

# Scroll Your Way to Better Health:

## Assessing the Key Determinants of Coverage Decision-Making for Digital Therapeutics in US and EU Markets

Rémy, Claire; Vyas, Hersh; [Perez-Kempner, Lucia](#)

International Society for Pharmacoeconomics and Outcomes Research, Inc. - May 8, 2023

parexel®

# Today's agenda

## AGENDA

---

- Objectives
- Methodology
- Results
- Key takeaway

## SPEAKER

---

- **Lucia Perez-Kempner**



- Pharm, MBS, MSc
- Senior Consultant, Parexel International
- In case of questions:
  - M: +34-650-607-377
  - E: [marialucia.perez-kempner@parexel.com](mailto:marialucia.perez-kempner@parexel.com)

# We assessed the DTx reimbursement landscape in the EU-5 and US to identify the main determinants for coverage



*DTx can be defined as software-driven therapeutic interventions that represent new treatment options for patients*



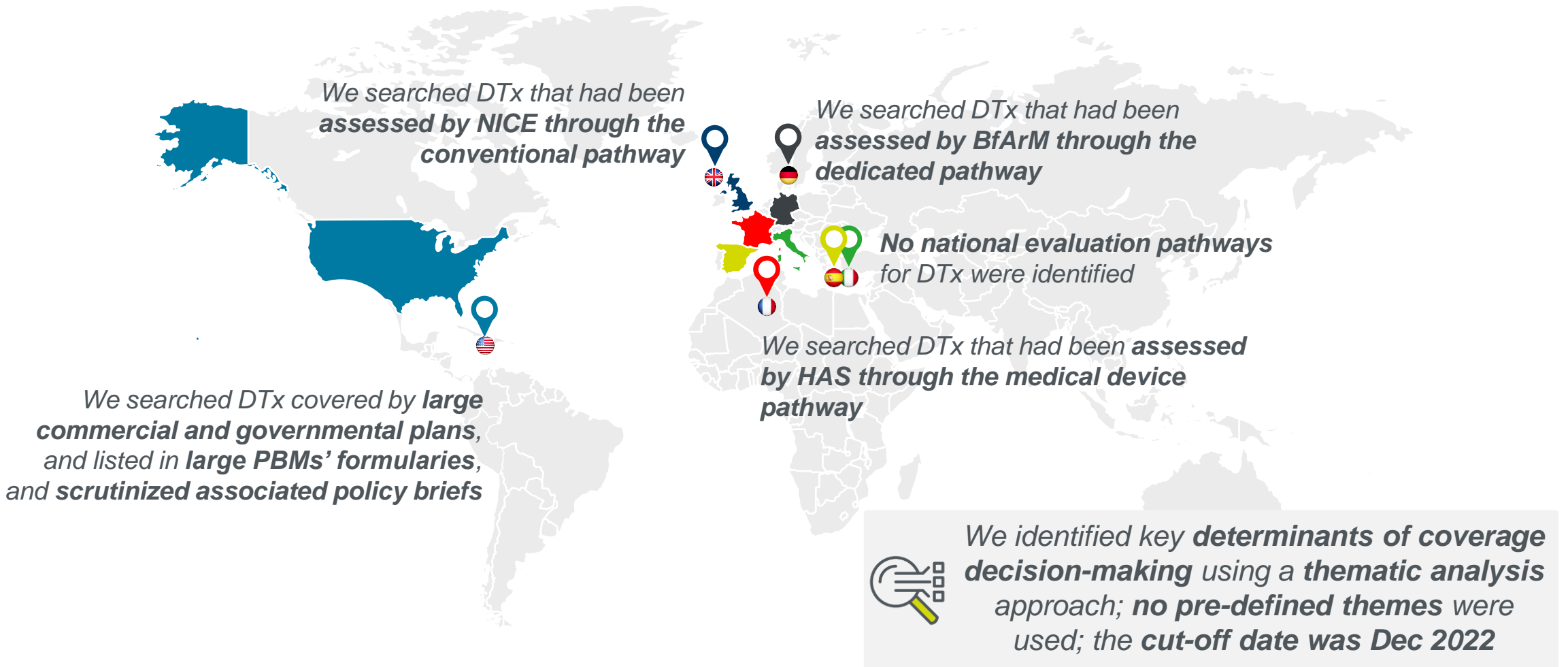
*As technological advances increase, the DTx market is growing rapidly, with an expected growth rate of x15.6 by 2030*



