Enteral Nutrition Reimbursement –
The Rationale for the Policy: The German Perspective

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Abstract
Both the German statutory and private health insurances cover enteral nutrition (EN) products. Approximately 100,000 patients receive reimbursed EN; 70% are tube fed for an average 9 months. 70% of the tube-fed patients are cared for in institutions (i.e. for the elderly) and 30% at home. The prescription and reimbursement of EN is covered by Volume Five of the Social Legislation Code (Social Code Book No. 5). Reimbursement for EN depends on medical prescription and is in principle guaranteed whenever normal food intake is impaired and modification of normal nutrition and other measurements do not improve nutritional status. It is unclear what effect the reform laws will have on EN but they may impact the prices for medical devices and negotiations between health insurance funds and product manufacturers.

Introduction: The German Healthcare System

Roughly 10% of the German gross domestic product is spent per year on health services in the broadest sense (approximately EUR 200 billion or USD 290 billion). Approximately EUR 125 billion (USD 175 billion) are accounted for by the statutory healthcare system, which links 82 million insured, more than 100,000 office-based physicians, 22,000 pharmacies, 2,200 hospitals and roughly 300 private and statutory health insurers. The funding of statutory healthcare and access to it is based on the concept of solidarity: wage-indexed contributions are made according to the financial abilities of the insured who receive benefits that correspond to their needs. At present, employees pay an average 7.5% of their salary for health insurance coverage, with their
employers contributing 6.6%. The choice of not remaining in the social sys-
tem has been made on a voluntary basis by 10% of the population who wish
to be privately insured due to their income (>USD 4,700/month) or because
they are self-employed.

The German statutory and private health insurances offer a comprehensive
package of services, including outpatient treatment and hospital treatment,
all necessary medication, dental treatment, dental prostheses, rehabilitation
as well as enteral nutrition/food for special medical purpose (FSMP) prod-
ucts. In principle they even reimburse every newly licensed drug and medica-
dal device without limitations which, on a global comparison, is unusual. All
other insurance schemes and healthcare systems throughout the world limit
the range of benefits and reimbursement by means of positive lists and/or by
means of admission hurdles. The pharmaceutical industry sets their prices
freely without control by authorities; neither prices nor profits are officially
controlled under the precondition that the products show evidence of a thera-
peutic improvement for patients compared with already existing products. In
these cases the statutory health insurance funds in Germany fully reimburse
the price set by the manufacturer for every product for the duration of patent
protection. For all other products, the health insurance funds are allowed to
fix maximum reimbursement rates based on the price of comparable prod-
ucts. The prices for medical devices are generally negotiated between the
health insurance funds and the product manufacturers. If they form part of a
comprehensive hospital treatment, they are factored in the hospital rates.

The statutory health insurance and packages of service is governed by spe-
cial legislation which is laid down in Volume Five of the Social Legislation
Code (Social Code Book No. 5).

Medicament Provisions, Diagnostic and Therapeutic Measures
Are Defined through Directives: Responsibility of the Federal
Joint Committee

A special feature in the regulation of medical services of the German health-
care system is the important role, alongside that of the legislature, played by
the self-governing body of doctors and health insurance funds. The legisla-
ture creates the legal framework; the medical self-governing body, formed
from the national associations of doctors and dentists, the German Hospital
Federation and the health insurance funds, gives concrete definition to the
legal requirements and implements them. The paramount decision-making
body of the joint self-governing body is the Federal Joint Committee (G-BA).
The G-BA was institutionalized by legislature as a legal entity under public
law. It has wide-ranging regulatory powers. The various duties and wide-rang-
ing powers of this committee are also laid down in Social Code Book No. 5,
which governs statutory health insurance.
One important area of responsibility of the G-BA concerns the assessment of new methods of medical examination and treatment. In the sphere of ambulatory (outpatient) care in particular, the G-BA represents the ‘eye of the needle’, through which a new method must gain positive evaluation in terms of benefit and efficiency before it can qualify for reimbursement from the statutory health insurance funds. The Federal Committee’s assessment of medical treatments and procedures follows a standardized procedure which rests on evidence-based medicine. The generally accepted current state of medical knowledge is ascertained for the purpose of assessing the effectiveness, quality and economic efficiency of the methods examined. The Federal Committee, however, is not responsible for licensing medicaments for the German market; this is the task of the Federal Institute for Drugs and Medical Products. In other words: in Germany, a Joint Committee of Physicians and Health Insurance Funds – and not the State – decides which treatment procedures are reimbursed by health insurance and which are not. The representatives of the health insurance funds, doctors, dentists and hospitals used to make important decisions on their own.

