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How to get listed in the digital health applications directory

With the Digital Healthcare Act (DGV), for the first time statutorily insured persons are entitled to healthcare services involving digital health applications (DiGA) in Germany. In cooperation with the insurers, DiGA may be utilized for patients for instance in the recognition, treatment or alleviation of diseases or injuries. As per definition, apps for contraception are not classified as DiGA. DiGA may only be prescribed at the expense of statutory health insurance (SHI), if they are listed in the DiGA directory.

Figure: Ecker + Ecker GmbH

More about DiGA

Listing in the DiGA directory and demonstration of positive healthcare effects

In order to be listed in the DiGA directory, manufacturers have to officially apply to the Federal Institute for Drugs and Medical Devices (BfArM) as per German Social Code (SGB V), § 139e. With this application, they have to prove the fulfillment of general requirements on safety, suitability for use and quality as well as on data protection and data security. The requirements on suitability for use and safety are considered as generally fulfilled with the CE marking. Since January 1, 2023, the manufacturers must prove the fulfillment of data security requirements through a certificate from the BSI (German Federal Office for Information Security). In addition to these general requirements, positive healthcare effects have to be demonstrated. Apart from the medical benefit, the legislator has introduced patient-relevant improvement of structure and processes as a category for the demonstration of positive healthcare effects. These include e. g. adherence, health literacy and patient autonomy.

BfArM decision (Fast-Track Process)

After submission of the application in the electronic application portal for the fast-track procedure for DiGA (DiGA application portal), the BfArM makes a decision about the inclusion of the application into the DiGA directory within 3 months. If the manufacturer has not sufficiently demonstrated any positive healthcare effects yet, a provisional listing in the DiGA directory for 12 months is still possible, provided that the other requirements are fulfilled and a scientific evaluation concept prepared by a manufacturer-independent scientific institution presents a plausible rationale as to the expected healthcare effect. In that case, a 12-month trial period in the regular medical care of SHI will start, during which the DiGA is already reimbursed at the price set by the manufacturer. After 12 months at the latest, the manufacturer has to subsequently submit proof of positive healthcare effects to the BfArM in order to obtain a final listing in the directory.

DiGA currently listed

Seventeen out of a total of 45 currently listed DiGA have a final listing in the DiGA directory. Among them are 7 DiGA which were able to demonstrate their positive healthcare effects during the provisional listing period and subsequently switched to a final listing.

However, manufacturers often do not succeed in reaching a final listing for all indications they had originally applied for at the time of the provisional listing. Thus, according to the BfArM decision, the reimbursability of 4 of those DiGA is limited to specific indications or age groups. Furthermore, 5 DiGA have so far been completely removed from the directory, as they were not able to demonstrate a benefit during the provisional listing period. The manufacturers of the final listed DiGA were all able to demonstrate a positive healthcare effect on the basis of a randomized controlled trial (RCT). Overall, the DiGA directory covers numerous indications which are continuously extended and already comprise e. g. musculoskeletal disorders, diseases of the nervous system, as well as mental, hormonal and metabolic, and cancerous diseases.

Price negotiations

Following the listing in the DiGA directory, the National Association of Statutory Health Insurance Funds (GKV-SV) and the manufacturer negotiate the remuneration sum as per § 134 SGB V. For that purpose, the GKV-SV and the associations representing the manufacturers have concluded a framework agreement regulating e. g. the constitution of the arbitration board, the determination of the actual prices in the first year, the calculation of maximum prices and thresholds, the rules of procedure such as deadlines and schedules, as well as invoicing rules. The remuneration sum is effective as from the second year after inclusion of the DiGA into the directory.

In case that the provisionally listed DiGA has been cancelled from the directory, GKV-SV and the manufacturer have to negotiate the claims for compensation for the period starting from the 13th month after the listing of the DiGA in the DiGA directory. The claims for compensation equal the difference between the price that have been charged to the health insurance funds for the cancelled DiGA so far, and the remuneration sum with the knowledge of the cancellation from the DiGA directory.

Arbitration board

In case that no agreement between the GKV-SV and the manufacturer is reached within a certain period of time, the arbitration board sets the remuneration sum within a period of 3 months. In the case of a permanently listed DiGA, this time period ends after 9 months, and in the case of a provisionally listed DiGA, the time period ends 3 months after the BfArM's positive decision on the permanent listing in the DiGA directory.

The arbitration board has set the remuneration sum for a DiGA for the first time in 2021 (arbitration award of Dec. 17, 2021 for somnio). Since then, the prices for 5 more DiGA were set by the arbitration board (velibra, elevida, deprexis, vorvida, and Vivira). The arbitration awards clearly show what the arbitration board uses for orientation in the pricing of DiGA. Technically speaking, in its previous decision-making practice the arbitration board has developed a model for the pricing of DiGA in the area of mental diseases. This was lastly also applied to Vivira (arbitration award of Jan. 10, 2023) for the treatment of back pain.

The arbitration board has recently also determined the amount of claims for compensation in the case of the cancelled DiGA M-sense Migräne (arbitration award of Sept. 7, 2022). Here the arbitration board has taken into account that, on the one hand, there will be no incentives for future manufacturers to take a DiGA to a prolongation of the trial period and to have it cancelled then from the directory without any proof of benefit, and, on the other hand, that care has nevertheless taken place.

In the case of the arbitration award for the DiGA Vivira (arbitration award of Jan. 10, 2023) a compensation was lastly claimed also for the indications knee- and hip pain that BfArM had cancelled.

Furthermore, the arbitration board has issued a ruling on maximum prices and thresholds for DiGA (arbitration award of Dec. 15, 2021).

Maximum prices and thresholds

According to the arbitration award, DiGA are grouped together according to their respective indications and the category of their positive healthcare effect for the purpose of setting maximum prices. Based on the actual prices (prices before price negotiation), group-specific maximum prices are determined every 6 months. DiGA that are listed provisionally and that cannot be assigned to a specific group, will be put into a fallback group. Additionally, an exemption has been defined for DiGA that are intended for the treatment of orphan diseases and DiGA that are based on artificial intelligence (AI). For example, an exemption was recently claimed for the DiGA companion patella due to the implementation of AI (arbitration award from April 11, 2022). The DiGA has thus been excluded from the grouping.

Besides maximum prices, thresholds were defined below which no price negotiation is mandated. The thresholds are a moving annual total revenue of maximum 750,000 Euro and an actual price below 25 % of the average price of all DiGA in the DiGA directory. When both criteria are fulfilled in conjunction, there will be no price negotiation with the GKV-SV.

Prescription and reimbursement of the DiGA

As long as electronic prescription processes are not implemented yet, the physician prescribes the DiGA using the sample prescription form 16. The patient then submits the prescription to their insurance company and receives a prescription code for the activation of the DiGA in return. In the long term, e-prescription via the telematics infrastructure will be possible.

Irrespective of a potential tentativeness of the listing, it is guaranteed that the physician may provide potential “new” or not yet reimbursable examinations, consultancy and therapies associated with the DiGA at the expense of the SHI. To facilitate this, the Physicians' Fee Scale (EBM) will be adjusted after the initial listing of the DiGA.

More about DiGA

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