

REMUNERATION OF DIGITAL HEALTH APPLICATIONS IN SWITZERLAND

A guide

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REMUNERATION OPTIONS FOR DIGITAL HEALTH APPLICATIONS IN SWITZERLAND: A GUIDE

A. Introduction

1. Aim of this guide

The aim of this guide is to provide an overview of the reimbursement options for digital health applications (German: digitale Gesundheitsanwendung = "**dGA**") in the Swiss healthcare system. The focus of the guide is on the reimbursability of dGA by health insurers. Both the various reimbursement models and the associated requirements are explained. References to sources of information, instructions for action and practical examples are intended to provide start-ups and SMEs with orientation in order to obtain sound information. The guide is aimed both at newcomers who are still unfamiliar with the Swiss healthcare system and at experts who want to deepen their knowledge in specific areas.

This guide does not constitute legal advice. Its sole purpose is to provide an overview of the remuneration options for dGA in the Swiss healthcare system. The information provided is intended as a general guide and cannot replace individual legal advice. For specific legal questions, it is recommended to seek qualified legal advice.

2. Potential of digital health applications

dGAs open up a wide range of possibilities to support the detection and treatment of diseases for both healthcare professionals and patients. In Germany in particular, the potential of **DiGA** (the German term for **dGA**) to increase the efficiency of healthcare provision has been recognised and promoted for years. Over 50 applications are currently (as of November 2024) included in the "**DiGA directory**"¹ of the German Federal Institute for Drugs and Medical Devices (BfArM) - and therefore in the reimbursement system under health insurance law. Since March 2024, France has also introduced "PECAN"² (La prise en charge anticipée numérique), a reimbursement pathway adapted to DiGAs and telemonitoring systems.

In comparison, the Swiss health authorities have so far been reluctant to embrace dGAs. Although the Federal Council has recognised the importance of digitalisation in the healthcare system as part of the "**eHealth Switzerland 2.0 Strategy**"³, implementation measures to date have been largely limited to the introduction of electronic patient records.

The Federal Office of Public Health (FOPH) has deliberately not yet introduced a reimbursement model specifically tailored to dGAs. Reimbursable, dGA-mediated medical services are to be added to the reimbursement lists generally available under current health insurance law. **For the time being, there is no explicit register for dGA in Switzerland.**

The integration of dGA into the Swiss healthcare system is currently proving cumbersome. The main reasons for this are the unclear cost implications and insufficient integration into existing

¹ <https://DIGA.bfarm.de/de/verzeichnis>

² <https://gnius.esante.gouv.fr/en/financing/reimbursement-profiles/early-access-reimbursement-digital-devices-pecan>

³ Strategy eHealth Switzerland 2.0 2018-2022, Objectives and measures of the Confederation and cantons for the dissemination of the electronic patient record and for the coordination of digitisation around the electronic patient record, Bern, 14 December 2018; see Section 3.1 "Vision".

systems and processes. In addition, the fragmented reimbursement structure hinders a standardised assessment of costs, which further complicates the market launch of dGAs.

Typically, treatment innovations lead to an initial increase in direct costs, such as for medical treatment, while indirect costs, such as lost working time for patients and relatives, and intangible costs, such as pain or loss of quality of life, tend to fall. However, there is currently a lack of reliable data for DGA to assess this dynamic in concrete terms.

At the moment, dGAs are mainly used as a supplement in Switzerland, which leads to an increase in volume and a rise in costs. However, with growing trust in dGA and wider acceptance, a substitution of conventional services could occur in the long term, which would offset the initial cost increase. To make this change successful, a nationwide strategy is needed that promotes interoperability, creates real added value and enables a well-founded cost assessment.

3. The Swiss healthcare system in brief

In principle, everyone living in Switzerland is obliged to take out health insurance.⁴ This compulsory health insurance (known as "**OKP**") offers protection in the event of illness, maternity and accidents. However, preventive services for the early detection of illnesses are not an essential part of the OKP.⁵ Instead, prevention campaigns are used in Switzerland, which are often financed from various sources, in particular from public funds.

In the event of illness, maternity and accident, the OKP only covers benefits that fulfil the criteria of **effectiveness, appropriateness and cost-effectiveness** (so-called "**WZW criteria**"). The legal basis for this is the Health Insurance Act ("**KVG**"⁶) and the associated ordinances (**KVV**⁷, **KLV**⁸). A user-orientated system applies to the reimbursement of services covered by the OKP: the starting point is the **principle of trust**, according to which it is generally assumed that the services provided by doctors are reimbursable if they are necessary for the treatment (see the explanations in chapter I.E.3). **In principle, doctors can therefore bill for all services provided that the WZW criteria are met.** It is the responsibility of the OKP to check compliance with these criteria. In the event of disputes regarding fulfilment of the WZW criteria, the competent court decides whether the OKP must pay for a particular treatment or medication.

In addition to the compulsory health insurance, it is possible to have **supplementary insurance** in Switzerland which is voluntary but comes at an extra cost.⁹ The legal relationship between the insured person and the respective supplementary health insurance is governed by a contract under private law, which is subject to the Insurance Contract Act ("**VVG**"¹⁰). Supplementary insurance makes it possible to cover benefits that are not covered by the

⁴ Sibilla Bondolfi; The Swiss healthcare system explained in brief; 2018; (https://www.swissinfo.ch/ger/gesellschaft/gesundheitspolitik_das-schweizer-gesundheitswesen-kurz-erklaert/44136626).

⁵ BAG Health Promotion & Prevention (<https://www.bag.admin.ch/bag/de/home/gesund-leben/gesundheitsfoerderung-und-praevention.html>).

⁶ SR 832.10 (https://www.fedlex.admin.ch/eli/cc/1995/1328_1328_1328/de).

⁷ SR 832.102 (https://www.fedlex.admin.ch/eli/cc/1995/3867_3867_3867/de).

⁸ SR 832.112.31 (https://www.fedlex.admin.ch/eli/cc/1995/4964_4964_4964/de).

