Initiative Faktor Lebensqualität

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"Intermittent Catheterization":

Care provision and reimbursement in Germany

Faktor Lebensqualität ("Quality of Life Factor") is a joint initiative of the leading German manufacturers of ISC devices that are members of BVMed. It unites the manufacturers of medical technical aids for intermittent self-catheterization (ISC) that put the well-being of the patients at the center of their activities.

> Coloplast GmbH
> Hollister Incorporated Niederlassung Deutschland
> Teleflex Medical GmbH
> Wellspect HealthCare (DENTSPLY IH GmbH)

Contents

Let's have a word

The Competition Reinforcement Law (GKV-Wettbewerbsstärkungsgesetz) introduced in 2007 and the amendments made through the Organizational Further Development Law (GKV-Organisationsweiterentwicklungsgesetz) in early 2009 were meant to increase competition between the Statutory Health Insurance funds. The fixed remuneration rates stipulated by the Federal Association of the Statutory Health Insurance Funds, with the contribution of the relevant manufacturer and care provider associations, which had applied before, were downgraded to the status of mere reference prices. This initiated a price competition process through tenders and framework agreements, that suppliers can join, but it did not implement effective quality assurance.

The developments described are particularly significant for those product groups (PG) of the register of medical technical aids where adjustment, choice of a particular medical device and the instruction of the patient by the physician or the professional staff working for the care provider[1] are a medical necessity in order to prevent diseases or a worsening of the condition, or to avoid the need for nursing care. These sensitive product groups include without a doubt the PG 15 Incontinence Helps, which lists absorbing as well as draining incontinence helps.

The current system e.g. allows for market participants that have no experience with the effort involved in intermittent self-catheterization (ISC) services to conduct the relevant contract negotiations and thus play a significant role in fixing the current reimbursement amounts. Some health insurance funds knowingly abuse this regulation. The experiences of specialized homecare companies and medical supply stores are frequently disregarded and these providers can then only accede to the framework agreement. In case of tenders they are often not able to compete in terms of price. Frequently, some providers are able to offer low prices only by factoring in the additional payments made by the patients for quality devices, thus undermining the principle of benefits in kind of the Social Security Code V (SGB V). Unfortunately, several health insurance funds tacitly accept this approach[1]. It should be mentioned that, fortunately, there are renowned health insurance funds that take their service obligation seriously and negotiate agreements with competent care providers, ensuring adequate remuneration and medically necessary quality of care with the individual patient in mind, as envisaged by the Social Security Code and the Medical Technical Aids Guidelines.

Against this background, this paper focuses on bladder catheters for intermittent self-catheterizing systems, which are used for instance by paraplegic patients, those with multiple sclerosis and spina bifida, as well as other conditions accompanied by neurogenic bladder dysfunction. Other types of draining incontinence devices, such as condom catheters and leg bags, will be covered as well. We have tried to present the anatomical-physiological and medical and nursing aspects as well as the necessary product differentiation in a compact and comprehensible way.

We think it is important that the decision-makers working for the funding institutions as well as politicians are made aware of the problems mentioned above. Our main concern is to initiate a rethinking process, leaving behind us a competition focusing on price alone and moving towards one based on the best quality of care. After all, it should be the aim of all those involved in providing care to patients to ensure a level of care that meets individual needs while providing state-of-the-art medical technology. In order to do this, we must work together on creating the necessary framework.

[1] The care providers are those other care providers listed in article 126 of the Social Security Code V, such as homecare companies, medical supply stores, and pharmacies.

1. Incontinence and bladder dysfunction – a growing problem

The most common type of bladder dysfunction, and also the fastest growing, are the different forms of incontinence in old age. This type of incontinence often occurs at a time when other bodily functions, and often mental functions, have decreased as well. Therefore, the incontinence care chosen, often automatically, for caring for old-age incontinence is absorbent incontinence care, i.e. diapers. But also in patients with old-age incontinence diapers should only be used after other types of incontinence care have been considered. This is especially relevant for the younger age-group of patients with incontinence, because bladder dysfunction can occur in people of all ages.

Intermittent self-catheterization is regarded as the type of care with the lowest rate of complications and the best prognosis for the patient and should always be considered first, as is also made clear by the recommendation of the commission for hospital hygiene and infection prevention "Kommission für Krankenhaushygiene und Infektionsprophylaxe (KRINKO)" of the Robert Koch Institute (RKI). The recommendation says: "In order to prevent catheter-associated infections, intermittent catheterization is preferable to an indwelling bladder catheter, wherever practicable."[3]

The most common reason for incontinence in younger patients is partial or complete paraplegia. Paraplegia can be caused by trauma or disease or be congenital, as in spina bifida, a malformation of the spinal cord. According to the available literature, there are an estimated number of about 1,500 to 2,000 new cases of paraplegia in Germany every year.[2] Only a few years ago, about 70 percent of all cases of paraplegia were caused by accidents, these days more than half are non-traumatic. Of all cases of traumatic paraplegia, 70 to 80 percent are in men, which can be attributed to the fact that men are more willing to take risks than women. Incontinence can also occur without paraplegia, e.g. because of circulatory disorders, inflammation, tumors or metastases, and neurodegenerative disorders such as multiple sclerosis.

However, bladder dysfunction can also occur without any of the above reasons, e.g. due to changes of the connective tissue in women after giving birth, prostate enlargement in men, or as a consequence of operations in the pelvic region. The regular care for this type of bladder dysfunction should be surgery.

We will have to face an increasing number of cases of bladder dysfunction in the coming years. While the number of cases of paraplegia caused by traffic accidents has decreased due to improved restraint systems, paraplegia because of leisure activities and sports as well as the number of cases of non-traumatic paraplegia are on the increase.

There is a clear connection between age and non-traumatic bladder dysfunction. Especially circulatory disorders, tumor metastases, and neurodegenerative disorders are more present in higher age and therefore will increase also in absolute numbers because of the expected demographic development. Together with the increase of incontinence in old age this will lead to a growing and challenging care problem.

2. Incontinence and bladder dysfunction in Germany: figures, data, facts

2.1 Definitions

Incontinence is a lack of or an insufficient ability of the body to safely store the contents of the bladder or the intestines and to decide when and how these are to be emptied. The consequences are involuntary loss of urine or feces [4], mostly as a result or a side effect of an underlying disease. Urinary incontinence is defined as “any involuntary leakage of urine” by the International Continence Society (ICS). This definition does not include urinary retention, which can lead to an overflow bladder and thus also to incontinence.

Paraplegia is a consequence of a damage of the spinal cord or cauda equina (anatomic structure of the lower end of the spine in the form of a horse's tail) caused by traumatic or non-traumatic (e.g. vascular, inflammatory, metabolic, neoplastic) factors and with acute or chronically progressing occurrence.

2.2 Patients

a. Incontinence

- In Germany, over 9 million people are affected by involuntary loss of urine and/or feces, which significantly interferes with their everyday lives.[4] Because the symptoms are treated as a taboo, however, the information regarding the prevalence of this condition varies, with different sources stating between five and over fifty percent. It is considered certain, however, that the problem will become more significant as the age distribution among the population continues to change.[5]

- The Statutory Health Insurance fund Barmer GEK with its around 9 million insured, spent 58.2 million euros on incontinence helps (7.4% of the total expenditure on medical technical aids) in 2013.[6] Extrapolated to the total number of people covered by the Statutory Health Insurance (SHI), the expenditure on incontinence products should be at around 450 million euros, i.e. about 0.24 percent of the total SHI expenditure in 2013.

- around 1.2 million patients who receive ambulatory care covered by the SHI.

