extent as a benefit catalogue as all listed services are covered by the SHI-scheme. However the binding character as explicit benefit catalogue varies largely. Inpatient services not listed in the DRG-catalogue can still be covered by the Statutory Health Insurance scheme while in the ambulatory sector only those procedures listed in the "Uniform Value Scale" (SHI-EBM) or in the "Uniform Value Scale for Dentists" (SHI-BEMA) are covered as benefits in the ambulatory sector. One must notice, that a procedure which is not part of the SHI-EBM will not be performed by physicians and dentists, even if it is a generally accepted treatment. However catalogues can be updated regularly for new procedures and indications covered under a certain scheme.

As these catalogues are primarily designed to set provider remuneration, they mostly describe medical procedures that are provided by them (for example in the SHI: DRG, EBM, BEMA, BEL-II). To some extent these catalogues display all the procedures (benefits) available to the beneficiary, but these definitions are imprecise for two reasons:

At first, these procedures aggregate numerous work-steps that a physician is allowed to perform. The denser the level of aggregation the more will the provision of an individual procedure (benefit) within a benefit catalogue differ among physicians. For example, a DRG aggregates multiple procedures and as only one DRG is assigned to a hospital case, the grouper software has to work on all OPS-procedures that have been provided during the hospital stay while calculating a DRG on basis of the most profound procedures according to their predefined hierarchical order. Therefore a DRG does not display explicitly which benefits are available for the individual indication respective for the individual patient. The actual procedures (benefits) provided will vary on the case, even though the calculated DRG stays the same.

At second, the procedures listed are – with the exception of care by non-physicians, OTCs and a few others (e. g. osteodensitometry) – not linked to indications. Even though some procedures may only be provided by the dedicated medical specialists (for example as defined in the EBM), the provision of these benefits is generally neither limited to a certain disease, nor are they excluded to be performed for another disease.

Those areas which are not explicitly defined in detail are further refined by the Federal Joint Committee. Based on the legislative framework of the Social Code Book, the Federal Joint Committee issues directives relating to all sectors of care. By taking the criteria of need, costs and sometimes cost-effectiveness into consideration directives can be positively or negatively defined lists of benefits which can also consist of precisely defined indications. The Federal Joint Committee gains more and more importance regarding the definition of benefits as the number of directives has largely increased over the last two years.

From an outsider point of view the definition of German benefit catalogues are clearly difficult to understand. Foreign investors e.g. manufacturers for medical devices have to conduct excessive market studies to collect the knowledge to register a product and be included in one of the various benefit catalogues. It is likely that this complex system of implicit and explicit benefit catalogues distracts possible investors. It would be easier to have only one central reliable catalogue.

So far cost-effective studies have rarely been taken into account for the decision making process of the Federal Joint Committee. There are even benefits covered which could not

prove any effectiveness. For instance numerous drugs are still on the market in Germany which are not available in most European countries due to lack of effectiveness.

On the other side strong efforts have been made by the German Government during the last years to move towards a more explicitly defined benefit catalogue. The creation of the Federal Joint Committee and its supporting institution the "Institute for Quality and Efficiency" in 2004 was one major step in this direction. The Institute for Quality and Efficiency increasingly commissions effectiveness-studies which are considered for the directives of the Federal Joint Committee. The number of issued directives since the inception of the Committee supports the assumption that it is more productive than its predecessors (several committees for different sectors). This development suggests that the German health care system is moving towards a more explicitly defined benefit catalogue. However, the consideration of cost-effectiveness studies is still unclear. In the past they were mainly considered for benefit decisions on medical devices but it might be possible that they are considered for other areas of care in future as well.

Bibliography

Arnold M, Strehl R (2000) Wie kommen Innovationen ins DRG- System? Die Steuerungsfunktion der Bundesausschüsse. In: Arnold M, Litsch M, Schellenschmidt H (Hrsg.) (2000) Krankenhaus- Report 2000. Schattauer:Stuttgart,159-171

BKK- Bundesverband (2003) Sozialgesetze: Politikausgabe. LexisNexis:Frankfurt, 97-342

Bundesarbeitsgemeinschaft für Rehabilitation (2000) Rahmenempfehlungen zur ambulanten medizinischen Rehabilitation: Konzeption zur ambulanten kardiologischen Rehabilitation. Veröffentlichungen der BAR:Frankfurt

Bundesversicherungsanstalt für Angestellte (2000) Klassifikation therapeutischer Leistungen in der medizinischen Rehabilitation. www.bfa-berlin.de

Busse R, Riesberg A (2005) Health Care Systems in Transition Deutschland. WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies:Copenhagen

Clade H (2003) Rehabilitation: Adaptationsprobleme. Dtsch. Ärzteblatt 100(24):A1653

Delbrück H, Haupt E (1998) Rehabilitationsmedizin: Ambulant, Teilstationär, Stationär. Urban und Fischer:Lübeck

Deutsche Krankenhausgesellschaft, Spitzenverbände der Krankenkassen, Verband der privaten Krankenversicherung, Institut für das Entgeltsystem im Krankenhaus (2003) Deutsche Kodierrichtlinien. Allgemeine und spezielle Kodierrichtlinien für die Verschlüsselung von Krankheiten und Prozeduren. Version 2004 http://inek.customer.msim.de/deutschedrg/drg_kodier.htm

Deutsches Institut für Medizinische Dokumentation und Information (2004) Basiswissen Kodieren – eine kurze Einführung in die Anwendung von ICD-10-GM und OPS. DIMDI:Köln