⁹ <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-versicherte-mit-wohnsitz-in-der-schweiz.html>.

¹⁰ SR 221.229.1 (https://www.fedlex.admin.ch/eli/cc/24/719_735_717/de).

compulsory health insurance, such as alternative treatment methods, psychotherapeutic treatment by non-medical therapists or dental treatment. Supplementary insurance thus covers benefits that go beyond the statutory catalogue of benefits provided by the OKP.

B. Definition of digital health applications

Swiss legislation does not currently recognise a legal definition of dGA. The FOPH defines "digital health applications" in an information sheet as follows:

Digital health applications (dGA) are products that are used to promote health, support and inform patients or for medical purposes and that utilise digital technologies.

A dGA can be software, an app, a mobile device (e.g. sensors for recording body parameters and software for digital analysis or transmission), or a combination of these. Artificial intelligence (AI) can also be used. A dGA can also be used in combination with a non-digital physical product (e.g. bathroom scales). dGAs can be intended for self-use by patients or healthy individuals or for use by healthcare professionals.¹¹

According to the information sheet, dGA with a **medical purpose** are those dGA,

which are used for the early detection, prevention, diagnosis, monitoring, prognosis, treatment and care of diseases and their consequences or which are used during maternity. Digitally documented data can be used to make medical analyses and provide individual recommendations for action.¹²

In regulatory terms, dGAs with **software** with a medical purpose are medical devices that are placed on the market and in this case must fulfil the requirements of Swiss medical device law (Therapeutic Products Act [TPA; SR 812.21], Medical Devices Ordinance [MedDO; SR 812.213]). The category of such "**medical device software**" includes, for example, app-based therapy for diagnosed diseases, telemedical monitoring of people with chronic diseases or intelligent diagnostic devices with decision support systems for specialists in the treatment of diseases.

C. Requirements for eligibility for reimbursement under compulsory health insurance

For medical device software to be reimbursed by the OKP, **two (2) basic conditions** must be met: The software must be marketable as a **medical device** and fulfil the **WZW criteria**.¹³

In order to be marketable as a medical device, it is first necessary that it is actually a medical device in accordance with the Medical Devices Ordinance (MepV; SR 812.213), which is affirmed if it has a **medical purpose**. In addition, the other requirements of the MepV must be met, in particular with regard to **conformity assessment, technical documentation** and the **basic performance and safety requirements**. Qualification as a medical device,

¹¹ FOPH; Fact sheet "Remuneration of digital health applications under the OKP"; November 2024; p. 1 (https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/leistungen-und-tarife/faktenblatt-verguetung-dig-anwendungen-vers112024.pdf.download.pdf/Faktenblatt_Verg%C3%BCtung%20digitale%20Anwendungen_Version%20Nov%2024_DE.pdf).

¹² Ibid.

¹³ Art. 23 Health Care Benefits Ordinance (KLV; SR 832.112.31), Art. 25 et seq. Health Insurance Act (KVG; SR 832.10).

categorisation in a risk class and conformity assessment are mandatory for reimbursement as a benefit under the OKP.

D. Scope of the Health Insurance Act

Under health insurance law, there is no restriction on the number of services that can be reimbursed as long as these services fulfil the legally defined WZW criteria. It cannot be ruled out that a dGA may provide several different medical services, each of which is separately reimbursable under the OKP.

The following OKP areas are eligible for the remuneration of dGA in OKP:

- For the diagnosis or treatment of an illness and its consequences (Art. 25 KVG)
- In the context of care services (Art. 25a KVG)
- As prevention measures for persons at increased risk (Art. 26 KVG)
- As maternity benefits (Art. 28 KVG)
- As part of dental services (Art. 31 KVG)

The scope of the OKP may include, in particular, dGA with a medical purpose and, in some cases, dGA to support and inform patients (self-management). If dGAs have additional functionalities outside the scope of the KVG, such as a link to a social network, these are not taken into account in the context of OKP reimbursement. However, such additional functions must not have any influence on the medical effect or their appropriate use.¹⁴

¹⁴ FOPH; Fact sheet "Remuneration of digital health applications under the OKP"; November 2024; p. 3 (https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/leistungen-und-tarife/faktenblatt-verguetung-dig-anwendungen-vers112024.pdf.download.pdf/Faktenblatt_Verg%C3%BCTung%20digitale%20Anwendungen_Version%20Nov%2024_DE.pdf).

E. Remuneration options for dGA

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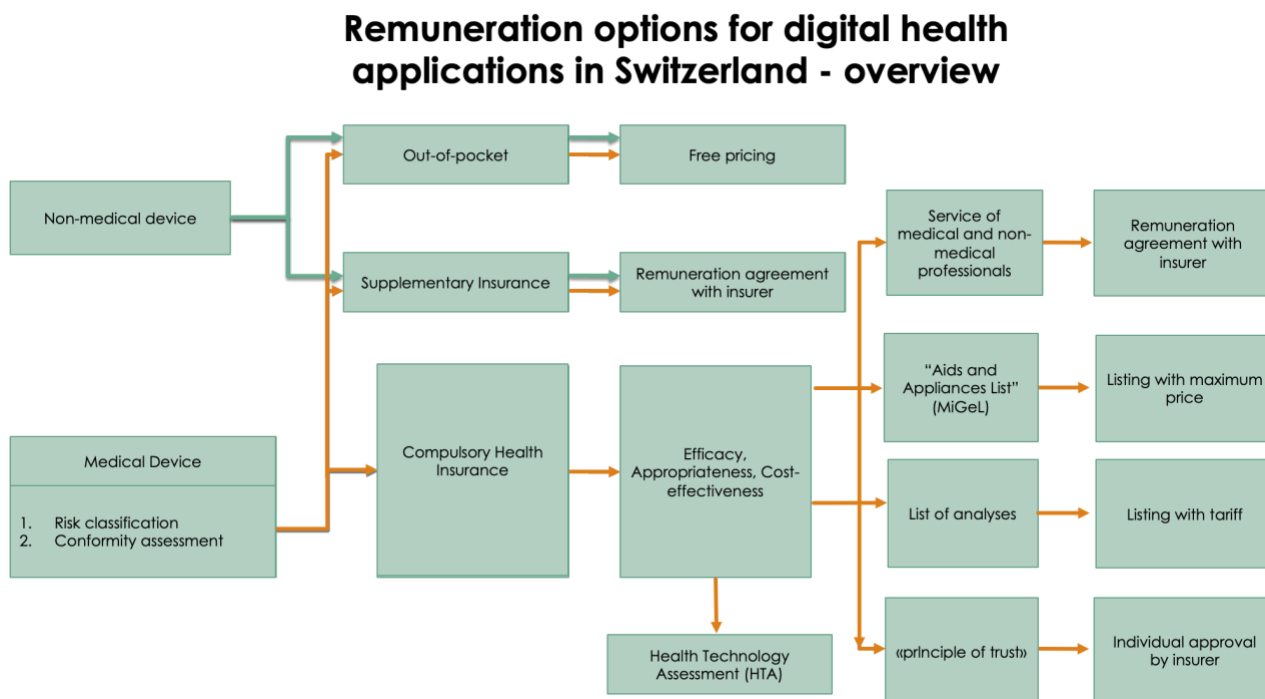


