Reimbursement Pathways for Digital Health Tools and Software - How to Bring Your FemTech Solution to Women

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In the EU, unlike the regulatory pathway to approval, reimbursement of a product remains the national prerogative of each country. Each is free to determine how to allocate its national budget or health insurance funds to reimburse treatments. The applicable reimbursement pathway and required evidence standards depend on whether a FemTech product is considered to be a "general consumer" (lifestyle and wellness) product, a medical or in vitro diagnostic device, or a "combination product" with a medicine. A FemTech product can be used and assessed either as a standalone product (e.g., a solution to diagnose or monitor/manage a condition) or as a companion diagnostic (e.g., an in vitro diagnostic device that can detect which patients may respond to a particular treatment). While there is no set pathway for lifestyle and wellness products, there can be concrete routes to market for the other two categories, which this article briefly examines.

Most EU countries, as well as the UK, perform a health technology assessment (**HTA**) of a particular medical device or relevant product in order to assess its clinical- and cost-effectiveness before it may be reimbursed. This process may run in parallel to or be followed by negotiations with the national payers or insurers. Different HTA agencies may require different data sets and possibly comparisons at different time points, which can be time- and resource-consuming. In addition, if a digital health technology (**DHT**) is tied to a medicinal product, they may be required to be assessed simultaneously.

Overview of reimbursement pathways in key European jurisdictions

In **Switzerland**, the "principle of trust" applies to the reimbursement of digital health tools in the context of a medical service, provided by health care professionals (**HCPs**). This means that in the case of medical services, it is generally assumed that HCPs use services that meet the legal requirements of effectiveness, expediency, and economic efficiency, and in principle, are reimbursed. Therefore, HCPs can treat patients innovatively in accordance with the latest state-of-the-art DHT, without prior health economic evaluation by the Federal Office of Public Health (**FOPH**) – provided that DHTs are CE-marked as medical

devices and are considered to be effective, expedient, and economical by the service provider. Furthermore, groups of medical devices are reimbursed by the compulsory health insurance if listed in the "*Mittel- und Gegenständeliste (**MiGel**)*" or "*Analyseliste (**AL**)*" where the maximum reimbursement is set.

Notwithstanding the listing, the supplier is in principle free to set the market price. However, if the market price is higher than the list price, the patient will have to pay the difference out of their pocket. Apart from this difference in assessing medical devices for reimbursement, many of the issues discussed in this article are equally valid for Switzerland.

Germany is the first country in Europe to introduce a specific pricing and reimbursement pathway for digital health apps (**DiGAs**), which is referenced as a benchmark by other countries, such as France. DiGAs, which are listed in the register for digital health apps, can be prescribed to patients and reimbursed (see our article Germany's "DiGA" Digital Health Fast Track Process Is Modeling a New Way To Regulate Market Access and Reimbursement). Currently, the register lists 35 DiGAs, including FemTech apps such as "*HelloBetter Vaginismus Plus"* for non-organic vaginismus and "*CANKADO PRO-React Oncoapps,*" "*PINK! Coach,*" and "*optimune*" for malignant neoplasm of the mammary gland.

The **UK** has implemented digital tool-specific reimbursement pathways through the introduction of the Digital Technology Assessment Criteria for Health and Social Care (**DTAC**) by the DIGITAL group of the National Health Service (**NHSX**), and the Evidence standards framework for digital health technologies of the National Institute for Health and Care Excellence (**NICE**). DTAC aims to ensure that the assessment frameworks and evidence standards in place for DHTs are robust and proportionate, support the needs and priorities of the National Health Service (**NHS**), and reflect the characteristics of different types of digital technologies. DHTs are presently evaluated within NICE's Medical Technologies Evaluation Programme (**MTEP**), but NICE is exploring the concept that DHTs require a bespoke evaluation method. This means that a new dedicated pathway for DHTs in the UK may be expected in the near future – but in any event authorities understand that the existing pathway might need to be re-addressed on a case-by-case basis in respect of FemTech products.

EU health technology assessment – towards European harmonization in determining the efficacy and benefits of new technologies

At the EU level, the HTA Regulation 2021/2282, which will apply from January 12, 2025, aims to streamline the diverse data requests developers receive by introducing a new single

procedure for EU Member States to prepare joint clinical assessments of health technologies, that Member States would have to take into consideration in their reimbursement decisions. As of 2025, these EU-level joint clinical assessments (**JCA**), which will include relative effectiveness assessments, will gradually become applicable for all medicinal products and selected medical devices. Only limited types of high-risk, novel and/or likely high-impact implantable medical devices and in vitro diagnostic devices will be affected, which the Commission and the Coordination Group will select by reference to one or more of the following criteria: (a) unmet medical needs; (b) first in class; (c) potential impact on patients, public health, or healthcare systems; (d) incorporation of software using artificial intelligence, machine learning technologies, or algorithms; (e) significant cross-border dimension; and (f) major Union-wide added value.

The regulation is an example of how existing methodologies and processes are not always made with these novel, continuously evolving digital health tools in mind. An evidentiary hurdle that is not clearly addressed in the JCA methodologies is the ability to reflect continuous generation and use of real-world data after-market launch, and incorporate this into the JCA. Many new technologies are continually learning and evolving systems throughout the lifecycle of the products; this particularity should be reflected in the timing and method of the JCAs. If these areas are not addressed in implementing rules and guidance, this new regulation could end up being insufficiently open to promising medical technologies, including FemTech products. It is therefore key for FemTech companies to participate in the dialogue about these topics and be aware of applicable requirements.

Trailblazing EU guidance and evolving DTx reimbursement models at a global level

Despite the identified gaps in the broader legislation, it is promising that organizations and health systems have started publishing guiding principles and evidence standards to facilitate the uptake of DHTs.

For instance, the European Commission's subgroup *eHealth Stakeholder Group* published the Proposed Guiding Principles for Reimbursement of Digital Health Products and Solutions, aimed to enable Member States to make informed decisions about the reimbursement of digital health products and solutions. Topics addressed in the guidance include the need for specific criteria, transparency, dialogue with all stakeholders concerned, flexible processes, allocation of dedicated funds including at the EU level, and guidance on evidence generation. At the same time, we have seen more concrete guides on specific products, such as the DTx Value Assessment & Integration Guide from Digital Therapeutics Alliance (**DTA**), which focuses on the difference between digital therapeutics

and wellness apps, and introduces elements for the assessment of the quality of clinical evidence and the incorporation of real-world evidence. This is a particularly useful reference for FemTech products, many of which fall under the category of "digital therapeutics," a term not defined in EU law but understood to mean evidence-based, patient-facing therapeutic interventions driven by software to prevent, manage, or treat a medical condition.

Rapid and innovation-friendly reimbursement pathways to realize the full potential of DHT and FemTech solutions

It is now understood that traditional HTA methodologies do not reflect the needs of DHT products and the way they are used in new models of healthcare delivery. As a result, HTA authorities are starting to be more accepting of the particularities of DHTs and FemTech products. HTAs should therefore take into account the specificities of DHT, and pricing and reimbursement procedures should be simplified and accelerated to fully exploit the potential of innovative medical technologies and thus promote health economic development and benefit for patients.

Manufacturers must be able to make a value case for their products, supported by data generated in accordance with applicable evidence standards (where available) and diagnostic and treatment pathways. FemTech product developers are advised to be up to date with applicable standards and engage early with relevant stakeholders in order to factor into their development and clinical plans the need to generate evidence for pricing and reimbursement decisions.