Ensuring appropriate **quality**, **access**, and **utilization** of digital therapeutics

Patients, clinicians, and payors all play a role in ensuring digital therapeutic (DTx) quality, access, and utilization.

Product Claims Matter.

Is this a digital wellness, diagnostic, or therapeutic product?

Products across the digital health spectrum serve different purposes. According to each product's claim, it is subject to different degrees of security and privacy requirements, regulatory oversight, clinical evaluation, and ongoing real world evidence.

	WELLNESS & SUPPORT	DIAGNOSTIC & MONITORING	THERAPEUTIC INTERVENTIONS
Overview	Products that capture, store, transmit health data	Products that measure and/or intervene	Products that deliver therapeutic interventions directly to patients
Clinical evidence	*Not typically required*	**Required**	**Required**
Real world outcomes	*Not typically required*	*Not typically required*	**Required**
Examples	▪ Lifestyle apps & fitness trackers ▪ Telehealth platforms ▪ Health Information Technology ▪ Consumer health information ▪ Enterprise support	▪ Digital diagnostics ▪ Digital biomarkers ▪ Remote patient monitoring ▪ Medication adherence tools ▪ Ingestible sensors ▪ Connected drug delivery devices	Digital therapeutics deliver interventions that treat, manage, and prevent a broad spectrum of behavioral, mental, and physical diseases and disorders

*More information provided on https://dtxalliance.org/aboutdtx/

Product Quality Matters.

What should I expect from a digital therapeutic?

DTx products must adhere to each of these foundational principles:

1. Prevent, manage, or treat a medical disorder or disease
2. Produce a medical intervention that is driven by software
3. Incorporate design, manufacture, and quality best practices
4. Engage end users in product development and usability processes
5. Incorporate patient privacy and security protections
6. Apply product deployment, management, and maintenance best practices
7. Publish trial results inclusive of clinically meaningful outcomes in peer-reviewed journals
8. Be reviewed and cleared or approved by regulatory bodies as required to support product claims of risk, efficacy, and intended use
9. Make claims appropriate to clinical validation and regulatory status
10. Collect, analyze, and apply real world evidence and/or product performance data

DTA's industry principles, code of ethics, and best practices establish expectations for high quality DTx products.

Product Access is Necessary.

How do payors provide access to DTx products?

Logistical considerations:

- **Patient access provided through a third-party payor?**
  e.g., public payor, private payor, employer
- **Screening process for appropriate patient access?**
  e.g., third-party review, clinician authorization, validated screening tool
- **Clinician authorization required?**
  e.g., clinician prescription, referral, recommendation
- **Product delivery to patient?**
  e.g., product activation code delivered by third-party, dispensed through a pharmacy, provided by manufacturer or vendor
- **Platforms used by patient to access product?**
  e.g., patient smartphone, tablet, computer, VR headset
- **Additional components necessary?**
  e.g., wearables, sensors, hardware, affiliated medical devices

Payors also consider product implementation and scalability, clinical appropriateness, patient engagement and sustainability, privacy and security requirements, and the value provided to patients, caregivers, and clinicians — including improved health outcomes, reduced overall costs, and individual and population health benefits.

Appropriate Utilization is Crucial.

How do clinicians ensure that DTx products are used appropriately?

DTx products provide evidence-based therapy options for a wide variety of physical, mental, and behavioral conditions.

For products requiring clinician authorization, clinicians may reference the following "rights" in assessing appropriate DTx product utilization:

- **The right indication:** Which disease or disorder does the product have an indication to treat, manage, or prevent?
- **The right patient:** For which patients does this product offer targeted, evidence-based, clinically evaluated therapies?
- **The right therapy:** Should the product be used independently, or with medications, devices, or other therapies? Does it align with the patient's current care?
- **The right timing and frequency:** What is the timing, duration, frequency, and termination of therapy use?
- **The right cultural references:** Is product content available to the patient in a familiar language and with appropriate cultural references?
- **The right outcomes documentation:** What clinical outcomes are collected by the product and shared with patients, caregivers, and clinicians?
- **The right response to therapy:** How are real world outcomes leveraged to detect adverse events and non-optimal outcomes, in addition to assessing product utilization, engagement, and success of therapy?
- **The right evaluation:** How are actionable insights leveraged by clinicians to assess and optimize overall therapy?

DTA will continue to develop resources for patients, caregivers, clinicians, payors, and government agencies to ensure the optimal utilization of, access to, and quality of DTx products.