Figure 1: Overview of DGA remuneration options in Switzerland

In Switzerland, a manufacturer of a dGA has three reimbursement options to choose from when entering the market: Self-payers, supplementary insurance or reimbursement by the compulsory health insurance. It is not possible to provide a generally applicable guide as to which reimbursement option is suitable for which type of dGA. The choice of reimbursement option depends on both the specific characteristics of the dGA and the manufacturer's commercialisation strategy.

1. Self-paying

The easiest and quickest way for a dGA to enter the market is via the self-payer model. In this case, consumers/patients pay for the dGA themselves and often purchase it directly from the provider.

1.1 Prerequisites

The regulatory hurdles for market entry via the self-payer model are comparatively low compared to reimbursement via the mandatory health insurance. However, the legal requirements relating to the marketability of medical devices must be complied with if the dGA is qualified as a medical device. In contrast to other reimbursement options, the focus here is on a B2C or B2B2C approach, which means that sufficient budgets must be planned for communication and marketing to the target group.

1.2 Procedure

There is no special process, as market access for self-pay patients is not regulated in terms of reimbursement. If the dGA is a medical device, a conformity assessment procedure must have been completed and a certificate of conformity must be available.

1.3 Opportunities

As there is no official admission process with regard to remuneration, market entry is generally faster, which can be particularly attractive for start-ups. Experience also shows that entering the Swiss market in this way often lays the foundation for later finding partners who enable dGA to be reimbursed via supplementary insurance or OKP. By initially positioning themselves outside of the OKP framework, providers can test practical applicability and user acceptance, which informs and improves product development. This early market presence can also help to systematically build the necessary evidence base for the WZW criteria and optimise products for later review by the regulatory authorities. However, it should be noted that the systematic testing of a dGA on users may fall within the scope of the Human Research Act (HRA).¹⁵

1.4 Risks

Despite the widespread use of digital media, there is a lack of awareness of digital therapies in Switzerland. Experience from Germany shows that even after the introduction of a legal basis for German DiGA, only around 2% of the population uses it and over 57% are not familiar with DiGA. This illustrates that digital (health) innovations - especially those with data protection requirements - need time and trust to be accepted by the population.

Direct market access often lacks multipliers such as platforms or other existing channels with access to the (sometimes relatively specific) customer groups. The challenge is therefore to scale a dGA without such multipliers and to reach the relevant target group directly.

1.5 Success factors: Raising awareness through integration in medical care

For self-paying patients to be willing to pay, three essential conditions must be met: Firstly, the problem must be urgent and associated with suffering for those affected. Secondly, there must be no immediate alternatives available. Thirdly, a recommendation from service providers is often decisive. Service providers, for their part, are more willing to recommend dGAs if they relieve their own capacities and offer added value for patients without replacing their own medical services.

2. Supplementary Insurance (VVG)

In contrast to Compulsory Health Insurance (OKP), signing up to supplementary health insurance is voluntary and subject to the principle of **freedom of contract**. In principle, there is therefore more room for manoeuvre for the reimbursement of benefits from dGA via supplementary insurance (Insurance Contract Act "VVG") than via the OKP. However, the target market for supplementary insurance is smaller because (i) not every patient in Switzerland has supplementary insurance and (ii) the market is very heterogeneous with a large number of supplementary insurance products (outpatient, inpatient, alternative; vaccinations, check-ups, complementary medicine, dentistry, etc.). In Switzerland, the

¹⁵ Human Research Act; SR 810.30.

proportion of people who have supplementary hospital insurance is around 20%.¹⁶ There are no official figures for supplementary outpatient insurance, but surveys show that the proportion is around 70%.¹⁷

2.1 Prerequisites

The legal basis for supplementary insurance is the Insurance Contract Act VVG, as well as the insurance-specific General Insurance Conditions (AVB) and the Supplementary Conditions (ZB). These have a variety of structures and therefore offer different options for the inclusion of new benefits. Although insurance companies have room for maneuver, a certain market maturity of the services is a prerequisite for product integration. Certification as a medical device is not mandatory, but is regularly requested or results from the provisions of the Medical Devices Ordinance anyway.

Prices should be set carefully: On the one hand, favourable benefits hardly generate any demand for insurance cover on the part of insurance customers (due to high willingness to pay as self-payers), but nevertheless cause administrative work for the insurance company to reimburse costs. On the other hand, high prices can place an excessive burden on insurance products. Both can be obstacles to inclusion in supplementary insurance.

The motives of insurance companies for covering benefits via supplementary insurance are variable and range from customer acquisition and image building to possible savings in benefit costs through the substitution of previous benefits.

