Freie Hansestadt Bremen

Apply for inclusion of a digital health application (DiGA) in the DiGA directory

If you are a manufacturer of a digital application that is to be included in the DiGA directory as a digital health application (DiGA), you must submit an application to the Federal Institute for Drugs and Medical Devices (BfArM).

Competent Department

- Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

Basic information

Since the Digital Healthcare Act (DVG) came into force, people insured under the statutory health insurance scheme (GKV) have been entitled to be provided with digital health applications (DiGA). These are, for example, medical health apps that can be prescribed by doctors and psychotherapists and are reimbursed by the health insurance fund. These are exclusively medical devices in risk classes I, IIa or IIb.

The prerequisite for this is that

- the DiGA must have successfully passed a test procedure at the Federal Institute for Drugs and Medical Devices (BfArM) and
- are listed in the "Directory of reimbursable digital health applications" (DiGA directory).

Only you as the manufacturer of the medical device or a person authorized by you can submit an application for inclusion in the directory. Inclusion in the BfArM directory is a prerequisite for reimbursement as part of the standard care provided by statutory health insurance (SHI).

The procedure is designed as a fast-track process: The BfArM usually evaluates the complete application within 3 months. Only in justified individual cases can the deadline be extended by up to a further 3 months. If there is sufficient evidence of positive treatment effects, the product is permanently included in the DiGA directory. If there is not yet sufficient evidence of the positive effects on care, an application for provisional inclusion can be submitted. The trial period is a maximum of 12 months. During this period, data can be collected, for example as part of clinical trials. In exceptional cases, this period can also be extended by a further 12 months.

However, when planning the extended trial period, the three-month evaluation period of the submitted evidence by the BfArM must be taken into account. Accordingly, proof of the positive supply effect must be submitted at least 3 months before the end of the extended trial period. This ensures that the duration of the trial period is limited to a maximum of 24 months in the event of an extension.

If you require support from the BfArM, you can arrange a consultation appointment with the Institute. The BfArM will advise you on the requirements for inclusion in the DiGA directory in order to support you at an early stage in generating meaningful documents and data for inclusion.

Requirements

To be listed in the directory, a DiGA must fulfill the following requirements:

- Security and functionality,
- data protection and information security,
- quality, in particular interoperability, and
- proof of positive supply effects, depending on the type of application.

What documents do I need?

- Power of attorney of an authorized person to submit the application, if applicable
- Declaration of conformity
- CE certificate, if applicable
- Certificate on the implementation of an information security management system (ISMS) according to ISO 27001 or according to ISO 27001 on the basis of IT-Grundschutz (BSI standard 200-2: IT-Grundschutz methodology)
- Proof that a penetration test has been carried out and that the vulnerabilities found have been remedied
- Instructions for use
- Study(s) to demonstrate positive effects on care or results of a systematic data analysis to justify the improvement in care (study protocol, study report)
- Scientific evaluation concept, if applicable
- Study to determine the test accuracy of the diagnostic instruments contained in the DiGA (if applicable)
- Minutes of the consultation with the BfArM (if applicable)
- Disclosure of data where legal requirements for the protection of trade and business secrets or the protection of personal data or intellectual property preclude publication
- Further documents, if further evidence is requested by the BfArM as part of the review

Procedure

The entire application procedure is carried out exclusively electronically via the BfArM application portal. The link can be found on the BfArM website.

- In order to submit an application for inclusion of a DiGA in the directory, you must register.

- To do this, you must create a user account (for initial registration). The following steps are necessary for this:
  - Registration in the portal with a valid e-mail address, the use of a functional e-mail address is recommended for data protection reasons.
  - Confirm the e-mail address via a link in the mailbox and
  - Set a password.
- For the submission of applications and notifications: Extended Validation (EV) certificate must be available and the public part of the certificate must be uploaded to the portal.

After successful registration, you can create one or more DiGAs in the application portal and complete and submit the following online forms for applications and notifications for each DiGA - depending on the issue:

- Application for inclusion in the DiGA directory
- Application for extension of the trial
- Submission of evidence for final inclusion in the DiGA directory after testing
- Notification of significant changes
- Application for removal from the directory

The application procedure begins when you have submitted the complete application for inclusion of a DiGA in the DiGA directory to the BfArM.

- Once the application procedure has begun, the BfArM first carries out an incoming goods inspection to check the formal completeness of the documents and evidence submitted.
- If the documents and evidence are complete, the BfArM will confirm receipt of the application documents within 14 days, stating the date of receipt as the start of the processing period.
  Otherwise, you will receive a letter with a list of the information and documents that still need to be corrected or submitted.
- At the heart of the procedure are the
  - checking the manufacturer's information on the required product properties
  - as well as the examination of proof to be provided by the manufacturer of the positive supply effects that can be realized with the DiGA.
- Upon receipt of a positive decision on the inclusion of a DiGA in the list, it will be published there.

Legal bases

- § 33a Sozialgesetzbuch (SGB) Fünftes Buch (V)
- §139e Sozialgesetzbuch (SGB) Fünftes Buch (V)
- Verordnung über das Verfahren und die Anforderungen zur Prüfung der Erstattungsfähigkeit digitaler Gesundheitsanwendungen in der gesetzlichen Krankenversicherung (Digitale Gesundheitsanwendungen-Verordnung - DiGAV)
- Gesetz zur Beschleunigung der Digitalisierung des Gesundheitswesens (Digital-Gesetz – DigiG)

More information

The BfArM charges fees for the processing of applications and notifications (inclusion of DiGA in the DiGA directory, notification of significant changes). Details can be found under Fees/Costs and related publications.

Appeal: Detailed information on how to lodge an appeal can be found in the notification of your application.

What deadlines must be paid attention to?

If the BfArM determines during the review that the application documents are incomplete, it will ask you to complete the application within a period of up to 3 months and submit the changes or additions via the application portal.

How long does it take to process

After receipt of the complete application. In justified individual cases, the deadline can be extended by up to a further three months.

What are the costs?

Decision on inclusion in the list

Fee: 1,500 - 9,000 EUR
Change notices

Fee: 300.00 - 4,900 EUR

Application for extension of the trial

Fee: 1,500 - 4,900 EUR
Submission of evidence for final inclusion in the DiGA directory

Fee: 1,500 - 6,600 EUR
Deletion from the list

Fee: EUR 200.00