The regulatory powers of the G-BA include:

- To encompass recommendations on requirements regarding the content of disease management programs
- To issue directives defining diagnostic and therapeutic measures and governing quality assurance in the ambulatory, inpatient and cross-sector spheres
- To issue the directives that are necessary for safeguarding medical provision. These aim to ensure that services for those with statutory health insurance in Germany is adequate, appropriate and efficient. The directives cover, for example, early diagnosis of diseases, dental treatment, psychotherapy and rehabilitation
- To regulate through the directives remuneration exclusions and restrictions in medicament provision based on the efficiency requirement

All directives issued by the G-BA are based on nationally and internationally recognized (evidence-based) guidelines and are submitted for approval to the Federal Ministry of Health. The Ministry responds within 2 months if it has any objections. Otherwise the directives are published in an official journal and come into force.

**Enteral Nutrition Reimbursement**

In the sphere of ambulatory (outpatient) care approximately 100,000 patients receive reimbursed enteral nutrition, 70% of them are tube fed for 9 months on average. 70% of the patients are institutionalized, i.e. homes for the elderly, and 30% are taken care of at home. The average costs per patient and month are accounted for by EUR 580–650. EUR 600 million are spent for
FSMPs in Germany per year: EUR 200 million for technical devices like tubes and pumps, and EUR 400 million for tube and sip feed.

Traditionally the prescription and reimbursement of enteral nutrition is also covered by Social Code Book No. 5, though FSMP products are neither drugs nor medical products. Consequently it fell under the responsibility of G-BA to issue a directive for prescription provisions. Since 2002 the Federal Committee has drafted such a directive three times and submitted it for approval to the Federal Ministry of Health. Applying the standardized procedure which rests on evidence-based medicine even for the dietary management of patients by means of enteral nutrition, the draft directive defined numerous exclusions and restrictions and thereby caused severe dispute with patient organizations, scientific societies and industry. Three times the Ministry responded as it had severe objections itself. As the committee refused to take the objections into account, the Ministry decided on its own to publish a directive with the necessary amendments; this came into force on October 1, 2005. A court case which aims to clarify whether the Ministry is empowered to act in such a way is still pending. A decision is not expected before the end of 2007.

According to the directive, reimbursement for FSMPs depends on medical prescription and is in principle guaranteed whenever normal food intake is impaired, and modification of normal nutrition and also other measurements do not adequately improve the nutritional status. Limitations for reimbursement exist for the type of enteral formula and the price level, but no submission is needed for a single product as long as the general legal regulation for reimbursement applies. No diseases/clinical conditions/indications are defined for reimbursement and no lists of recommended products exist. Enteral nutrition may be prescribed when adequate normal nutrition is impaired or not possible at all. Besides the medical prescription, no documentation is required.

The directive requires some compositional criteria for reimbursement as follows:

- Standard sip and tube feeds must contain $\geq 1$ kcal/ml for complete nutrition and must be consistent with the directive of the European Commission on foods for special medical purposes 1999/21/EC
- Fiber- or medium-chain triglyceride (MCT)-enriched formulae must not cause more costs than fiber- or MCT-free formulas
- Specifically composed age-adapted feeds for infants and children
- Disease-specific feeds for renal insufficiency
- Nutritionally complete sip feeds with highly hydrolyzed protein or amino acid mixtures for infants or children with cow's milk allergy or patients with multiple food allergies
- Low molecular or MCT-enriched products for patients with malabsorption (e.g. short bowel syndrome, HIV-associated diarrhea, cystic fibrosis)
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- Special amino acid mixtures (also products containing fats and carbohydrates) for patients with phenylketonuria or further inborn errors of enzymatic functions which are treated with special amino acid mixtures
- Special products for patients with rare inborn errors of carbohydrate and fat metabolism (depending on the disease also carbohydrate- or fat-free nutritional supplements) and for further diseases in need of specific dietary treatments
- Ketogenic diets for patients with epilepsy

All other disease-specific feeds are not reimbursed.

The directives do not lay down a specific pricing mechanism; the prices are set by the manufacturing company. The reimbursement of enteral feeds is 100% (health insurance) based on the purchasing price of pharmacies (AEP) minus EUR 5–10 per line of prescription, which is regarded as the patient contribution. Depending on the health insurance, there may be different rates in addition (e.g. AEP + 10%).