2.2 Procedure

Providers and manufacturers of medical services and products are recommended to seek inclusion in the catalogue of benefits of supplementary insurances within the framework of contractual negotiations under private law. It is necessary to enter into negotiations with the respective insurance company. The modalities of the negotiation process and the conditions of inclusion depend on the specifics of the individual case. For reasons of antitrust law, several insurance companies may not negotiate jointly with service providers in the supplementary insurance sector, as this could be regarded as an unauthorised agreement to restrict competition.

The FOPH provides lists of authorised health insurers, which are updated annually. This list can be used as a guide when searching for suitable supplementary insurance.¹⁸

2.3 Opportunities

Both for manufacturers of dGA and for insurers, the scope for supplementary insurance is greater than in the OKP and, overall, a significantly faster decision regarding the acceptance of benefits can be expected than in the OKP.

Reimbursement via supplementary insurance can also be an intermediate step towards possible OKP inclusion: Potentially larger numbers of users can be used to gather experience and evidence for subsequent OKP reimbursement.

¹⁶ Krämer, F.; Bedeutung von Spitalzusatzversicherungen in der Schweiz; Study commissioned by santésuisse; 2024.

¹⁷ Kaiser et al; 2019.

¹⁸ BAG directories of authorised health insurers and reinsurers 2024 (<https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-versicherer-aufsicht/verzeichnisse-krankenundrueckversicherer.html>).

2.4 Risks

In view of the large number of insurance companies with different supplementary insurance products, the effort for manufacturers to integrate their products or services into the heterogeneous VVG landscape is considerable (large number of negotiations with individual insurers). In some cases, insurance companies also limit which benefits can be included in accordance with the existing AVBs (General Insurance Conditions). And even if the decision to include a VVG benefit is made more quickly than in OKP, most insurers have processes and a certain time frame for the inclusion of new benefits in VVG products.

And even with positive coverage through supplementary insurance, there are other risks: Not all insurers actively advertise benefits from supplementary insurance over a longer period of time and customers/patients do not always know exactly which benefits are covered by the product. The recommendation by service providers, which is important for patient acceptance, is only slightly promoted by the VVG cover: It is generally not possible for them to know which (dGA) services are covered by which of the numerous supplementary insurance products on the market.

This is why direct sales/marketing to patients and service providers is also important when costs are covered by supplementary insurance.

Note: Admission to supplementary insurance excludes admission to the OKP and vice versa (i.e. admission to the OKP invalidates cover under the VVG).

2.5 Success factors

Around 70% of the Swiss population has supplementary outpatient insurance - an interesting basis for reaching patients.

In principle, those VVG benefits are attractive for insurers that offer high added value for a relevant customer group and that are already attractive for the customer in terms of sales.

If service providers play a role in the use of dGA, the *customer journey* must be clear and easy to integrate (both for the insurer and the service provider(s)).

3. Compulsory Health Insurance (OKP)

3.1 Overview of reimbursement options from the OKP

With the exception of the assumption of costs on the basis of the statutory presumption of compulsory benefits (principle of trust), the OKP may only reimburse those benefits that are listed in the catalogues of benefits issued and are provided by the service providers named therein.

The insurance companies have hardly any discretionary powers in OKP; they are obliged to cover benefits from the benefit catalogues, if the WZW criteria are met, but may not reimburse any additional benefits beyond this. The design of the specific service catalogues is left to the legislator. The Health Care Benefits Ordinance "KLV" and its appendices form the specific **benefit catalogues**, which include both positive and negative lists.

One special feature is that not all of these benefit catalogues contain specific prices. It essentially depends on whether an OKP benefits catalogue represents a service, such as medical treatment, or a benefit in kind, such as an aid or medication. The prices that prescribers (doctors or other medical service providers) are allowed to charge for medical treatment

services are regulated for OKP in collective agreements. A distinction is essentially made between the outpatient single service tariff in the practice or hospital ("TARMED") and the tariff for inpatient services (Diagnosis Related Groups; "SwissDRG" or flat rates per case) for an overnight stay in hospital. The prices also depend on which service provider (doctor, medical specialist, laboratory technician) provides the service.¹⁹

A selection of relevant tariffs and lists are:

- **TARMED**: Billing of outpatient services in medical practices and hospitals;
- **SwissDRG**: Reimbursement of inpatient hospital services based on flat rates per case;
- List of aids and appliances (**MiGeL**): This includes self-applications of aids and appliances by patients (and healthcare professionals);
- **Analyses list** (AL): Analyses performed by medical (certified) laboratories and specialists;
- **Specialities list** (SL): Tariff of prescription-only medicines (original preparations and imitation preparations such as generics and biosimilars).

Services that are to be reimbursed by the OKP must be covered by one of the above-mentioned reimbursement schemes. It is the responsibility of the manufacturers or providers of the medical services to submit applications for the relevant reimbursement scheme at an early stage. These applications are generally time-consuming and the processes for the respective systems differ greatly. Manufacturers should therefore be aware of which reimbursement scheme is applicable for their product before submitting an application for possible reimbursement.

For dGA, the remuneration options or "remuneration categories" are the same:

- Settlement via the **trust principle** (no listing);
- Inclusion as a **medical service** in KLV Annex 1;
- Inclusion as **aids and appliances** in the MiGeL in KLV Annex 2;
- Inclusion as an **analysis** in the AL in KLV Annex 3.

3.2 Selection of the appropriate compensation category

The choice of a suitable remuneration category for a dGA is often complex, especially as only a few dGAs have been included in the existing service catalogues to date and there are therefore no "role models". As a general rule, the remuneration vehicle that corresponds to the **main area of application** of the dGA should be selected. In certain cases, however, the obligation to provide benefits can be regulated in several areas. If you have any questions about the allocation to a remuneration category, enquiries can be sent to the Health Insurance Benefits department using a notification form²⁰ or by e-mail²¹.

The categorisation is particularly difficult in the case of dGA that include both digital and personal services provided by healthcare professionals.²² dGA that are used exclusively to read

¹⁹ <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-leistungen-tarife.html>.

²⁰ <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antragsprozesse/Antragsprozesse-Allgemeine-Leistungen.html>.

