HOW DO THE PRICING AND REIMBURSEMENT POLICIES FOR DIGITAL THERAPEUTICS COMPARE AND CONTRAST BETWEEN THE US, EU-5, CHINA AND JAPAN?

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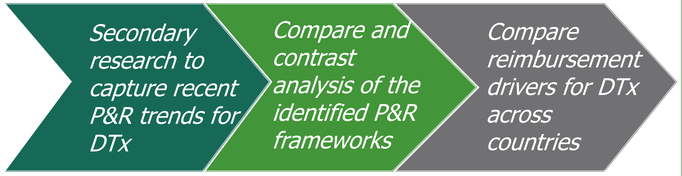
Introduction/objective

- Digital therapeutics (DTx) is a subdivision of digital health, which encompasses evidence-based therapeutic interventions, driven by high quality software programs to prevent, manage, or treat a disease[1].
- At least 25 DTx products have been granted regulatory marketing authorisation so far, another 23 are commercially available (they are exempt from regulatory approval), and nearly 100 are in earlier stages of clinical development[2]. More than two-thirds of all DTx are indicated for neurologic and psychiatric indications.
- The Covid-19 pandemic accelerated adoption of DTx globally. Number of DTx on the market and in development is rising each year, resulting in need for clear and transparent pricing and reimbursement (P&R) pathways globally. This study is set out to compare and contrast P&R policies for DTx in EU5, US, China and Japan.

Methods

- Secondary research of literature was conducted to identify the most recent P&R trends for DTx in markets in scope.
- National HTA bodies were searched to capture policies, frameworks and assessment criteria for DTx. Reimbursement assessment methodology for DTx was examined and compared across markets.
- P&R processes specific to DTx were examined to identify reimbursement drivers for DTx. These were compared across the markets.

Figure 1: Methods flow diagram



Results

Figure 1: Classification of countries by their P&R policies for DTx

Countries with an established P&R framework for DTx

- Germany is the first country that has developed a specific P&R process for digital health applications (DiGA) and more than 20 DiGAs have already been evaluated through this process[3].
- NICE in UK has developed a framework for assessing digital health technologies, however, final P&R decisions are made at a local level by clinical commissioning groups (CCGs).

Countries with a P&R process for DTx in development

- France and Italy currently assess DTx as medical devices. In France, HAS has recently developed a new framework which classifies digital solutions into 4 categories and 11 types of solutions with the aim of facilitating their integration into its healthcare system.
- In Italy and Japan, there are currently no specific P&R processes for DTx in place. However, experts in this field are calling for the development of such frameworks, which will streamline evaluation for reimbursement of DTx.
- In the US, Medicare and Medicaid Services (CMS) agency has yet to develop guidance for DTx reimbursement. Within the private domain, health plans tend to assess DTx individually and each of them have individual assessment criteria.

Countries with No P&R process for DTx

- Spain and China do not have a specific P&R process for DTx, nor criteria for assessment. It is unclear how DTx are reimbursed in Spain and their reimbursement is driven locally by hospital groups in digitally advanced cities. Despite the unclear reimbursement environment of DTx in China, these is a growing acceptance of DTx due to the low physician/patient ratio.

Reimbursement drivers for DTx across countries

- Each country has its own set of criteria which are taken into consideration in the P&R assessment of DTx (Table 1). The most important reimbursement drivers for DTx include regulatory approval, clinical effectiveness, safety, data protection and generation of RWE following reimbursement.
- Some countries, such as UK, also require cost-effectiveness data as CCGs are very resource optimisation driven.

Table 1: reimbursement drivers for DTx across countries

Requirements	Germany	UK	France	USA
Regulatory approval or CE mark	✓	✓	✓	✓
Clinical effectiveness	✓	✓	✓	✓
Safety	✓	✓	✓	✓
Cost-effectiveness / budget impact	✗	✓	~	~
Data protection	✓	✓	✓	✓
Generation of RWE	✓	✓	~	~

Legend: ✓ Mandatory ~ Nice to have ✗ Not required

Discussion and conclusions

- Whilst DTx are becoming an increasingly trending topic globally due to the increasing number of DTx in development, there are challenges with their P&R evaluation.
- From the countries in scope, Germany is the only market with a defined DTx P&R process in place, which has resulted in easier access to DTx. Most countries recognise the need of a streamlined DTx reimbursement framework and have initiated or are likely to initiate the development of such policies. Interestingly, despite the substantial government investment in digital health in China and Japan, there is no clear pathway and criteria that DTx are screened against.
- Moving forward, the pharmaceutical industry should work in close collaboration with healthcare authorities and payers to streamline the uptake of DTx in more countries because currently their reimbursement environment is quite challenging and unclear in many markets.

Abbreviations: CCG: Clinical commissioning groups; CMS: Centers for Medicare & Medicaid Services DTx: digital therapeutics; NICE: National Institute for Health and Care Excellence; HAS: French National Health Authority; P&R: pricing and reimbursement; RWE: real-world evidence

References: ***1.*** *Dang, A., Arora, D. and Rane, P, 2020. Role of digital therapeutics and the changing future of healthcare. Journal of Family Medicine and Primary Care, 9(5), p.2207.;* ***2.*** *IQVIA Institute for Human Data Science, 2021. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/digital-health-trends-2021/iqvia-institute-digital-health-trends-2021.pdf;* ***3.*** *The Federal Institute for Drugs and Medical Devices (BfArM), 2021. The Fast-Track Process for Digital Health Applications (DiGA) according to Section 139e SGB V. A Guide for Manufacturers, Service Providers and Users. Available at: https://www.bfarm.de/SharedDocs/Downloads/EN/MedicalDevices/DiGA_Guide.pdf?__blob=publicationFile*

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