- around 300,000 patients in nursing homes

b. Paraplegia

In industrialized countries the annual incidence (number of new cases) of acute traumatic spinal cord lesions is at 10 to 30 cases per one million inhabitants. With 70% of all cases, men are more frequently affected. The average age at the time of the accident is 40.[7, 8]. The incidence of non-traumatic paraplegia (amongst other reasons tumors, spinal circulatory disorders, myelitis) is unknown, but its occurrence increases with the aging of the population. Among the cases of non-traumatic, non-compression-related paraplegia the most common reason is multiple sclerosis (43%), followed by systemic autoimmune diseases (17%), spinal ischemia (14%), infectious myelitis (6%), and radiation onset myelopathy (4 %).[9]

Altogether, there are currently around 100,000 people with paraplegia in Germany.[10, 11]

2.3 Incontinence / paraplegia in nursing care homes

a. Incontinence

73.4% of those living in nursing care homes required devices helping them deal with incontinence or a bladder catheter in 2013.[12] While 76.8% of the residents needed incontinence helps (pads, incontinence pants), only 4.0% received care with a suprapubic catheter and 6.6% with a transurethral catheter.

b. Paraplegia

In Germany, every year there are about 1,500 to 2,000 new cases of paraplegia.[2, 13] About 90% of those patients receive their initial treatment in one of the qualified treatment centers, e.g. in one of the hospitals that are part of the group of hospitals of the German Social Accident Insurance (Klinikverbund der gesetzlichen Unfallversicherung gGmbH, KUV). These hospitals treat patients based on a comprehensive treatment program consisting of three phases: care for the newly injured, continuing rehabilitation, and lifelong aftercare.

2.4 Incontinence / paraplegia in ambulatory care

a. Incontinence

- 75% of incontinence patients are treated at home

- 53% of all patients cared for by ambulatory nursing services suffer from incontinence[14]

b. Paraplegia

The statistics of severely disabled persons 2013 ("Statistik der schwerbehinderten Menschen - 2013"), published by the Federal Statistical Office[15] according to article 131 of the Social Security Code IX, show only 17,031 paraplegic persons who are officially registered as severely handicapped. The actual number of cases of paraplegia, however, is much higher (see 2.2.b).

The distribution of costs among the funding organizations and insurance providers[16] is as follows:

- Statutory Health Insurance: 78%

- Employers' liability insurance associations: 8%

- Private funds: 7%

- Others: 7%

3. Structure and function of the urinary organs

In order to understand the complexity of care for bladder dysfunction, it is useful to be familiar with the anatomy and function of the urinary organs.

3.1 The kidneys

The kidneys filter urinary excretion substances from the blood, i.e. all those substances that would be harmful if their concentration in the body was too high. These include water, salt, and other metabolic products. The kidneys produce about 30 to 90°ml of urine per hour. Urine is produced continuously and it flows through the renal pelvis and into the ureters.

3.2 The ureters

The two ureters are narrow tube-like organs connecting the kidneys with the bladder. They are each about 25 to 30°cm long. The ureters end in the bladder via a kind of check valve that prevents the backflow of urine from the bladder into the ureters. The ureters have muscular walls actively used for the transport of urine. This means that urine is transported into the bladder not only through the force of gravity but also when lying down.

3.3 The bladder

The bladder is a hollow organ with a strong muscular wall. It stores urine and ensures voiding at short intervals. At a filling volume of about 200 ml the urge to urinate sets in. On average, the bladder can hold about 500°ml in a relaxed state. The urge to urinate can occur, individually and especially when urinary tract infections are present, already from much smaller bladder filling volumes. The size of the bladder varies significantly among individuals and is also gender-specific. Bladder emptying is a complicated process which involves involuntary as well as voluntary nervous activities. Once a certain filling level has been reached, the bladder signals to the brain that voiding is needed. Someone with a healthy nervous system is able to suppress this need over a longer period of time until they voluntarily enable the bladder to empty. During this process the sphincter muscles are opened and the bladder contracts, leading to a fast flow of urine from the bladder. The bladder should be emptied completely without any residual urine.

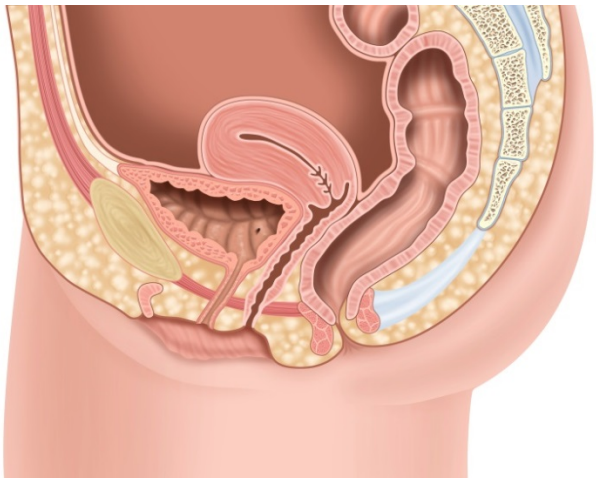
The flow of urine passes through the urethra, which has a different shape in men and women. Therefore, the urethra should be considered separately for both sexes.

3.4 The female urethra

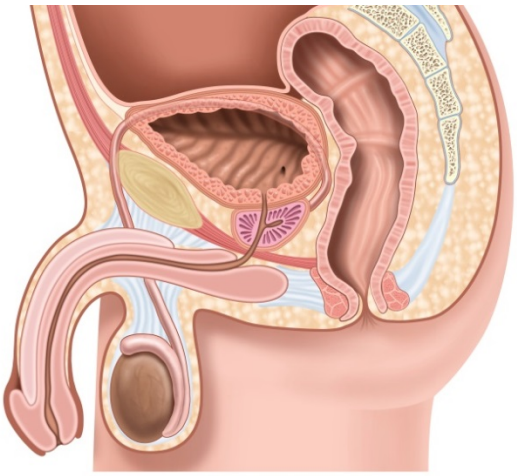
In women the urethra (picture 1) is only 3 to 5°cm long, and due to its shortness and the strains it is exposed to during giving birth the female bladder is a very vulnerable organ. This concerns infections as well as voiding dysfunction. Because the female bladder is straight it can however be easily catheterized.

3.5 The male urethra

In men the urethra (picture 2) is about 20 to 25°cm long. In a curved shape, it leads from the bladder through the prostate and the pelvic flow to the tip of the penis. Due to its length, its bend, and a possible prostatic hypertrophy catheterizing the male urethra is often difficult.



Picture 1: Course of the urethra in women



Picture 2: Course of the urethra in men

3.6 The role of the sphincters

Spontaneous voiding of the bladder is prevented by two circular muscles that surround the urethra, i.e. the inner sphincter and the outer sphincter. The inner sphincter is controlled involuntarily, the outer one is subject to deliberate control. Especially in women the sphincter function also depends on other muscles of the pelvic floor that keep the pelvic organs in place.

3.7 The role of the nervous system

The proper filling and voiding of the bladder depends on an intact nervous system. The spinal cord, at about the level of the first lumbar vertebra, contains a center that sends impulses to the brain when the bladder is filled. The brain then sends impulses for the contraction of the bladder and the relaxation of the sphincters. In doing this, the brain is able to prevent the relaxation of the outer sphincter through voluntary control and can thus suppress the emptying of the bladder.

4. Disorders of the bladder and urethra function

Basically, functional disorders of the bladder and the urethra can be distinguished on the basis of neurogenic disorders and mechanical disorders. Mechanical disorders comprise mostly benign prostate enlargement and urethral strictures in men, as well as sphincter insufficiency.