Reform

As early as 2003, Germany's two largest parties negotiated a comprehensive healthcare reform. This reform was also necessary because between 2002 and 2003, the statutory health insurance funds had run up deficits to the tune of EUR 3 billion (USD 3.6 billion) each year with a total expenditure of some EUR 140 billion (USD 170 billion). As a matter of fact, the reform significantly improved the funds' financial situation. The deficits turned into surpluses. In 2004, the funds chalked up a surplus of EUR 4 billion and a surplus of EUR 2 billion is expected for 2005. As a result, the unlawful indebtedness of the health insurance funds, which had risen to a total of EUR 6 billion (USD 7.3 billion), no longer exists.

Developments in medicine, pharmacology and medical technology along with demographic social and economic changes will put further pressure for rationalization measures on our healthcare system. Recently the reform law passed the governmental institutions and it should come into force on April 1, 2007.

It aims to stabilize the financing of the healthcare system and to reduce labor costs and thus help to boost the competitiveness of the national economy. To date it is unclear how the reform law will affect enteral nutrition. It is expected that the law will at least have an impact on prices for medical devices and the negotiations between the health insurance funds and product manufacturers.
Discussion

Mr. Jedwab: My job at Nestlé is product development and as I listen to this and some of the other presentations, the impression I have is that all these rules and restrictions are there for the obvious reason of cost containment which, in the end, will lead to a stifling of innovation. In other words, if we take the German case, when I see the list of things that is not covered today or will not be covered in the future, I wonder what the point is of a company like Nestlé even bothering to start costly innovation programs if there is no chance that we will ever be reimbursed or that it could work economically. Nestlé and the other companies are not charities, we have to answer to shareholders, like everybody. At the end of the day, I think the whole system coming into place is lose-lose situation for everybody. Cost cutting now won’t solve the issues for which there are needs for innovative products. By not treating the growing elderly population now and cutting out anything to do with malnutrition, it is just saving up the bill for the next generation. All of that is fairly negative, but on a more positive note, given the current climate in Germany, what is your opinion on how we can go about getting product XYZ covered? Assuming a great level of clinical proof, effectiveness and all the rest of it, what is the mechanism today by which we could go about influencing the various laws and regulations in countries like Germany?

Mr. Pahne: It is quite a difficult question. You are right that the evidence approach, if it is misunderstood, as is the case of the Federal Joint Committee, is innovation-blocking. What can we do, what can a company do to reach the goals? The very first thing to do is to try to make people understand the medical nutrition paradigm that we discussed yesterday. If you have a disease-specific product, it is not necessary to show evidence that it can cure the disease it is designed for, but to show that it helps the patient in a different way. In that way it is possible to save spending and costs. The cost argument is the most important one, but there is urgent need that the relationship between the product enteral nutrition on the one hand and the disease on the other hand is understood in the right way. This is not the case in Germany right now.

Mr. Jedwab: So, it’s back to health economics again?

Mr. Pahne: Yes, absolutely.

Mr. Tatakis: In 1991, there were 1,200 health funds while now there are only 250. What happened to the rest of them and their members? Second, do you see any shift from public to private spending? Third, looking at it more positively, since in the German system the incurables are excluded, are we then moving to a healthier society? Do you see a shift to private spending?

Mr. Pahne: Yes, there is a shift to private spending, but the problem is you have to distinguish between private spending of patients, if they pay for enteral nutrition on their own, and the private insurance system on the other hand. There is a shift towards the private insurance scheme but there are limitations because not everyone is allowed to become a member of the private insurance system. As far as the situation of privately bought products is concerned, there is a shift and companies in Germany would like to help this shift to private spending to increase. The patient is informed that there it is possible and necessary to get a private prescription from the doctor. In most cases, patients don’t know that it is possible to get a private prescription, but they have to pay for the product for themselves. In this case, the patients have to be convinced of the need for the products. Until now enteral nutrition products have not been well known in Germany, which is completely different to the situation in the US. Companies are switching to a different approach to make enteral nutrition and its advantages more public so that private people buy those products on a private basis. It is a different approach but it is a needed.
Mrs. Howard: Picking up a point that was made yesterday about the clinical remit being handed over to people who are telling us what to do, what is the composition of this Federal Joint Committee in terms of balance? How many clinicians are on it, how many bureaucrats, and how many lawyers? Is there any way to change that in the future? What is their term of office?

Mr. Pahne: The people on the Federal Joint Committee are, in most cases, physicians but are employed by either the health funds or physicians associations. So, they are more or less administrative people, and my experience is that most of them have never heard anything about nutrition. There is a lack of information and they do not know these products and they do not even understand the discussion if there is a hearing with people from the Medical Nutrition Society. They do not understand and still rely on the conventional medical paradigm. There is urgent need that these people somehow get an approach to medical nutrition, but I am not sure how this can be done. Due to the long process and long discussion procedure, it is a highly emotional issue in Germany now. Whenever we approach somebody from the Federal Joint Committee, just dropping the words ‘enteral nutrition’ upsets everyone. They do not listen to arguments anymore, so that is the situation and the reason why we have a court case now because discussion is over.

