5TH DIGITAL HEALTH SOCIETY SUMMIT

reimbursement models for digital healthcare

Hamburg

DIGITAL HEALTH APPLICATIONS (DIGA)

DiGA are reimbursable digital medical devices with a low risk that support the detection, monitoring, treatment or alleviation of diseases

"Insured persons are entitled to care with low-risk medical devices whose main function is essentially based on digital technologies, and which are intended to support the detection, monitoring, treatment or alleviation of illnesses or the detection, treatment, alleviation or compensation of injuries or disabilities in the insured person or in the care provided by service providers (digital health applications)." (Section 33a (1) SGB V)

Note: In the Digital Act, which comes into force in 2024, the scope of application of DiGAs will also be extended to medical devices of higher risk classes, for example to cover telemedical monitoring (risk class IIb) (Section 33a (1) sentence 1 SGB V)

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DIGITAL HEALTH APPLICATIONS (DIGA)

- **The so-called "apps on prescription" are modern therapy companions and enable greater therapy success**

- **Patients can use a DiGA either alone or together with their doctor**

- **Authorisation is granted by the BfArM, where a so-called "positive care effect" must be proven. This can be either a medical benefit or a patient-relevant structural and procedural improvement (Section 139e (1) SGB V)**

- **s it is often difficult for start-ups to immediately prove a benefit for the new application, manufacturers can also be included in the register for 12 months initially on a trial basis and provide evidence during this time (Section 139e (4) SGB V)**

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DIGITAL HEALTH APPLICATIONS (DIGA)

- **Since 27 May 2020, DiGA manufacturers have been able to apply to the BfArM for inclusion in the DiGA directory. Inclusion in the DiGA directory legitimises the manufacturer of the DiGA to negotiate remuneration with the payers.**

- **There are 48 available DiGAs, of which 22 are provisionally included and 26 permanently (DiGA directory | Digital health applications on prescription as of 02/11/2023)**

- **The following categories are covered by the DiGA: psyche (24 DiGA), muscles, bones and joints (six DiGA), metabolism (five DiGA), nervous system (three DiGA), ears (DiGA), urogenital system (two DiGA), other diseases (two DiGA), cardiovascular system (one DiGA), respiratory system (one DiGA), digestion (one DiGA), cancer (one DiGA)**

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DIGITAL HEALTH APPLICATIONS (DIGA)

- **People with statutory health insurance have the option of obtaining a DiGA via a prescription following a medical or psychotherapeutic decision, or they can apply directly to their own health insurance provider (Section 33a (1) No. 2 SGB V). In the latter case, they must provide evidence of a corresponding diagnosis to the health insurance fund.**

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THE HEALTH INSURANCES SUBMITS AN ANNUAL REPORT ON THE UTILIZATION OF DIGAS TO THE FEDERAL MINISTRY:

- Between 2020-2022, around 203,000 DiGAs were prescribed by a doctor or authorised by the health insurance fund (89% prescribed by a doctor, 11% authorised by the health insurance fund)

- The five most frequently used DiGAs account for 66% of all prescriptions

- The majority of DiGAs are located in the indication area "mental illness" and accordingly most prescriptions can be observed there

- The second most common category, with the most prescriptions, can be found in the indication areas "metabolic diseases" and "musculoskeletal diseases"

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OUTLOOK

Digital care applications (DiPA) are now also eligible for reimbursement (DiPA Ordinance of 6 October 2022) (Section 40a SGB XI). They are intended to support people in need of care in their independence, to promote their abilities or to facilitate care and support by relatives. This can include, for example, offers for leisure activities, memory training or fall prevention, or products that are used for communication with relatives or the care service.

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