In women, a common cause of sphincter insufficiency are changes to the shape of the urethra that can occur due to a weakening of the connective tissue in the lesser pelvis after giving birth. There are different methods of treatment available for this condition, from pelvic floor muscle exercises to various surgical therapies. Therefore, permanent incontinence should only occur in exceptional cases.

In men, the most common cause, apart from neurogenic disorders and old-age incontinence, is a previous operation on the prostate. An operation for a benign prostate enlargement should not normally lead to an impairment of the sphincter function. In radical surgery for prostate cancer, however, a certain percentage of mechanical or neural disorders of the sphincter function must be expected.

In the following, however, we will focus on neurogenic bladder dysfunction, i.e. those types that are caused by damage to the neural control of the bladder and the sphincter. In a simplified manner, four types of neurogenic bladder dysfunction can be distinguished.

4.1 The atonic or weak bladder

We talk about an atonic or weak bladder if, after an injury to the spinal cord, the bladder cannot contract. It cannot take an active part in emptying itself. This may also be caused by surgery to the pelvic area or by complications resulting from diabetes.

4.2 The reflex bladder

We talk about a reflex or spastic bladder if, once a certain filling level has been reached, a contraction reflex of the bladder sets in automatically and without the patient being able to influence it so that urine is being emptied. Often, this occurs when the spinal cord is damaged above the center of the bladder.

4.3 The disinhibited bladder

The disinhibited or uncontrolled bladder is characterized by a frequent and strong urge to urinate with disinhibited voiding, which is often caused by changes in the brain from injury, stroke, or multiple sclerosis.

4.4 Detrusor sphincter dyssynergy (DSDS)

This is a complex neurological disorder with disturbed coordination between bladder contraction and the function of the sphincter. The bladder contracts and at the same time the sphincter is closed, which in turn leads to increased pressure on the bladder. This can result in the complication of a backflow into the kidneys and in the long term to kidney damage.

4.5 Urinary tract infection as a possible complication of catheterization

A urinary tract infection can also occur in people without voiding dysfunction, especially in women, for a number of reasons. It is one of the most common forms of complication from emptying the bladder through a catheter inserted into the urethra. As an ascending infection it often affects other organs, e.g. the bladder, the prostate, and even the kidneys. In the long term, if it is not detected and treated, a urinary tract infection may therefore lead to kidney failure. The symptoms of a urinary tract infection are frequent urination, pain when urinating, involuntary voiding, in spastic paraplegia also increased muscle spasms, elevated body temperature, fever, back pain, cloudy or dark or malodorous urine.

Some of these symptoms do not occur in paraplegic patients because the patients are not able to detect them due to a disorder of the sensory nerves. When a urinary tract infection is suspected, it is therefore

important to immediately analyze a urine sample, if possible also with a urine culture, so that antibiotics may be given not haphazardly, but targeted to the relevant germ.

5. Continuous draining incontinence care

In general, for bladder dysfunction, draining incontinence care is to be preferred to absorbing incontinence care. While the use of diapers is relatively uncomplicated in infants, absorbing incontinence care in adults often leads to stigmatization of the patient and in old age to a number of complications, such as dermatitis, or increased risk of the formation of decubitus.

5.1 Medical devices available

In men, non-invasive urinary diversion is possible with the help of condom catheters. A condom catheter is a solution that leads to little stigmatization, especially when continuous, dripping discharge of urine is to be expected and therefore intermittent catheterization is not possible. During the day urine can be collected via a leg bag and during the night via bigger bed bags. External urinary drainage systems are a special type of care for immobile, incontinent men. The system enables secure sealing through individual adjustment of the skin protection surfaces to the anatomic conditions and it fits securely and comfortably even in problematic care situations such as retracted penis.

Incontinence care in women is more difficult. External urinary drainage systems are a special type of care for immobile, incontinent women. The system enables secure sealing through individual adjustment of the skin protection surfaces to the anatomic conditions.

If the application of external urinary drainage systems is not possible and intermittent catheterization cannot be used either, long-term catheterization is possible. Because of the probably lower infection rate and the protection of the urethra, suprapubic catheterization, i.e. drainage through the abdominal wall, is to be preferred.[17]

If the patient rejects suprapubic drainage or this does not seem appropriate, but catheterization must be carried out[17], urine can also be discharged through an indwelling urethral catheter. In general, this is secured against slipping back by means of a balloon that is inflated inside the bladder.

Urine can be collected in a number of different collection bags. Leg bags usually have a small volume so that they cannot be detected through the leg of the trouser, and they can normally be emptied. For the night, bigger bed bags are available that can collect the volume discharged during the entire night.

5.2 Necessary services

For non-invasive continuous draining care it is usually sufficient to instruct the patient in detail how to use the system. If invasive catheters are used, complications must always be expected. Therefore, the areas where the catheter is inserted must be controlled on a regular basis, they must be cleaned regularly and disinfected. It must be ensured that urinary tract infections are detected and treated early.

6. Intermittent catheterization

If a catheter is inserted through the urethra into the bladder for complete voiding and then removed, this is called intermittent single-use catheterization. If the patient performs this procedure themselves, it is called intermittent self-catheterization (ISC). If another person, e.g. a nurse or a relative, carries it out, the procedure may simply be called intermittent catheterization. Intermittent catheterization is the type of draining incontinence care that has the lowest rate of complications, as is also confirmed by the commission for hospital hygiene and infection prevention (KRINKO) of the Robert Koch Institute (RKI).[3, 17] Through the introduction of intermittent catheterization it was possible to half the incidence of renal failure and the resulting mortality in paraplegic patients.[18] In the following, we will look at intermittent self-catheterization (ISC).

6.1 Intermittent self-catheterization (ISC)

The use of modern lubricated or hydrophilic coated single-use catheters that are thus free from contamination only restricts the ability of patients to take part in social life to a very little degree. Catheterization can be undertaken in any toilet, if necessary even outside. There are no signs that reveal to anyone nearby that the user is incontinent. No pads or leg bags can be detected under the clothes and there are no tell-tale noises made by a leg bag when walking. If the patient's sexual function is not affected by the underlying condition, it will not be impaired by intermittent self-catheterization either. This is therefore a technology that can improve a patient's life-expectancy as well as their quality of life not only slightly, but dramatically.

6.2 Conditions, indications, paraplegia/complications

ISC can be used for almost all forms of incontinence, i.e. most of the types of bladder and urethra dysfunction mentioned in chapter 4 can be cared for with ISC. ISC is not suitable for complete sphincter insufficiency, which leads to continuous urinary discharge. The application of ISC may also be limited in case of a disinhibited bladder (4.3). The frequency of self-catheterization that is necessary depends largely on the underlying diagnosis as well as on the volume of fluid consumed. ISC leads to far fewer complications than permanent catheterization, but it is not free from complications.

A certain rate of urinary tract infections must be expected in ISC too, although with the use of catheters protected from contamination and an aseptic catheterization technique this can be kept low. Another risk are injuries of the urethra, especially in men. Most of those using ISC have restricted sensitivity of the urethra and thus do not notice injuries, which may lead to long-term consequences such as narrowing of the urethra. However, this risk may largely be avoided through the use of optimized catheters.

6.3 Safe single-use catheterization for men, women, and children

The male bladder is long and and has a prominent bend. Due to the length of the urethra it is not possible to hold the catheter only at the base and to insert it into the urethra without touching it with the hands. Touching the catheter with the hands or other body parts or clothes must be avoided by all means, however. When using simple catheters this can only be achieved with a sophisticated catheterization technique. The S2k guideline of the German Society of Urology[19] calls for: "[...] an atraumatic tip, rounded catheter eyes without sharp edges and a surface that, along with special lubricants, possesses optimal smoothness."