*This research aimed to analyze the reimbursement landscape of DTx coverage in the EU-5 and US, with the objective to identify:*

- ✓ *Key determinants for coverage in the EU-5 and US*
- ✓ *Differences in decision-making for DTx vs. conventional therapies*

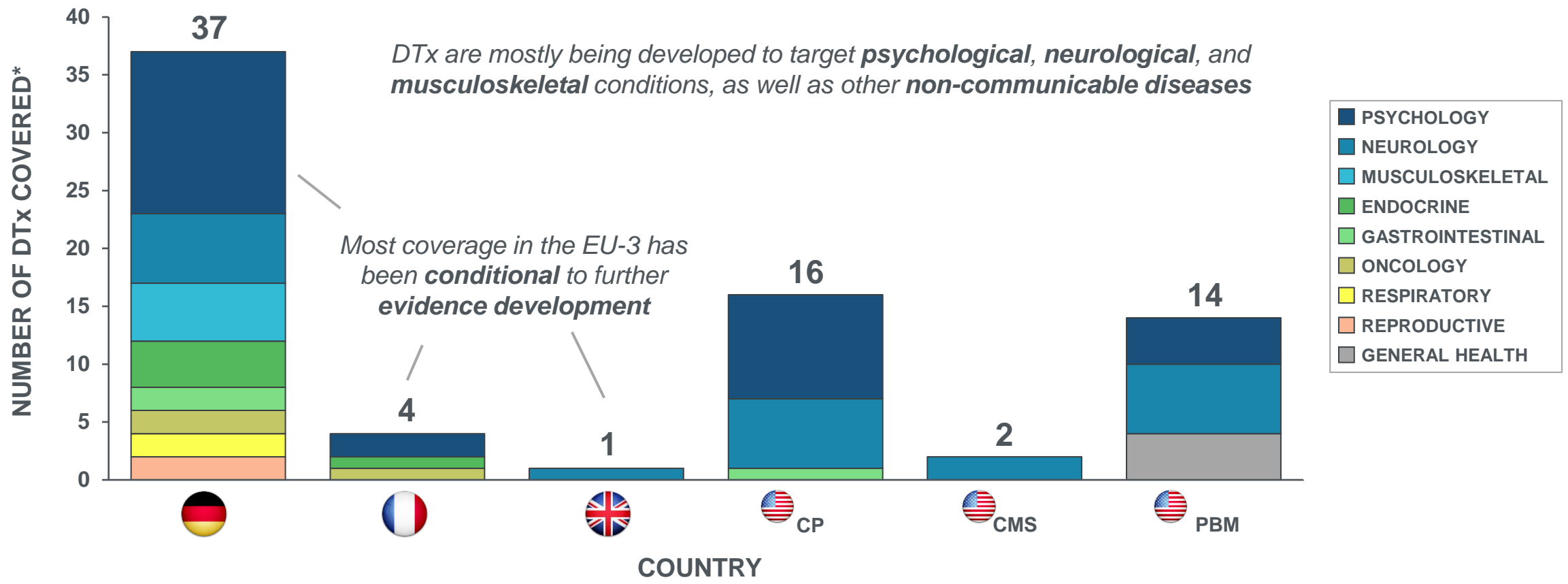
# We identified DTx that were assessed by HTA bodies in the EU-5 and covered by insurers in the US



BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte; DTx: Digital therapeutics; HAS: Haute Autorité de Santé; HTA: Health technology assessment; NICE: National Institute for Health and Care Excellence; PBMs: Pharmacy benefit management; US: United States

# The number of DTx covered across countries is increasing, with Germany leading the race

## TOTAL DTx COVERED AS PER PUBLICLY AVAILABLE DATA\*






\* Cut-off date: December 2022

CP: Commercial plans; CMS: Centers for Medicare and Medicaid Services; DTx: Digital therapeutics; EU-3: Europe 3, United Kingdom, Germany, France; PBM: Pharmacy Benefit management

# In the EU-3, HTA agencies have centered their decision-making on clinical and technical aspects of DTx

## KEY DETERMINANTS FOR COVERAGE IN THE EU-3

*Determinants of coverage identified through the **thematic analysis** of the identified **HTA reports***