Mrs. Howard: So, I gather that no approach was made to the Enteral Nutrition Society in Germany which, I gather, is pretty active. What a shame!

Mr. de Man: I am just wondering whether another argument is being taken into account. There is a European Court decision that benefits European citizens who are not reimbursed in their own country but are reimbursed in others. Whether this is reimbursed or not by local insurance companies needs to be assessed in the context of the evidence within the international medical community, not just the German medical or healthcare community as such. The evidence that certain benefits will be paid should be assessed within the entire European medical community rather than the national medical communities. It will be interesting to see if this decision holds up in the European Court, and if there is enough evidence that enteral nutrition works for certain kinds of diseases. Of course, it also depends on how curative and expressions like that are defined. It may well be that this court decision can be some kind of benchmark or at least may play a role in how this case will be defined in the near future.

Dr. Kondrup: I think this is limited to ambulant patients. A roundtable is being prepared by the European Commission to start discussions, but I don’t know if this will be discussed at this level.

Mr. Pahne: Perhaps we will end up at the European High Court, and without a doubt that would be quite amazing. You cannot imagine the amount of publications, documentation, position papers and whatever was available throughout the world that has been presented to the Federal Joint Committee. The documentation was not measured in pages but in kilos. All this information was not sufficient because the evidence-based medicine approach that they made use of is not available in the publications. There is no proof that food can cure disease. It is as simple as that.

Dr. Van Emelen: Are there similar decisions in other fields besides nutrition? I can imagine that in chronic disease management, or decisions related to it, there are similar decisions if evidence-based medicine is not followed. There are probably other decisions that are quite illogical. Among the 253 health insurance funds, do any of them represent the interests of their members? I can imagine that a lot of initiatives have been introduced to change the discussion.

Mr. Pahne: You are right, the Federal Joint Committee does not only decide on the reimbursement of enteral nutrition but they decide on medical devices, on innovations, on drugs, and there are even more cases comparable to ours. The approach of the Federal Joint Committee is to bring down costs, to look at the benefits and the efficacy
of a measure. There are quite a lot of similar cases where the Federal Joint Committee decided that some drugs or measures are not reimbursed anymore. So, we are not alone in the world and this is due to costs. Like everywhere, we have emerging costs and spending trends in the German healthcare system. The percentage growth rate in our system has gone down from 25 to about 3% over the past few years. Although every year there was reform of the healthcare system or a new law, the names of the laws have become even more complicated. In the 1990s, it was Gesundheitsreformgesetz, and in 2006 it was Arzneimittelversorgungs-Wirtschaftlichkeitsgesetz.

From one reform to the next one, even more stakeholders are involved. The measures in the beginning of this century were budgets, contracts, regulations, prize moratoriums, and exclusions from prescriptions to local contracts. The responsibility during the first steps was shared by physicians, the health funds became involved, the pharmacists, the manufacturers, and now the patients. Because of the lack of financial resources, there is a cut of reimbursement everywhere, so we are not alone in the world and I think everyone has the same problem. There is a need to show that, from the economic approach, prevention at a very early stage may save quite a lot of money at later stages. Until now, there is a lack of delivery and understanding of these facts.

Dr. Elia: I have a question on the consistency of thought across medicine and medical practice. Although medicine might aim to cure disease, often it does not and it does not aim to do so. It may aim to alleviate pain, suffering, discomfort, and to make people feel better. So, if the principle is not to fund nutrition because it doesn’t cure diseases, theoretically that line of argument should apply to other fields of medicine. If it doesn’t, why has nutrition been targeted?

Mr. Pahne: This issue has been addressed to the decision-makers, it has been addressed even by members of this small circle, and by Dr. Lochs, the president of the German Association of Medical Nutrition Physicians. But either the members of the Joint Committee were not interested in listening and understanding or the message was too complicated. In the end it was not accepted at all. Perhaps the main reason was that there is the task or duty to save money and to save it wherever possible, despite the nice or good arguments. I think the main approach is cost and the decision was made on the basis of costs. The simple costs of enteral nutrition products are EUR 600 million/year in Germany. It’s not too much compared to total expenses, EUR 250 billion, but even this sum is so high that the Joint Committee decided to cut it down considerably. You are right, it is not saving, it is out of balance.

Dr. Elia: Exactly the same argument could be used to save costs in other fields of medicine because they don’t cure conditions. I presume here it is because nutrition is a soft option. This is a case where we have to stand strong and send a message back that this should not happen for nutrition.