



DTx Value Assessment Dossier

DTx Product Evaluation: Clinical Impact & Intended Use



Step 1: DTx Product Basics

Digital therapeutics (DTx) provide patients with clinically validated, scalable disease treatment, management, and prevention options. The following questions provide healthcare decision makers (HCDM) with a baseline framework to begin evaluating a digital therapeutic product.

Product Overview

Product name: _____

Target disease or disorder(s): _____

Intended use(s): _____

Target patient population(s): _____

Clinical issues addressed and/or gaps filled by product: _____

Product Use Considerations

Approved indication(s): _____

Directions for use: _____

Duration of therapy: _____

Dosing regimen: _____

Potential adverse events: _____

Risks or warnings: _____

Drug interaction(s): _____

Device interaction(s): _____

Check all that apply.

Intended environment of initial therapy use:

- Patient setting (i.e., home, work, school)
- Healthcare setting (i.e., clinic, hospital)
- Aged or disability residential care (i.e., nursing home, rehabilitation center)
- Other: _____

Intended environment of ongoing therapy use:

- Patient setting (i.e., home, work, school)
- Healthcare setting (i.e., clinic, hospital)
- Aged or disability residential care (i.e., nursing home, rehabilitation center)
- Other: _____

What stage of development is the product currently in?

- Technical and pre-clinical development phase
- Clinical development phase
- Product is undergoing initial regulatory review
- Product has cleared all necessary clinical and regulatory requirements in one or more jurisdictions
- Other: _____

Most recently released version of the DTx product: _____

In addition to the DTx product delivering a therapeutic intervention directly to a patient via software, the product also has the ability to:

- Monitor, predict, or react to the progression of a disease or disorder
- Deliver clinical insights (immediate or trends) to the patient and/or caregiver(s)
- Deliver actionable clinical insights to a clinician or HCDM
- Enable remote patient monitoring
- Collect patient-generated insights and outcomes
- Collect information on patient-reported outcomes (PROs), quality of life, etc.
- Assist in the diagnosis of a disease or disorder
- Monitor medication adherence/outcomes
- Track non-medication therapy adherence/outcomes
- Enable medication and/or overall therapy optimization
- Provide patient with general health insights
- Connect patient with a therapist or health coach
- Support meaningful interactions between a patient and clinician
- Other: _____

What is the product's current stage of commercialization in the target jurisdiction of use?

- Product is not commercially available to patients
- Product is available to select patients who are engaged in pre-market studies
- Product is available to limited patient populations via pilot studies
- Product is commercially available to patients
- Other: _____

What is the product's stage of reimbursement in this or other jurisdictions?

- Product is in pre-coverage phase
- Product is undergoing initial coverage decision evaluations
- Product is being paid for by patients and other end users
- Product is covered by one or more payor entities
- Other: _____

Step 2: Clinical Impact

DTx products provide patients, caregivers, and clinicians with new therapeutic options to support, improve, or replace the current standards of care for a wide range of diseases and disorders. For example, in certain care pathways, medications have long been the only therapeutic option available to patients. However, with the introduction of digital therapeutics, patients now have the opportunity to benefit from therapies that use software in addition to chemical or person-driven interventions to achieve their therapeutic goals.

Check all that apply.

To directly impact patient needs and clinical outcomes, this product:

- Provides a clinically validated therapeutic option for a disease or disorder (i.e., further optimizes therapy, addresses an unmet or under-addressed patient need)
- Delivers a personalized therapeutic intervention (i.e., intervention based on patients' needs, tailored to patient outcomes and abilities)
- Improves patient outcomes (i.e., increased cognitive performance, lower risk of cardiometabolic complications, reduced disease state comorbidities)
- Consistently demonstrates beneficial clinical outcomes (i.e., clinical trials, real-world data [RWD], real-world evidence [RWE])
- Provides the patient with real-time results and insights (i.e., clinical outcomes, progress on personalized goals)
- Improves the patient experience (i.e., increased utilization, engagement, acceptance, enjoyment)
- Enables the analysis of patient- and population-level health outcomes (i.e., patient-specific outcomes, subpopulation analyses, population health trends)
- Makes therapies more accessible and scalable to patients (i.e., provided remotely, reaches underserved populations)

Types of clinical measures the DTx product uses: _____

DTx product's relationship to other therapies:

- DTx intervention is a standalone therapy
- DTx intervention indirectly supports another therapy: _____
- DTx intervention directly supports a concurrent treatment: _____
- DTx intervention complements a clinician-delivered therapy: _____
- DTx intervention can replace an existing therapy: _____
- Co-prescribed and/or concomitant therapies: _____
- Other: _____

Does the DTx have a comparator therapy? No Yes: _____

How does the DTx therapy relate to the current standard of care?

