September 2025

Real-world Data and Learnings: Germany's Prescription Digital Therapeutics Program (DiGA)

Prescription Digital Therapeutics (PDTs) have well-defined fit-for-purpose regulatory and reimbursement pathways in Germany. This reimbursement pathway, ensuring real world data is relevant, reliable, and accurately reflect the patient population and outcomes of interest, was finalized in late December 2019, and products are currently available to approximately 73 million people, about a fifth of the U.S. population (340 million people). This is the first analog demonstrating how coverage and adoption of clinically validated digital therapeutics function in a real-world setting.

While not a perfect comparison, Germany and the U.S. share some similarities, particularly in their demographic profiles and historical immigration patterns. In this brief, we will summarize recent real-world data from Germany's DiGA program for digital health applications (*Digitale Gesundheitsanwendungen*) in order to better understand long term costs and adoption curves for PDTs when the reimbursement pathway is clearly defined.

Note: The following public data is from BfArM, the German Federal Institute for Drugs and Medical Devices (*Bundesinstitut für Arzneimittel und Medizinprodukte*). BfArM is the German regulatory authority responsible for approving, monitoring, and regulating medicinal products and medical devices to ensure public health and safety. Access the full BfArM report here.

BfArM's Overview of the DiGA Program

Digital health applications open up a wide range of possibilities, both regarding the diagnosis and treatment of diseases as well as supporting an independent, healthy lifestyle. Thus, these applications, or DiGA, are considered to be "digital assistants" in the hands of patients.

A DiGA is a CE-marked digital medical device (DMD) that has the following properties:

- According to the Medical Device Regulation (MDR) or the transitional regulation Medical Device Directive (MDD), these medical devices are included in the risk class I, IIa, and IIb). Information as to "When is an App a Medical Device?" can be found at BfArM's Differentiation and Classification.
- The main function of the DiGA is based on digital technologies.
- The medical purpose is mainly achieved by way of its digital function.
- The DiGA supports the recognition, monitoring, treatment or alleviation of diseases, or the recognition, treatment, alleviation or compensation of injuries or disabilities.
- The DiGA is used by the patient alone or by the patient and healthcare provider together.

These requirements are defined in Section 33a of the German Social Code Book V (*Fünftes Buch Sozialgesetzbuch, SGB V*).

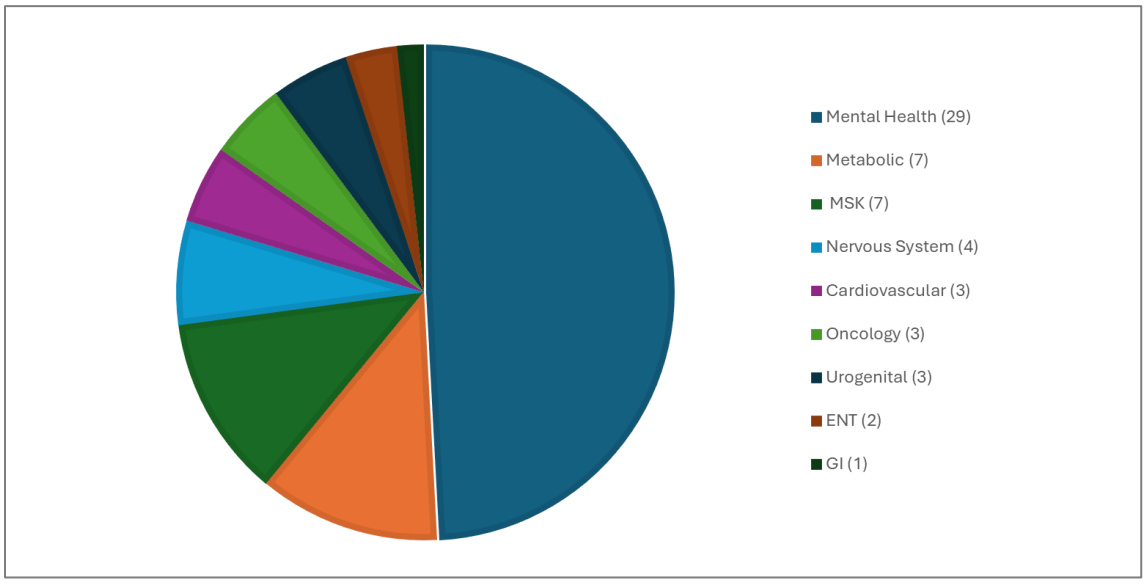
The enactment of the Digital Healthcare Act (*Digitale-Versorgung-Gesetz, DVG*) in December 2019, marked the introduction of the "app on prescription" for patients (Sections 33a and 139e of the German Social Code Book V). This means that approximately 73 million persons covered by the German statutory health insurance are entitled to use a DiGA prescribed by a physician or psychotherapist and are reimbursed by their health insurance.

Prerequisite for the above is that a DiGA must have successfully completed the assessment of the BfArM and are listed in a directory of reimbursable digital health applications (DiGA directory). The Federal Ministry of Health (*Bundesministerium für Gesundheit, BMG*) has regulated the details of this procedure in the supplementary legal regulation, the Digital Health Applications Ordinance (*Digitale Gesundheitsanwendungen-Verordnung, DiGAV*). NOTE: only the German version of the Digital Health Applications Ordinance is available.