²¹ leistungen-Krankenversicherung@bag.admin.ch

²² See also comments on *blended care* in Chapter I.E(iv)3.6.

out and analyse data or to control a device are considered to be part of a diagnostic service provided by a healthcare provider and are not regulated separately with regard to the obligation to provide benefits.²³ dGA, for example, that enable insured persons to record data as part of a diary, which is then transmitted to the medical profession for analysis, fall under the regulation of medical services - provided that the insured persons do not derive any direct actions for themselves from this data.²⁴

3.3 Prerequisites

(i) Principles and methodology of the evaluation of dGA remuneration

The FOPH provides a "Basic document on the operationalisation of the criteria 'effectiveness, appropriateness and cost-effectiveness' in accordance with Article 32 of the Federal Health Insurance Act (KVG)"²⁵ ("**FOPH basic document**"). It is based on the methods of **Health Technology Assessment** (HTA), which are increasingly being applied internationally. In the official process for determining benefits eligible for reimbursement, this document serves on the one hand as a basis for the preparation of an **assessment** dossier and on the other hand as a guideline for the **appraisal** of the benefits by the responsible federal commissions regarding the fulfilment of the HTA criteria and the issuing of a recommendation on the obligation to provide benefits (**decision**).

The first part of the document provides a general definition of the WZW criteria. The second part describes the content to be tested based on specific questions. The third part is dedicated to the assessment of the fulfilment of the WZW criteria based on key questions, and the fourth part describes the derivation of recommendations on the performance obligation based on this.

(ii) WZW criteria

The **WZW criteria**²⁶ are among the basic and cumulative requirements that must be met for the services covered by the OKP. They are understood as eligibility requirements on two levels: on the one hand as general requirements for the designation of the benefits reimbursed by the OKP and on the other hand as reimbursement requirements in specific individual cases.²⁷

The first "W" stands for effectiveness. **Effectiveness** refers to the causal link between cause (medical service) and effect (medical success). The decisive factor for the fulfilment of the effectiveness criterion is whether the service is objectively suitable for achieving the desired objective (diagnostic, therapeutic, preventive, nursing). A service is effective if:

- it is objectively suitable for achieving the intended diagnostic, therapeutic, nursing or preventive goals,

²³ FOPH; Fact sheet "Remuneration of digital health applications under the OKP"; November 2024; p. 3 (https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/leistungen-und-tarife/faktenblatt-verguetung-dig-anwendungen-vers112024.pdf.download.pdf/Faktenblatt_Verg%C3%BCtung%20digitale%20Anwendungen_Version%20Nov%2024_DE.pdf).

²⁴ Cf. on the individual remuneration categories from I.E(ii)3.4

²⁵ https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/bezeichnung-der-leistungen/operationalisierung_wzwkriterien_310322.pdf.download.pdf/Operationalisierung%20der%20WZW-Kriterien%20vom%2031.03.2022,%20g%C3%BCtig%20ab%2001.09.2022.pdf.

²⁶ Art. 32 para. 1 KVG.

²⁷ FOPH basic document "Operationalisation of the criteria 'effectiveness, appropriateness and cost-effectiveness' in accordance with Article 32 of the Federal Health Insurance Act (KVG)"; version dated 31.03.2022; p. 4.

- a favourable benefit/harm ratio compared to alternative services has been proven using scientific methods and
- The transferability of the study results to Swiss clinical practice can be assumed.²⁸

"Z" stands for the term "appropriateness". In the general assessment in connection with the designation of OKP benefits, the relevance (in particular the medical need) and suitability in the treatment pathway are considered in the context of **appropriateness**. A benefit is appropriate if:

- it is relevant and suitable for patient care compared to alternative procedures,
- it is compatible with the legal conditions, ethical and social aspects or values, and
- The quality and appropriate application in practice is guaranteed.²⁹

In the case of comparable effectiveness and expediency, the most cost-effective alternative is generally deemed to be **economical**. A service is cost-effective if:

- whose tariffs and prices are comprehensible,
- it has a favourable cost-benefit ratio in terms of direct healthcare costs compared to the alternative procedures, or
- the additional costs are offset by a corresponding additional benefit and
- the cost impact on compulsory health insurance is acceptable.³⁰

If the WZW criteria are still being clarified, Art. 33 para. 3 KVG stipulates that the Federal Council can determine the scope of the OKP coverage of benefits. The Federal Department of Home Affairs (FDHA) has published a checklist for so-called "Leistungen in Evaluation" (Coverage with Evidence Development, CED checklist)³¹ for this purpose, which serves to systematically assess medical services with CED criteria that still require clarification with regard to their suitability for mandatory OKP coverage in evaluation. However, the requirements set out in the CED checklist are not specifically tailored to dGA.

3.4 Procedure for inclusion in the OKP

The procedures for obtaining compensation from dGA vary depending on the compensation category:

(i) Principle of trust

For medical, chiropractic or other services recognised under the KVG in the event of illness, the OKP has a presumption of compulsory benefits. This means that such services can be billed via the OKP. Disputed services can also be reimbursed, provided they fulfil the WZW criteria and have not been specifically regulated or agreed otherwise. **However, it is crucial that a suitable TARMED item or a flat rate per case is available for billing**; otherwise billing is not possible in practice.

²⁸ FOPH basic document "Operationalisation of the criteria 'effectiveness, appropriateness and cost-effectiveness' in accordance with Article 32 of the Federal Health Insurance Act (KVG)"; 31.03.2022; p. 5.

²⁹ FOPH basic document "Operationalisation of the criteria 'effectiveness, appropriateness and cost-effectiveness' in accordance with Article 32 of the Federal Health Insurance Act (KVG)"; 31.03.2022; p. 6.

³⁰ FOPH basic document "Operationalisation of the criteria 'effectiveness, appropriateness and cost-effectiveness' in accordance with Article 32 of the Federal Health Insurance Act (KVG)"; 31.03.2022; p. 7.