Gibis B, Koch P, Bultman J (2004) Shifting criteria for benefit decisions. In: Saltman RB, Busse R (Hrsg.) Social health insurance in Western Europe. European Observatory on Health Care Systems:Copenhagen

IKK- Bundesverband (2003) Strukturgegebenheiten und Prozessabläufe im Hilfsmittel- und Pflegehilfsmittelbereich. http://www.ikk.de

IKK- Bundesverband (2004) Rahmenempfehlungen zur ambulanten medizinischen Rehabilitation.http://www.ikk.de/ikk/generator/ikk-gesund-plus/service-und-beratung.htm

Institut für das Entgeltsystem im Krankenhaus (2003) German Diagnosis Related Groups. G-DRG Version 2004. Definitionshandbuch, Bd. 1-5 http://inek.customer.msim.de/dokumente/kalkulationshandbuch.htm

Jung K, Gawlik C, Gibis B, Pötsch R, Rheinberger P, Schmacke N, Schneider G (2000) Bundesausschuss der Ärzte und Krankenkassen: Ansprüche der Versicherten präzisieren. Dt Ärztebl 97:A-365-370

Kassenärztliche Bundesvereinigung (2004) Einheitlicher Bewertungsmaßstab für ärztliche Leistungen (EBM 2000plus). Geschäftsführung des Gemeinsamen Bewertungsausschuss nach § 87 Abs. 3 SGB V

Kassenzahnärztliche Bundesvereinigung (2004a) Einheitlicher Bewertungsmaßstab für zahnärztliche Leistungen (BEMA) nach § 87 Abs. 2 und 2d SGB V

Kassenzahnärztliche Bundesvereinigung (2004b) Schwere Kost für leichtes Arbeiten – Hinweise und Berechnungsbeispiele zur Einführung von Festzuschüssen für Zahnersatz ab 2005

Kassenzahnärztliche Bundesvereinigung (2003) Rundschreiben zur Änderung des einheitlichen Bewertungsmaßstabes für zahnärztliche Leistungen. 2. Auflage

Kassenzahnärztliche Vereinigung Thüringen (2004) Bundeseinheitliches Verzeichnis zahntechnischer Leistungen für das Bundesland Thüringen (BEL-II)

Kern AO, Kistler E, Mamberer F, Unteutsch RR, Martolock B, Wörner D (2004) Definitionsprobleme und Implikation von Leistungsausgrenzungen in der gesetzlichen Krankenversicherung. In: Wasem J (Hrsg.) Die Bestimmung des Leistungskataloges in der gesetzlichen Krankenversicherung. Hans-Böckler-Stiftung:Düsseldorf, Bd. 1. Nr. 107

Kleinebrinker M (2004) Zahnärztliche Versorgung: vom individuellen Zuschuss zur Pauschale. KrV 11/2004:282-285

Kupsch S (2000) Health service provision on a microcosmic level- an international comparison; results of a WHO/IGSF survey in 15 European countries. Institute for Health Systems Research:Kiel

Langer B, Kern AO, Matolock B, Pfaff AB (2002) Vergleich der Vergütung zahnärztlicher Leistungen in der vertragszahnärztlichen Versorgung und im Standardtarif der PKV. Untersuchung für den Verband der privaten Krankenversicherung e. V.

Niebuhr D, Rothgang H, Wasem J, Greß S (2004) Verfahren und Kriterien zur Bestimmung des Leistungskataloges in der gesetzlichen Krankenversicherung vor dem Hintergrund internationaler Erfahrungen. In: Niebuhr D, Rothgang H, Wasem J, Greß S (Hrsg.) Die Bestimmung des Leistungskataloges in der gesetzlichen Krankenversicherung. Hans Böckler Stiftung 108(2):13-96

OECD (2000) A system of health accounts. OECD Publications:Paris

Polikowski M, Santos- Eggimann B (2002) How comprehensive are the basic packages of health services? An international comparison of six health insurance systems. J Health Serv Res Policy 7:133-42

Rabbata S (2004) GKV- Leistungskatalog: Streichlisten statt Staatsgarantien. Dtsch. Ärzteblatt 101(10):C499-500

Roeder N, Bunzemeier H, Glocker S (2004) G- DRGs 2004: Erreichtes und Nicht- Erreichtes. Das Krankenhaus 4/2004:251-260

Rutten F, van Busschbach J (2001) How to define a basic package of health services for a tax funded or social insurance based health care system? The European Journal of Health Economics 2:45-46

Sachverständigenrat für die Konzertierte Aktion im Gesundheitswesen (2003) Finanzierung, Nutzerorientierung und Qualität, Gutachten 2003

Scharnetzky E, Deitermann B, Michel C, Glaeske G (2004) GEK- Heil- und Hilfsmittel-Report 2004. GEK Schriftenreihe zur Gesundheitsanalyse Bd. 31:12-26

Schauenburg B (2004) EBM 200plus – die neue vertragsärztliche Gebührenordnung. Die BKK 06/2004:241-242

Statistisches Bundesamt (1996) Gesundheitswesen: Gesundheitsausgaben Deutschland. http://www.destatis.de/basis/d/gesu/gesutab4.php

Statistisches Bundesamt (1998) Soziale Sicherung: Rehabilitationsmaßnahmen. http://www.destatis.de/basis/d/solei/soleiq31b.php

Verband Deutscher Rentenversicherungsträger (1997) Statistik Rehabilitation des Jahres 1996. VDR:Frankfurt

Wirth A (1990) Rehabilitation statt Kur. Dtsch. Ärzteblatt 87(29):C1628-1630

Zuck R (2003) Hilfsmittel und die rechtliche Bedeutung des Hilfsmittelverzeichnisses. MedR Bd. 21(6):335-338