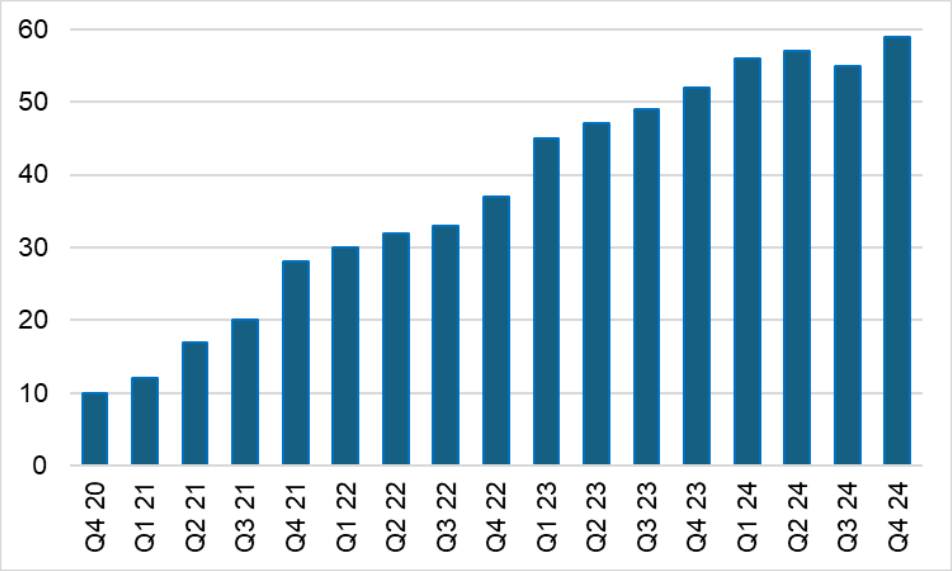
Utilization Data (Q4 2020 to Q4 2024)

The DiGA program, as of Q4 2024, has a total of 59 PDTs listed in the DiGA Directory, (38 permanently listed, 21 provisionally listed, year one), and revoked nine products after their provisional listing. The number of products has grown over the past four years on a linear trend.

DiGA Applications by Disease State



Number of Reimbursable Digital Health Applications in the DiGA Directory

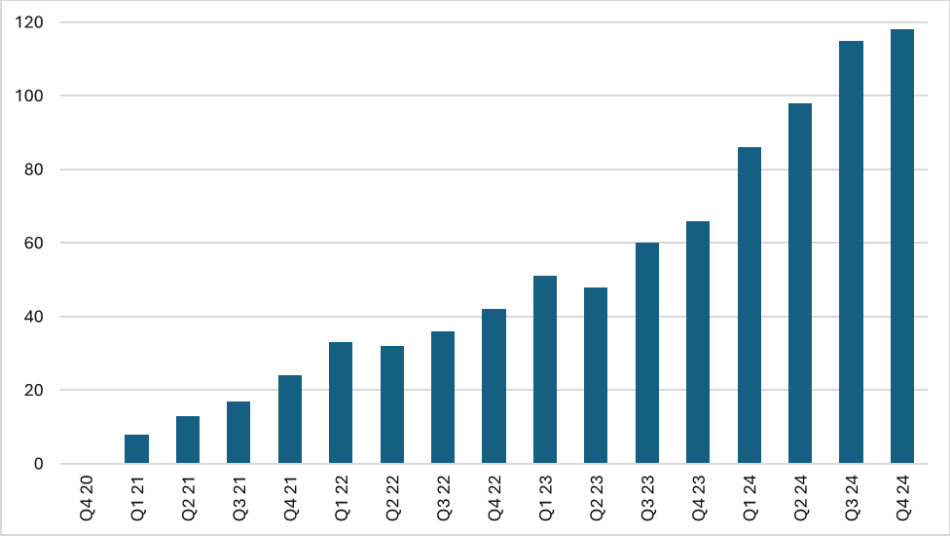


There has also been a steady increase of patient and provider adoption over time. In the future, breakdown by therapeutic category and product could help bring further clarity to predictive models and forecasting tools used by the Congressional Budget Office (CBO) as we consider the adoption curve in the U.S.

Key Points:

- **85% growth from 2023 to 2024**: Compared to the previous year, digital health app utilization increased approximately 85% (225k in 2023 to 423k in 2024)
- **Average cost <271 EUR (US$317)/app utilization**: From 2020 to 2024, cost totaled 234 million EUR (US$274M) covering nearly 861,000 digital health app activations, far less than the cost of untreated conditions and downstream complications.

Number of Redeemed Activation Codes (in thousands)



Conclusion

This data from Germany demonstrates the potential, in the real world, if both fit-for-purpose regulatory and reimbursement pathways exist for Prescription Digital Therapeutics.

The U.S. has been slow to create standardized reimbursement pathways for innovative healthcare products. This is due to a concern that coverage will lead to a significant increase in cost. However, the 2025 Physician Fee Schedule (PFS) issued by the U.S. Centers for Medicare and Medicaid (CMS) now covers Digital Mental Health Treatment (DMHT) devices, with some digital tools covered under Durable Medical Equipment (DME) if they have a device component, and others as services through remote monitoring. Additionally, we see a future where pharmacy benefit covers Drug-Software paired products through a Prescription Drug Use Related Software (PDURS) framework. But a major gap still exists for software only, U.S. Food and Drug Administration (FDA) regulated products making a therapeutic claim.

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About ATA Action

ATA Action recognizes that telehealth and virtual care have the potential to transform the healthcare delivery system by improving patient outcomes, enhancing the safety and effectiveness of care, addressing health disparities, and reducing costs. ATA Action is a registered 501c6 entity and an affiliated trade organization of the American Telemedicine Association (ATA).

About the Advancing Digital Health Coalition

The ATA Action Advancing Digital Health Coalition (ADHC) is the leading industry forum advancing policies that protect access to virtual care and support healthcare innovation at every level of government. ADHC brings together a diverse community of stakeholders to share insights, shape advocacy strategy, and amplify the collective voice of digital health leaders in priority areas, including AI, digital therapeutics, Prescription Drug Use Related Software (PDURS), and remote monitoring devices.

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