³¹ [https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/bezeichnung-der-leistungen/Antragsprozesse%20Allgemeine%20Leistungen/ced-checkliste-fuer-medizinische-interventionen.pdf.download.pdf/CED-Checkliste%20f%C3%BCr%20Medizinische%20Interventionen%20\(German%20and%20English\).pdf](https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/bezeichnung-der-leistungen/Antragsprozesse%20Allgemeine%20Leistungen/ced-checkliste-fuer-medizinische-interventionen.pdf.download.pdf/CED-Checkliste%20f%C3%BCr%20Medizinische%20Interventionen%20(German%20and%20English).pdf).

(ii) Medical and non-medical services or service providers (KLV Annex 1)

An application must be submitted to the Federal Commission for Benefits and Policy Issues (ELGK) for the inclusion of a **medical benefit** in KLV Annex 1. The FOPH assesses the application as a first step. The ELGK then formulates a recommendation based on the existing systematically presented facts. The final decision of the FDHA requires an amendment to the ordinance of the KLV or Annex 1 KLV or the rejection of the requested amendment to the ordinance.

The application forms can be found on the FOPH website: [Link](#)³²

The application and the summarised assessment by the FOPH correspond to the HTA phase of the assessment. The formulation of a recommendation by the ELGK, based on the systematically presented facts, corresponds to the appraisal. The amendment or rejection of an ordinance of the KLV or its Annex 1 by the FDHA represents the final phase, the Decision.

In the event of successful inclusion in KLV Annex 1, however, providers still require a tariff agreement with the insurance companies, which is negotiated by purchasing groups such as Tarifsuisse and/or HSK.

With regard to the services provided **by non-physician service providers**, the OKP only reimburses those services that are provided by service providers that are expressly authorised to charge the OKP in accordance with the KVV. The services of these service providers covered by the OKP are listed exhaustively in the KVV.³³ The procedure for submitting an application is the same as described here for medical services.

(iii) MiGeL (KLV Annex 2)

DGA that are used by the insured person independently or, if necessary, with the support of non-professional persons involved in the examination or treatment (e.g. carers) must ensure demonstrable progress in treatment or a learning effect for patients and the promotion of independent disease management (self-management) within the framework of MiGeL.

An application must be submitted to the EAMGK for the inclusion of a benefit in the MiGeL. After clarification, the applications are submitted to the EAMGK, which makes a recommendation to the FDHA. The FDHA makes the final decision on inclusion or rejection in the MiGeL. Since the revised MiGeL, there are now also benefits that are included with the note "under evaluation" (e.g. item 21.01.04.01.1 Pulse oximeter for outpatient monitoring of acute Covid-19 patients at home).

The application forms can be found on the FOPH website: [Link](#)³⁴

In the context of the HTA, the application and the FOPH's summarised assessment correspond to the assessment phase. The formulation of a recommendation by the EAMGK, based on the systematically presented facts, corresponds to the appraisal. The amendment of the ordinance

³² <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antragsprozesse/Antragsprozesse-Allgemeine-Leistungen.html>

³³ Cf. art. 57 ff. KVV; see also Kohler Stefan/Rau Angelina, Vergütung von digitalen Gesundheitsanwendungen (DGA) in der Schweiz, LSR 2023 p. 13 ff., 18.

³⁴ <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antragsprozesse/Antragsprozesse-Mittel-undGegenstaendeliste.html>.

to the KLV or Annex 2 KLV, or the rejection of the requested ordinance amendment by the FDHA, represents the Decision.

Even if a mandatory benefit is included in the MiGeL, contracts must be concluded with the insurers, as with the KLV Annex 1, in order to be able to settle with an insurer in the Tiers Payant. The negotiating partner here is tarifsuisse (for all Santésuisse insurers) or otherwise the individual insurers. In these negotiations, a discount is agreed in particular on the maximum reimbursement amount listed in the MiGeL.

(iv) List of analyses (KLV Annex 3)

An application must be submitted to the EAMGK for the inclusion of a service in the list of analyses (AL). Interested persons who wish to have new analysis items added, changed or deleted must first submit a written request with their request by e-mail or post to the EAMGK secretariat (eamgk-al-sekretariat@bag.admin.ch). The secretariat processes the requests and forwards them to the EAMGK after the necessary clarifications. The Commission then makes a recommendation to the FDHA. The Department ultimately makes the final decision on acceptance or rejection.

The application forms can be found on the FOPH website: [Link](#)³⁵

In the context of the HTA, the application and the summarised assessment by the FOPH correspond to the assessment phase. The formulation of a recommendation by the EAMGK, based on the systematically presented facts, corresponds to the appraisal. The amendment of the ordinance to the KLV or Annex 3 KLV, or the rejection of the requested ordinance amendment by the FDHA, represents the Decision.

3.5 Opportunities

The reimbursement of dGAs by the OKP offers numerous opportunities for manufacturers and for the Swiss healthcare system. One major advantage is the broad market access: everyone in Switzerland will have access to dGA. Chronically ill people in particular, who are often unable to take out supplementary insurance and are therefore excluded from the services covered there, benefit considerably from this broad access.

This can lead to significant advances in digital healthcare in the medium term. For example, the use of dGA can reduce the number of physical visits to the doctor, allow therapies to be continued from home or provide better support for patients living with chronic illnesses. These developments not only help to improve patient care, but could also contribute to a reduction in the overall costs of the healthcare system.

3.6 Risks

The time factor represents a significant risk for manufacturers: The process for inclusion in basic insurance currently takes at least a year. In addition, there are only a few examples of dGAs that have successfully completed this process and can serve as role models.

Another risk is the lack of experience among healthcare staff. Many doctors and healthcare professionals are not yet sufficiently familiar with dGA and are therefore reluctant to proactively include it in the treatment of their patients. The learning process takes time, which is why the

³⁵ <https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen/antragsprozesse/Antragsprozesse-Analysenliste.html>.

introduction of dGA will not immediately lead to a sharp increase in the number of users. In Germany, this slow increase was sometimes wrongly interpreted as a failure.