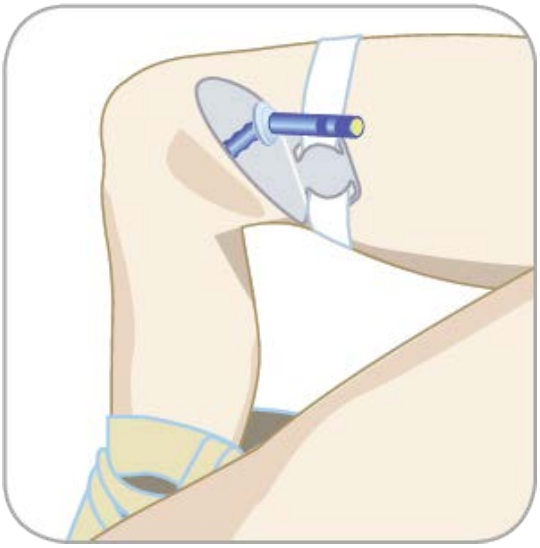
The catheter must not be touched with the hands or non-sterile gloves.

Modern ready-to-use catheters (picture 3) are protected from accidental touching through different measures. Applications make safe catheterization much simpler.

Picture 3: Different catheters for ISC

Because of the high rate of repetitions it is very important that the catheter glides well and is constructed in an atraumatic way. This is especially important with regard to the side holes of the catheter, the so-called catheter eyes, because these are very close to the wall of the urethra, especially because of the bend of the male urethra. In order to avoid micro-lesions of the mucous membrane it is necessary that the catheter eyes are rounded and have no sharp edges. (S2k guideline[19], "Material für den ISK", p. 13) In order to ensure ready-to-use handling, different devices are available where the hydrophilic surface coating can be activated fast and easily and without adding water from the outside, i.e. where the gel is already inside the packaging or inside a gel sachet and will moisten the catheter automatically when used. Both versions are available in film packaging in order to prevent accidental touching of the catheter.

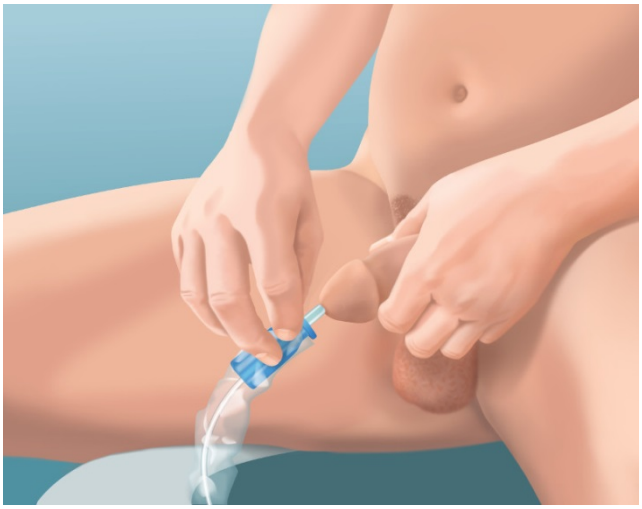
The female bladder is short. Therefore, the catheter can be short as well. However, this does not really make the application much easier because due to anatomic reasons a woman cannot see the point where the catheter is inserted. There are aids available, however, such as mirrors which can be stuck to or between the thighs (picture 4), or labia spreaders, which enable the entrance of the urethra to be viewed. As the catheter is short it is possible to hold its base and to directly insert it into the urethra in a targeted manner (picture 5) without the catheter touching any surfaces. Of course, the catheter may also be inserted out of its film packaging and thus safely avoid any contact with other parts of the body. Another possibility is an applicator with a safe design (picture 7).



Picture 4: Mirror with light

Picture 5: Short catheter for women

From a certain age, children too are able to learn self-catheterization. Especially modern catheter sets that are designed specifically for children permit an easy and safe procedure. A simple, sterile single-use catheter is an inexpensive device. Its disadvantage, however, is the fact that it cannot be inserted without touching and thus it does not comply with the present standard of medical care.[19]



Picture 6: Insertion of a no touch catheter in men

Picture 7: Catheter with applicator

Modern single-use catheters are designed in a way which allows safe and sterile insertion of catheters through applicators, or they have an additional protective sleeve [cf. picture 3: no. 2. picture 6]: Medical safety must always be the most important aspect, but it is especially important e.g. for mobile patients that the catheter systems are as discrete and small as possible and are supplied in convenient packaging.

Catheter systems e.g. for mobile patients often contain an attached urine collection bag, which means that the patient can use the device immediately, even when no toilet is available.

Some of these devices have been adapted specifically for patients with impaired movement and contain finger-holes for easy opening, or other aids. It will not be surprising that devices that have been optimized with these impairments of the patient in mind are more expensive than simple catheters. Any price comparison must also take into account the fact that with simple catheters also accessories such as sterile lubricants must be included in the price.

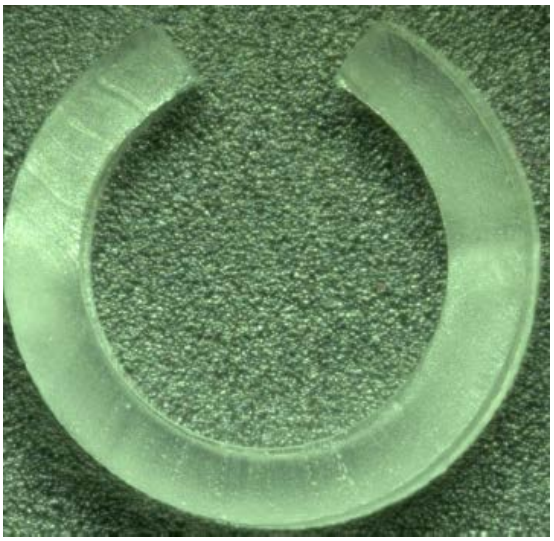
Patients who need catheterization even when their bladder contains a relatively small amount of urine may use ISC only during the day and a condom catheter at night so as not to have to get up for catheterization. Mobile patients may use single-use catheters with an attached collection bag when needed.

6.4 Catheter properties

A catheter that is used for intermittent self-catheterization has to meet many, sometimes conflicting, requirements. On the one hand it must be sufficiently flexible in order to be guided along the bends of the urethra without much obstruction, but on the other hand it must be firm enough to be inserted without buckling.

It must be assured that the surface of the catheter, if it is guided through a lubricant reservoir, will collect a sufficient amount of lubricant. If it has a hydrophilic coating, moistening with sterile water should be possible without danger of contamination.

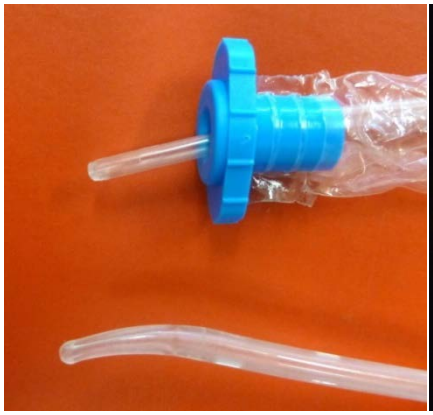
Avoiding any trauma to the urethra is of much greater importance in ISC than with permanent catheters. The latter is inserted about once within a period of four weeks, while ISC is carried out more than six times a day. It is also essential that the catheter has optimal gliding properties when it is inserted into the urethra. At the tip of the catheter there are inlet openings for the urine, the so-called eyes. In all high-quality devices their design and production control guarantee that the eyes are atraumatic, i.e. they do not cause any injury to the urethra.



