Fast Track for Digital Health Applications

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Introduction
German health care system – key Figures

• Population: 83 million

• Covered by statutory health insurance: 73.3 million

• Among the largest integrated health care markets
New entitlement for members of statutory health insurance funds

• § 33 SGB V: medical aids
• §§ 33a, 134 SGB V: Digital Health Applications
  ▪ on prescription or if approved by health insurance fund
• § 32 SGB V: medical services such as physiotherapy or speech therapy
• § 31 SGB V: drugs
DVG and DiGAV

Digitale-Versorgung-Gesetz (DVG), 12 December 2019

Digitale Gesundheitsanwendungen-Verordnung (DiGAV), 21 April 2020
What is a DiGA?

**Definition** of Digital Health Applications (DiGA):

- medical device I or IIa
- supports the recognition, monitoring, treatment or alleviation of diseases, injuries or disabilities
- main function based on digital technologies
- used only by the patient; or by the patient and the healthcare provider together

**Requirements** for being listed in the DiGA Directory:

- Safety and performance (MDD / MDR)
- Data protection, information security and further quality requirements
- positive healthcare effects
Application and Requirements
Application for final or preliminary listing in the DiGA Directory

Framework agreement

Associations of manufacturers

GKV-SV (Ntl. Assoc. of Publ. Health Care Funds)

Optional: Price caps

Manufacturer

Negotiations on price

Manufacturer’s price

DiGA can be prescribed by all physicians; all statutory health care funds will cover costs/reimburse manufacturer

Negotiated price

(valid from month 13; renegotiable after 12 months)

BfArM

Application for final or preliminary listing

Approval

Monat

0

+3

+12 (up to 24)
DiGA Guide
https://www.bfarm.de/EN/MedicalDevices/DiGA/_node.html
Data protection

• DiGAV specifies and supplements the requirements of the General Data Protection Regulation (GDPR)

• If not permitted or required by other legislation, processing of personal data is based on consent and restricted to specific purposes:
  # intended use, # evidence/trials § 139e, # agreements § 134,
  # permanent guarantee of technical functionality and further development of the DiGA

> no extensive tracking for advertising purposes
> no data processing outside EU
Information security

• Information security concerns product and organization; manufacturers need to provide “state-of-the-art“ information security at any time.

• requirements refer to the protection of confidentiality, integrity and availability of all data processed via a DiGA

• specifications in the DiGAV for information security are based on the relevant publications and recommendations of the Federal Office for Information Security (BSI),

• ISMS (information security management system) must be implemented from 2022 onwards
Interoperability and further quality requirements

- **Interoperability**: using standards
- **Robustness**: no loss of data, transmission errors etc.
- **Consumer protection**: no advertising, transparency, user support
- **Ease of use**: intuitive learnability
- **Support for healthcare providers**: explain use of DiGA in therapy
- **Quality of medical content**: based on recognized medical standards
- **Patient security**: lower risks by appropriate measures
Positive healthcare effects

DiGA listed in the directory must have proved one or more positive healthcare effects.

According to the definition in DVG and DiGAV, positive healthcare effects (positive Versorgungseffekte, pVE) are
> either a medical benefit (medizinischer Nutzen)
> or a patient-relevant improvement of structure and processes in healthcare (patientenrelevante Struktur- und Verfahrensverbesserungen, pSVV).

pSVV aimed at
> supporting the health behaviour of patients or
> integrating the processes between patients and healthcare providers

pSVV include in particular the areas of:

1. coordination of treatment procedures,
2. alignment of treatment with guidelines and recognized standards,
3. adherence,
4. facilitating access to care,
5. patient safety,
6. health literacy,
7. patient autonomy,
8. coping with illness-related difficulties in everyday life, or
9. reduction of therapy-related efforts and strains for patients and their relatives
Pricing
Pricing - manufacturers

Initial phase of reimbursement (from months 1 to 12):
„manufacturer’s price“
• price regulated in framework agreement
• Framework agreement provides guidance on calculation and/or price caps for individual groups of DiGAs
• Price caps depend on evidence provided by manufacturers
• No additional charges for patients

Second phase of reimbursement (beginning at month 13):
„negotiated price“
• Individual negotiations between manufacturer and GKV-SV:
• Based on positive healthcare effects
• German market prices
• Prices in further European countries
• Regulated by the framework agreement
• Performance based reimbursement (partially)

• Price applies to all statutory health care funds
• No additional charges for patients
Pricing – Physicians and psychiatrists

- BfArM will determine if a DiGA requires complementary treatment by physicians and psychiatrists
- Efforts of physicians and psychiatrists will be remunerated
- GKV-SV and self-governing bodies of physicians and psychiatrists will agree on remuneration within three months after BfArM listing (final and preliminary)
- No quantitative limitations for physicians
Coming soon...
First DiGAs coming soon

- 19 Dec. 2019: DVG entered into force
- 21 April 2020: DiGAV entered into force
- 19 Feb. 2020: Public hearing on draft DiGAV
- 5 May 2020: BfArM published DiGA guide
- 27 May 2020: BfArM examines first DiGAs
- 21 April 2020: BfArM receives first applications
- 18 Nov. 2020: BfArM approves first DiGA (estimated)

Start DiGA Directory
First DiGAs comming soon

• Since 27 May 2020: 25 applications for BfArM listing and 71 requests for advice
• Wide variety of indications e.g. diabetes, hypertension, psychiatric diseases, pain, obesity...
• Negotiations on framework agreement on pricing are ongoing; first results expected in October 2020
First DiGAs coming soon

Prescriptions:

• Initial phase: paper-based prescriptions (“form 16“)

• For a transitional period: Prescriptions to be filled via service apps of individual statutory health care funds and personal release codes

• Mid-term perspective: electronic prescription within national health infrastructure (TI/ gematik)
Thank you for your attention!

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