Questions regarding billing arise particularly in the case of blended care forms in which online and face-to-face interventions are combined. In this form of therapeutic services, both the online and face-to-face components contribute to the treatment. How these two interventions are interlinked and structured can depend on the treatment guidelines for the respective indication, the technological possibilities and the characteristics and needs of the people being treated. The intermeshing of online and face-to-face interventions can take place both at the level of overall treatment (e.g. online aftercare following a conventional face-to-face intervention) and at the level of individual sessions (e.g. alternating between online and face-to-face interventions). The challenges in connection with the remuneration of services in the area of blended care lie in the fact that the existing remuneration schemes and tariffs do not provide for a combination of online and face-to-face interventions.³⁶

3.7 Success factors for the OKP

Practical experience has shown that proving efficacy and setting prices in the context of the WZW criteria for dGAs are associated with considerable challenges. Studies that provide evidence of efficacy must be submitted for the application. The FOPH has indicated that such studies can also be submitted subsequently under certain conditions. However, it is currently unclear how the FOPH will deal with insufficient or delayed evidence of efficacy in the future and this could have a significant impact on market dynamics. In the context of obtaining evidence of efficacy, a key problem is the often patchy evidence base for dGA, as robust randomised controlled trials (RCTs), which are considered the gold standard, are rarely conducted. Instead, many dGA applications are based on data from observational studies or retrospective analyses, which are methodologically more susceptible to bias. In addition, there are difficulties in defining and measuring suitable digital endpoints. While classic endpoints such as mortality or hospitalisation are well established and comparable, dGA often lacks validated digital endpoints that are specifically tailored to the benefits of digital applications.³⁷

Health economic aspects also play a decisive role. For the evaluation, the benefits of dGA must not only be proven in comparison to the current standard of care, but their potential budget impact must also be taken into account. The cost-benefit ratio and potential savings through the reduction of indirect or intangible costs are key evaluation factors. However, there is often a lack of robust models that can map such analyses with a high degree of accuracy, which makes pricing even more difficult.

After successful inclusion in an OKP benefits catalogue and concluded price negotiations, dGA manufacturers must of course still plan marketing and sales with the target group of service providers (= prescribers).

As already mentioned, the OKP offers the greatest opportunity for scaling in the Swiss market, despite sometimes lengthy processes.

³⁶ See the explanations in chapter I.E.3.1.

³⁷ See Rau Angelina, *Kombinationsprodukte zwischen arzneimittel- und medizinproduktrecht: eine rechtliche Untersuchung unter besonderer Berücksichtigung von digitalen Therapeutika (DTx)*, p. 202 f.

F. General information on market access strategies and success factors

In a healthcare system such as Switzerland's, which is still in the early stages of digitalisation, start-ups and SMEs developing dGA are advised to develop or scale up gradually as part of their business model. A sensible approach begins with the introduction on a self-payer basis, followed by inclusion in the VVG benefits of some major insurance companies and concludes with an application for inclusion in a suitable OKP reimbursement scheme. So far, only a few start-ups have successfully completed this path, many are still on their way and have shared their experiences so far with the authors.

It is important to note that different skills are required in each marketing phase. In the initial phase, the focus is on effective marketing to commercialize the dGA and gain initial users. In the phase of inclusion in supplementary insurance, negotiation skills are crucial to convince insurance companies to include the dGA in their benefits. Finally, for inclusion in basic insurance, a deep regulatory understanding is required in order to fulfil the strict legal requirements and successfully provide proof of fulfilment of the WZW criteria.

The following three use cases illustrate the approach taken by the three companies on their way to market access for their products.

G. Use cases

1. CARE4CARDIO

CARE4CARDIO is a telemedicine programme that combines telecoaching and telemonitoring for patients with chronic heart failure (CHI) and was developed by Health Care Systems GmbH (HCSG). The first study phase and market launch of the programme took place in 2016 in collaboration with Novartis Switzerland and the health insurance company Sanitas. The initial funding was secured through a study budget³⁸, and this phase resulted in valuable insights into the target group, the technical solution and the handling and design, which were of great importance for the further development of the CARE4CARDIO programme.

Following this phase, the costs were covered by supplementary insurance. Initially Sanitas, and later also CSS and Helsana insurance, covered the costs for patients with corresponding supplementary insurance. For HCSG, the size of the insured collective in the target group was decisive in the selection of the insurance companies with which discussions were held.

As part of a second study phase, which was conducted in Germany until 2022, the effectiveness of CARE4CARDIO was proven in a comprehensive matched-pairs study with 2 x 6,000 participants. A significant reduction in the mortality rate was observed.³⁹ Following these results, discussions were initiated with the FOPH regarding the inclusion of the programme in KLV Annex 1, and a corresponding application was submitted. Inclusion in the OKP finally took place on 1 April 2024. The criteria previously defined by the individual supplementary insurers were adjusted slightly based on the OKP criteria that patients must meet to qualify for the programme. In some cases, this meant that people who previously made use of the programme via supplementary insurance were no longer considered qualified on the basis of the OKP

³⁸ HSLU; Care4Cardio; Study together with the Lucerne University of Applied Sciences and Arts between November 2016 and June 2017; (<https://www.hslu.ch/de-ch/hochschule-luzern/forschung/projekte/detail/?pid=3606>).

³⁹ Care4Cardio; Care4Cardio from HCSG; 2024; (<https://www.hcsg.ch/program/#/program/benefits/details>).

criteria. In order to solve this problem, transitional agreements were made that enabled the patients concerned to continue to receive financial support for the programme.

After admission to the OKP, the actual negotiation of billable tariffs began, which was still ongoing in April 2024. It became apparent that the effort required up to OKP inclusion, including proof of fulfilment of the WZW criteria as well as coordination and clarification as part of the inclusion process, was considerable. In this case, it was an advantage that the programme was already being reimbursed in Germany and Switzerland via individual supplementary insurances. However, it turned out that the process leading up to enrolment and beyond, in particular the pricing, was not transparent and the responsibilities often remained unclear. It would therefore be advantageous in terms of time if the tariff could be set at least partially in parallel with the OKP application.