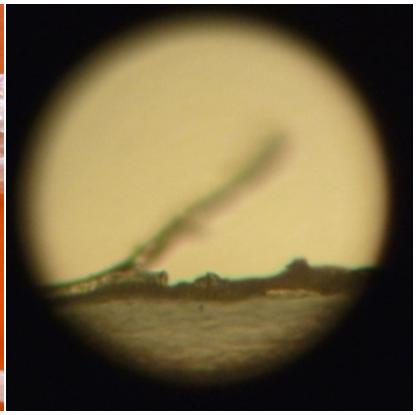
Picture 8: Sharp catheter eye

Picture 9: Atraumatic catheter eyes

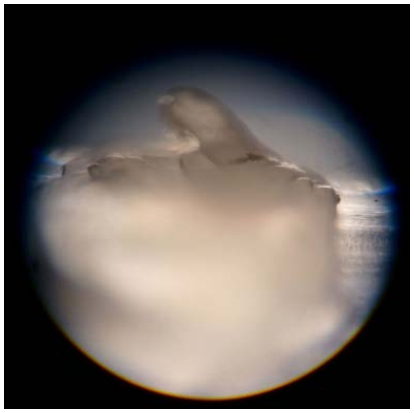
There are several technologies used for rounding the side-eyes of the catheter (picture 8), such as warm forming, by treatment with solvent, or already during the manufacturing process.



10a: Device with sharp eyes of a winner of a tender contract



10b: Catheter eye of catheter 10a under a microscope: sharp, cutting edges on the outside of the eye, long barb on the inside of the eye



10c: Catheter eye of catheter 10a under a microscope: short barb on the surface

Even though the short contact period means that the material properties are less critical, no PVC catheters with phthalate plasticizers, such as DEHP, should be used in ISC. DEHP is suspected of being carcinogenic[20]. Catheters made from DEHP-free PVC, PUR, or POBE with a microrough surface and atraumatic side-holes as well as possibly a tip made of softer material, that already contain the lubricant (picture 3; no. 1 and 2; page 15), are considered state-of-the-art technology nowadays, or alternatively catheters with hydrophilic coating.

6.5 Representation of the requirements in the register of medical technical aids

The present structure of PG 15 of the register of medical technical aids was developed in 2006.

Since then, significant progress has been made in the technology of ISC catheters, both with regard to their safe applications as well as handling by the patients. This progress, however, has so far not led to a definition of minimum requirements in terms of quality nor has it been included in the group structure of the register of medical technical aids. Thus, devices that have different quality properties and therefore cannot be compared are included in the same product type.

6.6 Correct choice of ISC care and the relevant services

The safe performance of ISC requires a learning process. The length of this learning process depends on how well the patient is able to use his or her fine motor skills. The instruction of the patient and the choice of the type of ISC care needed should therefore not be standardized but adapted to the specific needs of the patient. In addition, it must be pointed out to the patient which symptoms indicate complications, e.g. a developing urinary tract infection.

It might also be appropriate that, based on a decision made together with the physician, the patient requires different catheters in different situations (at home, outside the home, at night). Depending on the requirements of the situation, systems in small packages or systems with integrated bags may be used. If the patient self-catheterizes at night as well, it might be useful to make available a system with a collection bag.

The sectoral interest group Ostomy and Incontinence Care (FBSI) of the German Medical Technology Association BVMed and the professional society for ostomy, continence and wound care (Fachgesellschaft Stoma, Kontinenz und Wunde e.V., FgSKW) have each developed service criteria for the choice of ISC devices. The following section presents the service criteria of BVMed.

Quality of care	**PG 15 (here 15.25.14. Single-use catheters for intermittent self-catheterization)**	Version: 0.6 Date: 14 October 2015
Structural quality = fulfilling the suitability criteria according to the prequalification (PQ)		
General conditions	ultimately PQ, cf. the current version of the recommendations made by the Federal Association of the Statutory Health Insurance Funds	
Organizational conditions	ultimately PQ, cf. the current version of the recommendations made by the Federal Association of the Statutory Health Insurance Funds	
Material conditions	ultimately PQ, cf. the current version of the recommendations made by the Federal Association of the Statutory Health Insurance Funds	
Staff requirements		
a) technical director	ultimately PQ, cf. the current version of the recommendations made by the Federal Association of the Statutory Health Insurance Funds	
b) carers/advisors	**Qualification** - Qualified nurse[2] - The care provider must assure that the patient/insured person receives care by the provider's own staff who have additional professional qualifications in counseling, training and instructing patients. Cf. for instance the requirements for further training as a nursing expert for ostomy, continence and wound care or the further training in urotherapy[3] **Advanced and further training** The relevant members of staff must prove that they take part in regular trainings (once a year, at least 8 hours of training) dealing with the following topics: - medical basics - continence care - medical technical aids - law - development and advancement of methodological expertise	
Process quality / description		
(acute care) hospital		
a) preoperative		
b) postoperative		
Rehabilitation clinic		
Ambulatory care[4]		

[2] A qualified nurse is a person who has finished their training in one of the following nursing professions with a state examination and certification: nurse, pediatric nurse, or geriatric nurse.

[3] Access is calculated on the basis of a patient-staff ratio as follows: 1-500 patients cared for: 1 nurse with the relevant qualification, 501-1000 patients cared for: 2 nurses with the relevant qualification, 1001-1500 patients cared for: 3 nurses with the relevant qualification, etc.

[4] By personal counseling provided by the chosen care provider.

a) (initial) care	**(month 1 to 6)** - First home visit on the day the patient is discharged from hospital or the day the prescription is made out, at the latest on the following working day - **Indication paraplegia:** ▪ Two further home visits during the first 4 weeks after discharge/referral - **Indication pouch care:** ▪ Two further home visits during the first 4 weeks after discharge/referral - **Indication spina bifida:** ▪ Four to five further home visits during the first 4 weeks after discharge/referral - **Indication multiple sclerosis:** ▪ Four to five further home visits during the first 4 weeks after discharge/referral - **Other indications** ▪ Two further home visits during the first 4 weeks after discharge/referral - Further home visits based on needs - Contents: ▪ Needs assessment ▪ Education of patients and relatives with the goal of patients leading independent lives as much as possible and assuring that patients change their care devices themselves, as well as information about any possible complications during care ▪ The patients should learn the technique of intermittent urinary diversion and be able to use it safely. ▪ Hygiene measures ▪ Patients must be able to recognize complications and to initiate required measures in consultation with the physician treating them in ambulatory care ▪ Feedback to the acute-care hospital or to the primary care or specialist physician treating the patient ▪ Providing information to the patient about offers made by self-help organizations
b) Follow-up care	**(from month 7)** - yearly advice and control - Contents: ▪ Checking the ISC care and adjustments if necessary ▪ Education of patients and relatives ▪ Patients must be able to recognize complications and to initiate required measures in consultation with the physician treating them in ambulatory care ▪ For children, personal counseling will take place when they reach a new developmental step (e.g. start nursery or primary school or learn self-catheterization) or device adjustment becomes necessary due to growth
c) Special requirements	
Outcome quality	
	- The patient is able to use the medical technical aids themselves. - The desired continence/therapy goal has been reached. - The patient or their relatives are aware of the risk factors and the signs of complications. - Measures and medical technical aids have been adapted to the individual patient's need for support. - The patient and their relatives are aware of the ways of and points of contact for initiating any measures that become necessary. - If needed, the patient is aware of any measures that preserve continence and knows how to apply these.

Sources and further information
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6.7 Recommendations on levels of consumption

In this area, no fixed targets for consumption are possible. Patients with a weak or atonic bladder will always need relatively few catheters because they need to catheterize only when the bladder is full. Patients with an autonomous bladder need to catheterize before the trigger level for spontaneous voiding has been reached. This trigger level can vary and it can change over time as well. Accordingly, it is only the physician in consultation with the patient who can decide on the number of catheters needed per day. This decision cannot and must not be made by the care provider or the health insurance fund. There is no reason to fear that the patient may demand more catheters than needed because no-one will catheterize more often than is necessary.

