Policymaker & Payor DTx Evaluation Toolkit

As healthcare decision makers (HCDMs) across the world seek out, assess, approve, and implement DTx products, it is important for these clinicians, policymakers, and payors to have access to reliable resources and frameworks that enable more consistent evaluation and implementation of DTx products across local, national, and regional settings.

Increasing Patchwork of Frameworks

HCDMs play a critical role in providing patients with access to high-quality, clinically validated digital therapeutic (DTx) products.

Policymakers and payors already use consistent frameworks to evaluate other evidence-based clinical therapies such as pharmaceuticals. However, given the recent growth of the DTx industry and lack of frameworks defining what "good" looks like, many HCDMs have needed to develop their own methods to evaluate DTx products.

As a result, a patchwork of HCDM requirements and frameworks are emerging for DTx manufacturers at the local, national, and regional levels.

Harmonizing DTx Requirements

DTA developed this Toolkit to provide a common language and process for HCDMs and DTx manufacturers to jointly use throughout DTx product evaluation and implementation processes. It addresses a wide spectrum of HCDM considerations across various settings—ranging from health systems, employers, and private payors, to single-payor government systems—and will continue to be updated to ensure ongoing relevance in this quickly evolving ecosystem.

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To evaluate and implement DTx products, HCDMs should consider the following steps and resources:

STEPS	RESOURCES
Understand the digital health technologies (DHT) that are available to patients, caregivers, and clinicians today	▪ *Fact Sheet:* DHT Ecosystem Categorization (2023) ▪ Comparison Guide: Patient-facing DHTs (2023) ▪ *Report:* Guidance to Industry: Classification of Digital Health Technologies (DHT) (2023)
Account for DHT products that have multiple functions and components	▪ Proposing a Harmonized Multi-Functional DHT Approach (2023)

STEPS	RESOURCES
Know how to define a digital therapeutic (DTx)	▪ *Fact Sheet:* International Organization for Standardization (ISO) Digital Therapeutic Definition (2023) ▪ ISO Technical Report (TR) 11147: Health informatics—Personalized digital health—Digital therapeutics health software systems (2023) ▪ *Fact Sheet:* DTA's Adoption & Interpretation of ISO's DTx Definition (2023)
Recognize DTx industry core principles and policy positions	▪ *Fact Sheet:* Digital Therapeutics Industry Core Principles (2018) ▪ DTx Industry Code of Ethics (2019) ▪ DTx Product Best Practices (2019) ▪ *Fact Sheet:* DTA Policy Positions (2022)
Understand DTx place in clinical therapy	▪ *Fact Sheet:* DTx Intended Uses & Mechanisms (2023) ▪ DTx Disease State Targets (2023) ▪ 'Is This Product a DTx?' Flowchart (2022) ▪ 'Where Do Digital Therapeutics Fit into Healthcare?' Flowchart (2022)
Identify specific DTx products to consider, review, and evaluate ***Note:*** *DTA does not endorse, review, or certify DTx products.*	▪ DTx Product Library (2023)
Review existing regulatory and reimbursement pathways for DTx products	▪ European DTx Regulatory & Reimbursement Pathways (2023) ▪ *Fact Sheet:* Australia DTx Regulatory & Reimbursement Pathways (2022) ▪ *Fact Sheet:* China DTx Regulatory & Reimbursement Pathways (2022) ▪ *Fact Sheet:* Japan DTx Regulatory & Reimbursement Pathways (2022) ▪ *Fact Sheet:* South Korea DTx Regulatory & Reimbursement Pathways (2022) ▪ *Fact Sheet:* United States DTx Regulatory & Reimbursement Pathways (2022)

STEPS	RESOURCES
Develop, or refine, a formal process to evaluate DTx foundational components	▪ DTx Value Assessment Dossier: DTx Product Benchmark Questions (2022) ▪ DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Impact & Intended Use (2022) ▪ DTx Value Assessment Dossier: DTx Product Evaluation: Regulatory & Security (2022)
Develop, or refine, a formal process to evaluate DTx clinical impact	▪ DTx Value Assessment Dossier: DTx Product Evaluation: Clinical Evidence (2022) ▪ *Publication:* Digital Therapeutic Clinical Evidence Basics (2022) ▪ *Publication:* Digital Therapeutic Clinical Evidence Quality & Timing Recommendations (2022) ▪ DTx Real-World Evidence in Practice: Pragmatic Clinical Trials as a Compelling Approach to Inform Healthcare Decisions (2023)
Educate target end users, including patients, caregivers, and clinicians	▪ *Fact Sheet:* Demystifying DTx (2023)
Develop, or refine, a formal process to evaluate DTx health economic impact	▪ DTx Value Assessment Dossier: DTx Product Evaluation: Economic Assessment (2022) ▪ *Report:* Digital Therapeutics: Reducing Rural Health Inequalities (2020)
Implement and scale DTx products to enable appropriate patient access	▪ DTx Integration Guide: Implementing Digital Therapeutics in Practice (2022) ▪ US DTx Workflow & Integration Report (2023) ▪ *Fact Sheet:* DTx Market and Patient Access Pathways (2023) ▪ *Fact Sheet:* DTx Prescription vs. Non-Prescription Pathways (2023)