2. KSM-Somnet

Internet-based cognitive-behavioural therapeutic treatment of insomnia (KSM-SOMNET), ZURZACH Care - Clinic for Sleep Medicine

The therapy concept for the digital health application KSM-SOMNET was developed back in the early 2000s by the Clinic for Sleep Medicine (KSM) as an internet-based psychotherapeutic treatment for patients with chronic insomnia. The manual-based cognitive behavioural therapy for insomnia (CBT-I) is carried out via a specially developed internet platform by psychologically trained therapists (so-called "guided online CBT-I").

First, patients are specifically examined for alternative causes of insomnia and sleep disorders (e.g. sleep apnoea, movement disorders, parasomnias) and, if necessary, referred to ZURZACH Care's interdisciplinary sleep centres in Bad Zurzach and Lucerne or to a sleep medicine facility in their place of residence for further sleep medicine treatment. In a second step, patients with pure insomnia are assigned a therapist. This therapist communicates with the patient via the online therapy platform and treats the sleep disorder using cognitive behavioural therapy.

After the development of the customised therapy concept (appropriateness) by the experienced KSM therapist team, a cooperation with an internationally established partner for online therapies in the psychological and psychiatric field was established to create the therapy platform. For KSM/ZURZACH Care, the technical experience in the field of online therapies and the professional expertise with similar patient groups were of decisive importance.

After the development work on the platform was completed, the effectiveness of the KSM-SOMNET health application was scientifically proven as part of a pilot study.⁴⁰ Other scientists also confirmed the effectiveness of online therapies. In addition, in the context of cost-effectiveness, it was shown that "guided online CBT-I" can be more cost-effective than CBT-I in a conventional face-to-face setting.⁴¹ On the basis of this scientific data, the KSM was able to submit an application to the Federal Office of Public Health (FOPH) for cost coverage by the

⁴⁰ Burkard M et al. in: Abstracts of the 22nd Annual Meeting of the DGSM, 4-6 December 2014, Cologne. *Somnology* **18** (Suppl 1), 3-82 (2014). (<https://doi.org/10.1007/s11818-014-0691-8>).

⁴¹ Lancee J et al. Guided Online or Face-to-Face Cognitive Behavioural Treatment for Insomnia: A Randomised Wait-List Controlled Trial. *Sleep*. 2016 Jan 1;39(1):183-91. doi: 10.5665/sleep.5344. PMID: 26414893; PMCID: PMC4678352.

OKP as early as 2015, which led to the inclusion of "guided online KVT-I" in the KLV by the FDHA in 2016.⁴²

Since then, the digital health application KSM-SOMNET from ZURZACH Care has been established on the market as a successful online therapy for insomnia, and billing is guaranteed. This form of therapy is regularly used by patients as an alternative to traditional psychotherapy for chronic insomnia and sleep disorders. Patients from all over Switzerland as well as Swiss nationals abroad (e.g. in Scandinavia or Africa) appreciate KSM-SOMNET online therapy.

3. Akina Cloud

Akina Cloud is a dGA to support the therapeutic movement training of patients with musculoskeletal disorders. During use, patients receive continuous access to an indication-specific, multimodal therapy programme in accordance with guidelines. Depending on the indication, three therapeutic modalities are combined: Exercise therapy, information and education as well as psychosocial measures.

Exercise therapy is guided interactively by an artificial intelligence (AI) integrated into the product. Based on the video signal from commercially available webcams, the AI can provide real-time assistance with the execution of exercises, comment on the training progress and automatically document it. This supports the safe, effective and regular execution of exercises as well as effective guidance for patients on health-promoting behaviour in everyday life. Akina Cloud was developed by Akina AG, a spin-off company of ETH Zurich, and has been available as a Class I medical device for self-paying patients in Switzerland since April 2024.

As a dGA, Akina Cloud is primarily intended for self-administration by patients. The product therefore falls within the scope of the MiGeL. After reviewing a notification form submitted by Akina AG, the FOPH decided in May 2024 that the OKP has a basic obligation to provide benefits. Akina is (as of July 2024) about to submit an application for the inclusion of a new item in the MiGeL. In addition to the digital core function of the product, physiotherapists can optionally monitor pain symptoms and training results (movement volume and movement quality) via an interface integrated into Akina Cloud. The availability of this interface is intended to further support the safe and appropriate use of the product and, if necessary, the coordination of overall treatment with parallel physiotherapy. As this is a non-medical service, the optional monitoring does not fall within the scope of the MiGeL and must be regulated separately from the remuneration of the digital product within the framework of the corresponding tariff agreement. However, there is currently no suitable tariff item.

⁴² FOPH; FDHA Ordinance on Benefits under Compulsory Healthcare Insurance (Healthcare Benefits Ordinance, KLV); amendment of 25 November 2016.

H. Useful links and documents

Name	Link
Fact sheet on the reimbursement of digital health applications under the OKP (FOPH, November 2024)	https://www.bag.admin.ch/dam/bag/de/dokumente/kuv-leistungen/leistungen-und-tarife/faktenblatt-verguetung-dig-anwendungen-vers112024.pdf.download.pdf/Faktenblatt_Verg%C3%BCtung%20digitale%20Anwendungen_Version%20Nov%2024_DE.pdf
BAG basic document WZW criteria	https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-bezeichnung-der-leistungen.html (at the bottom of the page)
Information on medical devices from Swissmedic	https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/regulierung-medinprodukte.html
Lists of authorised health insurers and reinsurers of the FOPH	https://www.bag.admin.ch/bag/de/home/versicherungen/krankenversicherung/krankenversicherung-versicherer-aufsicht/verzeichnisse-krankenundrueckversicherer.html
In-depth readings	Rau Angelina, Kombinationsprodukte zwischen arzneimittel- und medizinprodukterecht: eine rechtliche Untersuchung unter besonderer Berücksichtigung von digitalen Therapeutika (DTx). Kohler Stefan/Rau Angelina, Remuneration of digital health applications (DGA) in Switzerland, LSR 2023 p. 13 ff.

Links to information on remuneration in other countries (not exhaustive)	<i>coming soon</i>
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