7. Care situation

Those patients insured with the Statutory Health Insurance have a right to receive medical technical aids, i.e. also draining incontinence devices. The legal basis is article 33 of the Social Security Code V. The insured person's entitlement to receive benefits in kind funded by their health insurance fund is defined in more detail by the register of medical technical aids, which is developed by the Federal Association of the Statutory Health Insurance Funds.

The prescription made out by the physician is "submitted" to a provider (pharmacy, medical supply store, homecare company) in order to receive the medical technical aid prescribed. After provision of the service, the provider presents the prescription to the relevant health insurance fund for remuneration.

The entitlement to receive benefits in kind of those patients who are incontinent and insured with a Statutory Health Insurance (SHI) fund was originally limited to the relevant fixed amount stipulated. If the manufacturers were able to provide also more advanced devices for the fixed amount, these incontinence aids whose quality was above the relevant "standard" were funded by the SHI as well.

Legal changes were meant to increase competition between the Statutory Health Insurance funds (Competition Reinforcement Law, 2007, and Organizational Further Development Law, 2009). The average remuneration amounts decreased and have been decreasing dramatically since that time. If the actual prices continue to fall due to tenders and framework agreements, it will hardly any longer be possible to provide advanced devices without additional payments. The patient will have to pay an additional contribution in order to still receive their specific medical technical aid, or they will be forced to use a less suitable, even lower quality device. This situation has already become a reality under a number of contracts. The entitlement to receive benefits in kind has thus been abolished.

Statutory additional contributions

Statutory additional contributions and (economic) additional contributions (see above) are often not distinguished by consumers and thus interpreted wrongly. Therefore we have included a brief description of the regulation covering additional contributions:

Incontinence aids are classified as disposable medical technical aids. For these the statutory regulation covering additional contributions states that 10% of the amount must be paid as an additional contribution, however no more than 10 euros per month for all disposable medical technical aids. The maximum amount per month includes all disposable medical technical aids. The amount must be invoiced, and the collection risk remains with the provider.

7.1 Care structures

The law allows two options for providing patients with medical technical aids and the relevant reimbursement:

- payment per incontinence aid up to the amount of the fixed remuneration stipulated by the Federal Association of the Statutory Health Insurance Funds (article 36 of the Social Security Code V).
- remuneration of contractual prices for incontinence care based on supplier contracts with the providers that result from tenders (article 127, section 1 of the Social Security Code V), negotiations (article 127, section 2 of the Social Security Code V), or individual agreements (article 127, section 3 of the Social Security Code V). These contracts may stipulate individual contractual prices per device, contractual prices per type of device, or monthly lump sums.

Fixed amounts as contractual prices have recently become less important. Also, tenders for draining incontinence care have only been implemented in a few cases, and contracts for monthly lump sums have

been concluded rarely. At present, the dominant form are negotiated or framework agreements according to article 127, section 2 of the Social Security Code V.

7.2 Fixed remunerations

The Federal Association of the Statutory Health Insurance Funds determines the same nationwide fixed remuneration rate for each medical technical aid, which will then be the upper limit of remuneration. These fixed rates are based on the types of devices contained in the register of medical technical aids. The respective descriptions for the register of medical technical aids can be viewed on the website of the Federal Association of the Statutory Health Insurance Funds.

https://hilfsmittel.gkvspitzenverband.de/hmvAnzeigen.action?gruppeId=15#orteTable.

By way of example, the following table lists the so-called fixed remunerations of the product group "15.25.14 Single-use catheters for ISC", which have not changed since 2007 and are nowadays used only as reference prices for contract negotiations. The amounts are inclusive of value-added tax.

15.25.14	Single-use catheter for ISC (per item)	
15.25.14.4	Single-use catheter, non-coated, not ready-to-use	€0.57
15.25.14.5	Single-use catheter, non-coated, ready-to-use (with lubricant)	€3.27
15.25.14.6	Single-use catheter, coated, not ready-to-use	€2.59
15.25.14.7	Single-use catheter, coated, ready-to-use in packaging	€3.27
15.25.14.8	Single-use catheter with collection bag, non-coated, ready-to-use in packaging (with lubricant)	€5.80
15.25.14.9	Single-use catheter with collection bag, coated, ready-to-use	€5.83

Modern developments, such as improved handling for patients with impaired movement, are not represented by the system. It does not take into account medical-technical progress and does not remunerate innovations regarding devices and processes.

7.3 Flat rates

The lump sums refer to the amounts per item for single-use catheters. Few health insurance funds try to use flat-rate contracts for regulating the costs of care. The flat rate applies to estimated monthly volumes per patient. Therefore, the remunerations the providers receive are estimated averages. If ISC users need more single-use catheters than estimated on average, the provider will have to bear the additional costs of patient care as it invoices flat rates instead of the actual quantity required. In this way, the health insurance funds are shifting the care and cost risk to the care providers. The providers are forced to use cheaper devices, to regulate quantities, or to stop offering devices from certain product groups. The users and patients are losing the ability to choose their devices themselves and to use single-use catheters as needed. This reduces the quality of care of the users and patients, whose quality of life is impaired significantly.

7.4 Tenders

Article 127, section 1 of the Social Security Code V enables the health insurance funds to put to tender the provision of incontinence aids to their insured. The benefits are not limited to supplying the medical technical aid to the patient, but include the expenditure for individual counseling given to the patient, the

needs assessment, stocking the supplies, logistics, as well as administration, such as processing the additional contributions and settling the prescriptions with the health insurance funds. Care provision is therefore more than just supplying products. Providers such as pharmacies, medical supply stores, and homecare companies can submit their tenders. With tenders too there is no incentive whatsoever to offer alternatives to the patients and to find the best type of care possible. The users and patients are losing the ability to choose their devices themselves and to use single-use catheters as needed. This also reduces the quality of care for the users and patients, whose quality of life is impaired significantly.

7.5 Framework agreements

Another form of care regulated by contracts are framework agreements according to article 127, section 2 of the Social Security Code V. The health insurance fund negotiates the conditions for the provision of care with a provider (supplier) or an association of providers. Structural and qualitative aspects of care may also be considered. The contents of the agreement are then published. Other suppliers can join the agreement based on the same conditions and become providers as well. With these types of agreement too the administrative costs that are caused by the health insurance funds and should therefore be assumed by them, are transferred to the providers.

On the one hand, it is a welcome step that large funds such as Barmer GEK, DAK-Gesundheit, and AOK Baden-Württemberg have recently decided to conclude negotiated contracts in order to ensure the required quality of care and to guarantee the insured persons' freedom of choice with regard to the provider. On the other hand, however, this has led to a significant reduction of the remuneration rates and resulted in the needs as well as the feelings of shame of the patients being increasingly ignored because of economic reasons.

7.6 Additional costs

Patients are legally entitled to receive funding for medically necessary incontinence devices for their individual needs in sufficient quantity and quality from their health insurance fund without any additional payments. At the same time, the patient can receive higher quality care as desired. The difference between the health insurance funding and the actual price is paid for by the patient themselves. These additional costs may be much higher than the stipulated additional contribution rate of €10.

With the prescription the physician defines the device that is medically necessary in the medically required quantity. Especially if the prescription lists a particular device, the medical necessity has been clearly defined and the patient is entitled to receive the prescribed quantity of this device without having to pay any additional contribution. Should the patient wish to receive a different device or a higher quantity, they have to pay any resulting additional costs themselves.