			
<b>COMPARATIVE CLINICAL BENEFIT</b>	High	High	High
<b>DTx FUNCTIONALITY*</b>	High	High	High
<b>DATA REGULATIONS**</b>	High	High	High
<b>HUMAN BENEFIT (PRO/QoL)</b>	Low	Not a determinant	Not a determinant
<b>SOCIETAL BENEFIT (PRODUCTIVITY)</b>	Low	Not a determinant	Not a determinant
<b>HEALTH LITERACY IMPROVEMENT***</b>	Low	Not a determinant	Not a determinant
<b>PUBLIC HEALTH INTEREST</b>	Not a determinant	High	Not a determinant
<b>IMPROVED PATIENT ACCESS</b>	Not a determinant	Not a determinant	High
<b>COST-EFFECTIVENESS</b>	Not a determinant	Not a determinant	High

**IMPORTANCE IN DECISION-MAKING**

- HIGH
- LOW


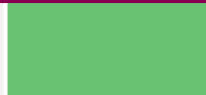







\* DTx functionality refers to the functional, safety, and quality characteristics of the DTx that ensure the DTx is both user-friendly and safe; \*\*Data regulations refers to the legal framework that oversees the management of patient data, which are in line with those required for the marketing authorization of the DTx; \*\*\* Health literacy refers to patients' ability to obtain, process, understand, communicate, and act on health information and services

DTx: Digital therapeutics; EU-3: Europe 3, United Kingdom, Germany, France; HTA: Health technology assessment; QoL: Quality of life; PRO: Patient reported outcomes

# In the US, key determinants for DTx coverage are largely linked to their regulatory status




## KEY DETERMINANTS FOR COVERAGE IDENTIFIED ACROSS POLICIES IN THE US

*While the key determinants for coverage represent the most influential themes for coverage observed across publicly available coverage policies, no unified key determinants for coverage exists to mandate the coverage of DTx in the US*

	
PHYSICIAN PRESCRIPTION	
USE WITHIN THE APPROVED/CLEARED INDICATION	
FDA APPROVAL OR CLEARANCE	
CREDIBLE SCIENTIFIC EVIDENCE	
COMPARATIVE CLINICAL BENEFIT	
PATIENT > 18 YEARS OF AGE	
USE FOR OUTPATIENT CARE	
ABILITY TO INTERACT WITH SOFTWARE	

*Determinants of coverage identified through the thematic analysis of the identified policies of the insurance companies*

**IMPORTANCE IN DECISION-MAKING**

-  HIGH
-  MEDIUM
-  LOW

# While most key determinants for coverage of DTx align with those for drugs, a few differences exist



DTx: Digital therapeutics

# Learnings from the established access pathways in the EU-3 and US can help optimize commercial success in other countries

## KEY TAKEAWAYS

-  **DTx** represent *innovative disease-management approaches* that can *fill in the unmet needs* observed in certain **disease areas** and **health systems**
-  **Insurance funding channels** can offer a **route for access** as the DTx landscape continues to evolve, without **exposing patients to financial hardship**
-  **Unified frameworks** for DTx assessment, as observed in the EU-3, can drive **equitable access** to DTx while ensuring **efficient resource allocation**
-  **DTx policy-making** in countries/insurers **without unified frameworks/policies** could **leverage** what is observed in the **EU-3 and US policies** when defining the **key coverage determinants/drivers for policy-making**

## KEY ACTIONS

-  **Seize the opportunity** offered by DTx to advance **personalized medicine**, creating **synergies** between **drugs, devices, and DTx** to **improve clinical outcomes**
-  **Collaborate** in the development of **unified value-based policies and assessment frameworks** for DTx coverage that **promote patient access to DTx**
-  **Optimize** the DTx **CT design** to ensure that the **outputs align with the key coverage determinants** and **meet the expectations from funding authorities**
-  **Develop** **value communication documents and evidence packages** that demonstrate **the value of DTx to patients, physicians, and funding authorities**

## For follow up and questions

### › Lucia Perez-Kempner



- › Pharm, MBS, MSc
- › Senior Consultant, Parexel International
- › M: +34-650-607-377
- › [E: marialucia.perez-kempner@parexel.com](mailto:marialucia.perez-kempner@parexel.com)

# Thank you

parexel®