Expert interview

Innovative diagnosis and treatment methods – regulation of their reimbursement in the German healthcare sector

The German healthcare cost reimbursement system differentiates between in- and outpatient medical products. In an interview with Caroline Ref and Jasmin Dabrowski from BIOPRO Baden-Württemberg, Michael Weißer, Chief Operating Officer of AIM GmbH in Lörrach, gives interesting insights into the reimbursement of medical care products, in particular with regard to the introduction of new and innovative diagnosis and treatment methods.

Medical products are used both in outpatient and inpatient care. How is the remuneration system for in- and outpatient medical services regulated in Germany?

As far as ambulatory treatment is concerned, the therapeutic and diagnostic methods used are subject to authorisation from the respective authorities. This means that innovative medical procedures and products do not become part of the statutory health insurance (SHI) reimbursement system until they have been officially examined and approved essentially on the basis of their application. This is where the Federal Joint Committee (G-BA) plays a decisive role. The G-BA carries out a benefit assessment in order to determine the benefits of the method and whether it should become an integral part of SHI remuneration. Benefit assessments can take several years. Different rules apply to certain medical products (notably medical aids, drug-like medical products, wound dressings) and in some cases also application procedures initiated by manufacturers.

Federal Joint Committee (G-BA) and Institute for Quality and Efficiency in Healthcare (IQWIG)

The Federal Joint Committee (G-BA) is the highest decision-making body of the German joint self-governing system of physicians, dentists, hospitals and health insurance funds. The G-BA has the authority to make decisions relating to the benefits catalogue of SHI schemes, thus specifying which medical care services are reimbursed by the SHI. In addition, the G-BA specifies measures for quality assurance in inpatient and outpatient areas of the German healthcare system.
Prior to making any decision, the G-BA regularly commissions the Institute for Quality and Efficiency in Healthcare (IQWiG) to prepare scientific reports/assessments on the relevant medical measure. The IQWiG also develops comprehensible health information for the public, as well as scientific reports on health topics suggested by members of the public.

Quite the opposite applies to the reimbursement of inpatient treatment. In this case, innovative procedures are permitted with so-called reservation of prohibition. This means that an innovative diagnosis and treatment method may in principle be applied by hospitals as long as it has not been excluded by the G-BA in accordance with § 137c SGB V.

Reimbursement of hospital services by the health insurance funds is based on the German Diagnosis Related Groups system (G-DRG system). It goes without saying that the hospitals have to adhere to certain principles. Basic quality and profitability requirements must be met. The method must also have the potential to be a valid alternative to the current standard.

**DRG codes**

Since January 2004, German hospitals have been required to classify diseases into so-called “Diagnosis Related Groups” (DRG). The DRG system is used to classify treatment cases based on financial aspects. A DRG code is assigned to each patient during a hospital stay. Hospitals for patient cases with similar medical problems and similar treatment costs are given the same DRG for the hospital stay.

What about methods that are not included in the DRG code, where costs would therefore exceed the current base rates?

**Neue Untersuchungs- und Behandlungsmethoden (NUB)**

Every autumn, all hospitals are given the opportunity to submit requests for reimbursement of “new and innovative diagnosis and treatment methods” (NUB; Neue Untersuchungs- und Behandlungsmethoden) that have not yet obtained a G-DRG code to the InEK, the Institut für das Entgeltsystem im Krankenhaus (Institute for the Hospital Remuneration System), which subsequently checks whether the method is already properly remunerated as part of the existing DRG pricing system and whether it is in principle a “new and innovative diagnosis and treatment method”. If the method meets InEK criteria, it is given status 1 and the InEK recognises the method as NUB. The following year, the hospital may negotiate with insurance companies regarding additional charges for the method.

How long does it take for DRG codes to be adjusted, i.e. before “innovative diagnosis and treatment methods” are included in DRG codes?

How many requests for NUB reimbursement are submitted per year?

Up to around 700 different NUB reimbursement requests have so far been submitted on an annual basis. Around 25% of these have been given positive status, i.e. status 1.
In short, obtaining remuneration status requires a great deal of patience. So when should start-ups start dealing with this topic?

From experience, I would say that it makes sense to start dealing with the issue around a year before CE certification is planned. Especially in cases when the start-ups plan to start commercialising their products immediately after obtaining the CE mark.

In any case, it is important to deal with the issue at a very early stage, find out how everything works and which clinical evidence is needed. As I see it, it's also important to find out what needs to be done in order to guarantee that the end customers can actually get the product/procedure reimbursed. Furthermore, the start-up can already start looking at the markets that it wants to serve and how the reimbursement systems of these markets are structured.

---

**Expert interview: Part 2**

New § 137h SGB V in the German reimbursement system – what will change for medical device manufacturers?

**About AiM GmbH**

AiM GmbH has been providing support to the medical device industry for 10 years and since 2014 has been part of the IGES Group, a network of research and consulting companies from the infrastructure and healthcare fields. The core of the IGES Group is the IGES Institute, founded in 1980. The IGES Institute provides comprehensive knowledge and tools to healthcare system, transport and education sector stakeholders to enable them to make well-informed decisions. In addition, the company network also involves the CSG Clinical Studies Group, which is active in the field of clinical research, as well as IMC clinicon, a consulting and service institute specialised in hospitals.

With regard to "evidence-based cost reimbursement", AiM GmbH develops concepts for the smoothest possible market introduction of medical devices. AiM’s support includes advice on appropriate study protocols, the performance of cost reimbursement research, the elaboration and implementation of market access strategies.

Another area that AiM is involved in is the preparation of benefit assessments and health economy models. The company uses scientifically established methods used by evaluation institutes or decision-makers such as the IQWiG and the G-BA. AiM also provides support for preparing and monitoring selective contractual negotiations between service providers and cost bearers.