8. Basic quality requirements

8.1 Medical Technical Aid Guideline

The Joint Federal Committee (JFC) has published revised regulations for the prescription of medical technical aids by a contractual physician, which came into force on 29 October 2014. Article 3, section 1 describes the benefit entitlement:

"Medical technical aids can be prescribed at the expense of the health insurance funds if they are necessary in individual cases to

- ensure successful medical treatment,
- prevent the threat of disability, or
- compensate for a disability which impedes the fulfillment of basic everyday needs,
- remove a weakening of the state of health which would lead to a disease in the foreseeable future,
- counter any danger to the development of a child's health, prevent diseases or their worsening, or prevent the need for long-term care."

Unfortunately, this regulation is often not implemented in practical care, which leads to amongst others the problems described.

8.2 Register of medical technical aids (article 4 Medical Technical Aid Guideline)

"The Federal Association of the Statutory Health Insurance Funds will develop a systematically structured register of medical technical aids according to article 139 of the Social Security Code V, which lists the medical technical aids covered by the duty to provide benefits. [...]"

With the involvement of major associations (especially the manufacturers that are members of the German Medical Technology Association (BVMed)) the product group 15 of draining incontinence helps was revised in 2006 and individual devices were integrated into restructured types of devices.

The medical devices manufacturers are facing tough competition and are trying to launch innovative new devices or improvements of existing devices, which will offer greater medical benefits or increased quality of life to the users. The update of the register of medical technical aids with its types of products is not keeping pace with the developments. Many low-quality and high-quality devices are grouped in the same category despite different costs. In short: The CE quality mark is sufficient for allocating devices a relevant number in the register of medical technical aids. The differences between the devices are not adequately represented. In addition, at present the legal framework does not allow the adequate representation of all the differences between devices and the medical needs in the register of medical technical aids.

The following example helps to illustrate why: Leading manufacturers work with modern, environmentally friendly synthetic materials that do not contain any plasticizers, or with PVC that contains phthalate-free plasticizers.[20] This increases production costs, which however are not taken into account in the register of medical technical aids and therefore for remuneration. There are other examples as well: atraumatic tips, catheter eyes, as well as innovative "packaging" that consider the motor impairments of the users etc. There can be no doubt that action is required in order to open the system.

8.3 Health insurance fund contracts

A number of health insurance funds create barriers within their contracts, which ultimately restrict the choice of devices, the medically necessary quantity, or even the patient's free choice of a provider. Often this happens only to cut costs in the budget for medical technical aids without calculating the long-term total costs, which also include the costs of complications. If e.g. a patient who carries out intermittent catheterization does not have access to the medical technical aid they actually require or to the quantity

needed, this can seriously harm their health and eventually lead to follow-up costs much higher than the savings generated with regard to the actual device.

The neuro-urology working group of the German-language Paraplegia Association (Deutschsprachige Gesellschaft für Paraplegie, DMGP) has commented on this issue as follows:

"[…] In addition, attempts are made by health insurance funds to regulate the quantity of urological medical technical aids that these patients may receive. With these considerations, the funds' desire to cut costs is diametrically opposed to medical requirements. Health insurance funds have approached patients asking them to use permanent catheters instead of single-use catheters. This contradicts the current standard of care.

Permanent transurethral catheters lead to serious complications, such as destructions and strictures of the urethra. Moreover, permanent transurethral and suprapubic catheters can lead to the formation of bladder stones, chronic infections with multiresistent germs, or the development of malignant tumors in the bladder. In cases of neurogenic bladder dysfunction, their use is subject to strict indications.

The Robert Koch Institute[17] recommends that the number of catheter days be kept as low as possible in order to contain catheter-associated urinary tract infections through germs with particular resistance. The economically motivated attempts by the health insurance funds to increase the number of permanent catheters used directly counteract this public goal and contradict the law. [...]"

The contracts that the funds may conclude must ensure not only the quality of the medical technical aids but also the counseling services required by the insured and the provision of other services needed as well as the provision of care near where the insured live (cf. article 127, section 1 of the Social Security Code V). Contracts may also be realized through tenders (article 127, section 2 of the Social Security Code V). The same stipulations are understood to apply here with regard to services. Moreover, the service criteria should be specified in the register of medical technical aids.

Leading funds have defined laudable service criteria in their contracts. What use are these, however, if service providers are either not able to fulfill them or do intentionally not fulfill them in order to be able "to do business" through low prices and thus force other providers to conclude "inadequate" contracts? The situation can only be remedied with tight controls conducted by the funds in order to identify and sanction the quality standards. A new quality competition must be started.

9. Costs of care – care providers and manufacturers under pressure

Each of the over 100 Statutory Health Insurance funds sets the details of its contracts itself. This means an enormous administrative burden for pharmacies, medical supply stores, and homecare companies (providers). Companies that are active all over Germany and offer a large number of the 33 product groups of the register of medical technical aids have to manage thousands of contracts. It is obvious that this is associated with high costs. A working group of representatives of federal associations of leading health insurance funds and of BVMed have been trying to standardize individual parts of the contracts (regulatory approval, settlement procedure, etc.) for years, however without much success so far. Moreover, the legal regulation of article 127, section 7 of the Social Security Code V (establishment of a framework regulation for reducing bureaucracy) has not been implemented by the Federal Association of the Statutory Health Insurance Funds yet.

The providers are faced with rising general costs in order to be able to meet the requirements of the contracts. Apart form the costs for quality management and the ISO certification, a costly industry software is essential for representing the settlement and logistics processes. The number of employees working in administration and logistics has risen significantly over the past years.

The cost and time burden for advanced and further training of the employees has been increasing continuously. The largest cost item is the actual work connected with the patients or their relatives. This includes:

- choice and adjustment of the medical technical aid

- training how to handle the devices used

- consultation and coordination with the relevant physician

- instructing the patient how to be self-reliant

- giving advice how to recognize and avoid complications

- care and hygiene measures

- documentation

The professional staff working for the care provider pay regular visits to the patient at home or in care institutions. This takes some of the burden off the practice-based physicians and ambulatory nursing services. All these services surrounding the devices are included in the contractual rates. More on the services in section 6.6.

9.1 Development of remuneration rates based on the example of ISC

The current price development has been showing a significant decrease. Several years ago, the provider received a surcharge of about 15 percent on the manufacturer’s list price/pharmacies' purchase price and charged this rate to the health insurance funds. This process was abolished in 2007 with the introduction of the nationwide fixed remuneration amounts. This huge initial step marked the start of a downward spiral, which has not stopped so far.

The nationwide fixed remuneration amounts, which are based on the list prices of the manufacturers for individual devices, have been fixed on the basis of the classification system of the register of medical technical aids. This means: One price per type of product, including value-added tax, was fixed. Since then, i.e. 2007, the fixed amounts have not been adjusted, even though the value-added tax was increased twice and production costs have risen (e.g. through inflation effects).

In addition, the fixed remuneration amounts have lost their effect through the Competition Reinforcement Law (GKV-Wettbewerbsstärkungsgesetz) and only function as a reference point for framework

agreements. This price competition supported by some of the providers and health insurance funds is ruinous, a danger to innovation, and lowers the level of service.

How is it possible today for a reputable provider to work on a break-even basis, despite the costs of duties with regard to logistics and counseling described? So far this has only been possible with the help of the manufacturers that have been trying to compensate for the margin losses of the reputable providers. It is obvious, however, that this approach cannot continue forever. The manufacturers are already burdened with rising commodity prices and the general effects of inflation, and cost reductions through process improvements have largely been exploited. Therefore, the only alternative open to the providers is supplying the cheaper device to the patient.

