Digital Health Applications (DIGA) in Germany- an Observation of Clinical Evidence Submissions

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Background

In December 2019, Germany took a significant step toward digitizing its healthcare system with the introduction of the Digital Healthcare Act. This act allowed for the prescription and reimbursement of DiGAs by healthcare professionals, marking a pivotal moment in the country's healthcare digitalization efforts.

Objectives

As of December 2019, DiGA in Germany can be reimbursed by statutory health insurance (SHI) under the Digital Healthcare Act. To qualify for reimbursement, a DiGA must be listed in a directory of reimbursable digital health applications after assessment by the Federal Office for Drugs and Medical Devices.

Our objective was to gain an understanding of the clinical evidence submitted to support the reimbursement application of DiGAs.

Methods

Records for DiGAs listed on the directory website were screened and analysed by two independent reviewers for the type of listing, therapy area and clinical evidence parameters such as study design, population sample size and study outcomes with data cut-off date as 20/09/2023.

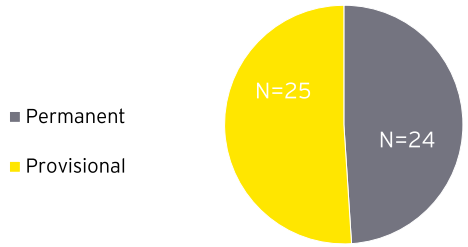
Results

A total of 55 DiGAs were listed in the directory: 24 (44%) permanent, 25 (45%) provisional, and 6 (11%) were removed from the directory (figure 1).

Top three therapy areas with most DiGAs were psychological disorders (N=21, 43%), musculoskeletal disorders (N=8, 16%) and metabolic disorders (N=5, 10%), all others (N=15, 31%).

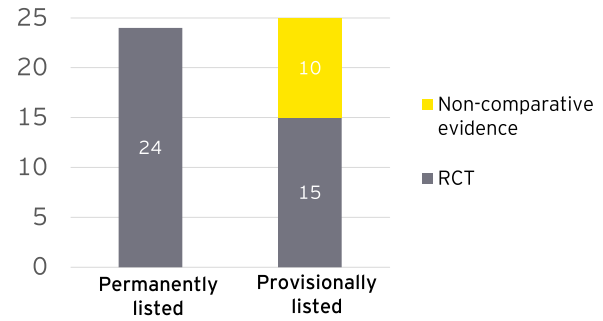
All DiGAs with permanent listings provided evidence from randomized control trials (RCTs). For provisional listings, 15 of the 25 provided evidence from RCTs with the remainder providing non-comparative evidence (figure 2).

Figure 1: Types of DiGAs listed in the directory



Results (continued)

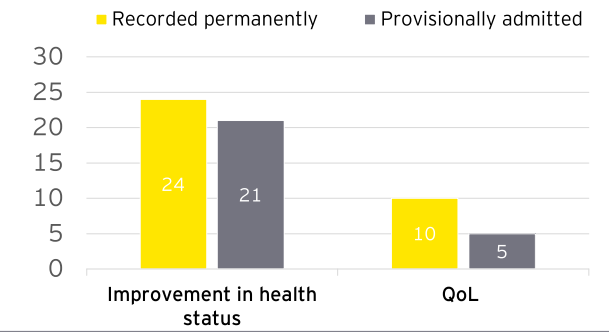
Figure 2: Types of study design used for assessment



The medical benefits demonstrated by permanently and provisional listed DiGAs were improvement in health status (n= 24, 100%); (n=21, 84%) and QoL improvement (n= 10, 42%); (n=5, 20%) respectively.

The study population size varied from the median of 168 (range, 50-1237) for RCTs and the median of 71 (range, 37-153) for non-comparative studies.

Figure 3: Claimed medical benefits by permanent and provisional DiGAs



Conclusions

Based on our analysis, it appears that providing an evidence package based on RCT data is crucial for supporting reimbursement of DiGAs. Our recommendation to developers is to ensure that payer relevant endpoints, such as evidence on the improvement in health status and improvement in QoL, are included as endpoints in their trials. Early payer engagement to align on data requirements for reimbursement is advised.

References

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