10. Consequences resulting from the present care situation

Implementing further reductions of contract prices for ISC devices and other draining incontinence care devices will not result in patients receiving cheaper quality products. Instead, the choice and provision of lower-quality devices will inevitably lead to reduced quality of care, or it will become necessary for providers to introduce additional contributions for economic reasons. This cannot be in the patients' best interest. There are already an increasing number of examples where innovative devices are no longer being included in the register of medical technical aids, but are offered as over the counter products for patients who buy these devices themselves.

These are trends leading to a system of two classes of medicine. From our point of view this cannot be in the best interest of the present federal government and its healthcare policy.

Already in 2010, the sectoral interest group Ostomy and Incontinence Care (FBSI) of the German Medical Technology Association BVMed developed a position paper on the basis of the Social Security Code in order to prevent predictable negative developments. Therefore, from our point of view it is imperative that the following principles are adhered to in order to assure adequate and medically necessary provision of medical technical aids on the basis of the current state of scientific research:

Basic principles for a well-functioning and effective system for the provision of medical technical aids:

Maintaining the principle of benefits in kind

The patients should continue to receive those medical technical aids which in their individual case are medically sufficient, necessary, and suitable.

Right to choose the service provider

Patients insured with the Statutory Health Insurance should have the right to choose their service provider and be offered an unlimited choice of devices based on the individually sufficient, necessary, suitable, and economic provision of care.

Product variety

In order to do justice to individual differences and demands and to enhance the competition for quality and efficiency, it is essential that the variety of available products is maintained.

Quality of life and medical-technical progress as equally important selection criteria

The patient's quality of life and medical-technical progress are important selection criteria, which according to legal guidelines and decisions by the German Constitutional Court should be taken into account when a medical technical aid is chosen and must not be excluded because of economic considerations alone.

Competition for quality of care

The quality of care provided with medical technical aids must conform to the current state of research and development. Market competition of devices and services should primarily be based on quality.

Remuneration related to performance and stimulating innovation

The remuneration system must do justice to the manufacturer and the care provider without cutting the patient off from innovations and medical-technical progress. This leads to the necessity of reviewing and developing the standards on a regular basis. Therefore, the remuneration system should offer adequate incentives for the further development of care based on medical-technical progress and efficiency.

The provision of medical technical aids must be viewed as a single process consisting of supplying the medical technical aid and providing the associated services (e.g. adjustment and instruction) and be remunerated accordingly.

Local care

The provision of care must take place locally in order to ensure the right to choose their service provider for the patient as well as the competition between the providers.

Physicians' responsibility

It is the physician alone who decides whether the provision of medical technical aids is necessary. In consultation with the patient, the physician is responsible for complying with the legally required criteria for the provision of medical technical aids.

Individual care situations, medical-technical progress, and the wishes of the patient must be taken into account even under the efficiency rule.

Adjusting product volumes to individual needs

The product volumes prescribed for a given period of time should be based on the individual, i.e. different, needs of each insured person. The recommendations made by patient support groups, professional associations, and medical societies should be considered. Eventually, it should be the physician who prescribes the volume required by an individual patient on the basis of their personal medical needs.

Fast decisions in cases of urgent need for care

Certain situations make it necessary to provide care immediately. Therefore, regulations for emergency care for cases of acute care requirements must be established, which the health insurance funds must follow when they review the coverage of costs.

Administration

The administrative burden in relation to providing medical technical aids should be limited to what is actually necessary for the payers as well as the care providers.

The current framework basically allows for the implementation of all the above points. Unfortunately, the health insurance funds do not always implement this basic principle.

Surveys among patients have shown that even today some patients do not receive adequate care and the majority fear that their care situation will worsen.

If we compare the care situation that was presented in detail above with the basic principles outlined, it has to be noted that some funds have at least tacitly accepted these negative developments.[22] A number of surveys confirm this observation. Three quarters of those surveyed expect the care situation to worsen while one in ten say that they no longer receive the devices they need. Another survey is being prepared with the aim of highlighting the current care situation in more detail.

11. Quality of Life Factor

The quality of life initiative "Faktor Lebensqualität" is a joint initiative of the leading German manufacturers of ISC devices[5] that are members of BVMed. It was founded in 2013 and unites the manufacturers of medical technical aids for intermittent self-catheterization that put the well-being of the patients at the center of their activities.

The initiative aims to establish quality of life as a generally recognized, measurable outcome goal of healthcare, which will shift the present focus of quality of care to one of quality of life as the core aim of the efforts of those providing care. In this respect, the concept of quality in healthcare must be developed further. The goal of quality of care is the avoidance of death and pain. With the quality of life factor, however, the individual and their well-being is placed at the center of all activities.

Chronic illness and handicaps always mean a noticeable loss of the quality of life. A system based on solidarity must do everything it can to make this loss as bearable as possible for the persons concerned. Therefore, quality of life and the ability to participate in social life must become the decisive factor for the provision of medical technical aids. A patient who feels they are living a self-determined life will always cause fewer costs for the solidarity system than someone whose primary feeling is one of helplessness.

The goals of the initiative are consistent with the intentions declared by politicians and many of the actors in the healthcare system. With the quality of life initiative we wish to advance public dialog, accelerate the development of a generally recognized quality of life factor, and prevent aspirations that run contrary to this goal for society as a whole.

"For me, quality of life means that my life is not determined by my condition but by myself. Therefore, I need the medical technical aids that are suitable for me, and not those that someone else thinks are suitable." Olaf Lüken, 48, multiple sclerosis

We invite all those involved in this process to get involved in developing a generally recognized catalog of criteria which can be used as a comparable standard for the quality of life of healthy and chronically ill persons.

[5] namely Coloplast GmbH, Hollister Incorporated Niederlassung Deutschland, Teleflex Medical GmbH, and Wellspect HealthCare (DENTSPLY IH GmbH)

12. Demands/summary

Up to now the German healthcare system has been regarded as one of the best worldwide. By reducing the number of urinary tract infections through the introduction of intermittent self-catheterization instead of permanent catheterization it has been possible to half the incidence of renal failure and mortality in paraplegic patients.[18] Amongst other things this has led to a rise in costs for medical technical aids.

The treatment of chronic renal failure with dialysis is among the most expensive therapies. Each case of renal failure avoided therefore significantly reduces the burden on the solidarity system.

However, the additional costs of ISC are possibly offset even by the lower rate of urinary tract infections and the fact that care for a permanent catheter is no longer necessary.[18]

Therefore, it is important that we help the relevant patient group regain part of their independence and self-determination – without any additional contributions. It is up to the health insurance funds to review the quality of care when developing contracts, tenders, etc. so that cost savings are not achieved at the expense of the patients. The political institutions should ensure that the contracts of the funds guarantee both the necessary product and service quality and the required volumes. This should be achieved by introducing accompanying mandatory controls to monitor the fulfillment of the details of the contracts.

Medical progress must not suffer because of economic considerations. In the interest of the patients' health a change from ISC to permanent catheterization for financial reasons must be prevented.

It is important to put a stop to a competition focusing on price alone and to take the right steps towards an economic competition for the best quality. After all, experience shows that eventually quality pays off.

Optimization and rationalization processes are desirable if through them the necessary medical care can be secured and improved. They must not, however, endanger the state of health of the patient.

In order to provide the patients with devices that comply with the current state of medical technology, the legal framework for the register of medical technical aids must be adjusted. Moreover, the register must be updated regularly.

The patients' quality of life and needs, as well as the therapy goals of the physician, must again become the measure of care instead of the sweeping calculation based on a pot of money practiced by the health insurance funds.

To this end, a system of ongoing exchange and regular discussions with all those involved in the care process, e.g. patients, health insurance funds, specialist physicians, and providers and manufacturers of medical technical aids, should be established. Only our joint efforts will be able to improve the situation.

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