- There is no current standard of care for this condition
- DTx therapy supports current standard of care
- DTx therapy improves standard of care
- DTx therapy replaces standard of care
- Other: _____

How does the intervention align with evidence-based clinical guidelines?

- DTx therapy approach is reflected in an evidence-based clinical guideline(s): _____
- DTx therapy (i.e., product name) is specifically included in an evidence-based clinical guideline(s): _____
- DTx therapy is not currently represented in clinical guidelines: _____
- Other: _____

The following data sets may be used to determine patient progress in therapy:

- DTx-generated data (i.e., real-world outcomes, therapy trends)
- Standardized patient assessments (i.e., GAD-7, PHQ-9, PSS)
- Patient-reported outcomes (i.e., validated outcome measures, disease state triggers, pain perception)
- Therapy status (i.e., duration, stage, progression of therapy)
- Other: _____

Step 3: DTx Product Authorization and Distribution

Because DTx deliver clinical interventions to patients for a specific disease or disorder, these products should be used by the right patient, at the right time, and for the right purpose. As such, DTx products typically undergo some form of an authorization process prior to patient use to ensure that each therapy is used appropriately.

Check all that apply.

Product Authorization

Patient access to the product may be provided via:

- Formal prescription from a qualified clinician (in-person or virtual engagement)
- Clinician referral for a non-prescription DTx product (in-person or virtual engagement)
- Direct authorization by an employer for a non-prescription DTx product
- Direct authorization by a payor for a non-prescription DTx product
- "Authorized clinical protocol" established by a HCDM to authorize automatic patient access when necessary qualification requirements are met
- "Clinically validated screening tool" that patients use to determine whether they qualify for the therapy
- "Over-the-counter" model where no form of third-party authorization is necessary
- Other: _____

Ability and/or necessity of DTx therapy to be reauthorized or terminated following the first use cycle:

Product Distribution

Patients may access or download the DTx product shell (without access to the product's content until a patient-specific authorization code is used):

- On the following online app stores: _____
- On a dedicated device: _____
- Other: _____

Patients receive a product access code following authorization of a non-prescription or prescription product—and any necessary product components (i.e., hardware, wearables)—via:

- Remote delivery via SMS or email
- Remote delivery via mail
- In-person delivery at a clinic or hospital
- In-person delivery at a pharmacy
- Other: _____

Entities involved in product distribution may include:

- DTx product support center
- Clinician and/or clinical team
- Virtual health coach or provider
- Telehealth provider
- Pharmacy
- HCDM
- Other: _____

When appropriate, following the use of DTx hardware product components (i.e., sensors, wearables), these are:

- Retained by the patient
- Returned to the DTx manufacturer
- Other: _____

Commentary: This framework provides a high-level overview of the DTx product's ability to be authorized and/or reauthorized by HCDMs. DTx products may either be incorporated into traditional healthcare distribution processes or enable novel methods of therapy authorization and distribution.

Step 4: Patient-Facing Technical Considerations

DTx are software-based and can be hosted on multi-purpose or dedicated hardware platforms. DTx products may be used independently or in concert with medications, devices, or other therapies to optimize patient care and health outcomes.

Check all that apply.

What component(s) are required for the software to deliver its therapeutic value?

- Multi-purpose computing device (i.e., smartphone, tablet, computer, virtual reality [VR] headset)
- Dedicated computing device (i.e., delivery device is specific to the DTx therapy)
- Hardware (i.e., wearable, sensor, scale)
- Medication
- Service (i.e., virtual or in-person care)
- Other: _____

DTx product may be used on the following host technology(ies):

- Smartphone
- Tablet
- Laptop or desktop computer
- Headset
- Wearable (i.e., smartwatch)
- Medical device
- Other: _____

Hardware components that may be required for, or to enhance, product use:

- Hardware or affiliated medical device; specifically: _____
- Wearable or sensor; specifically: _____
- Other: _____

Hardware components may be:

- Patient-owned; specifically: _____
- Provided to the patient; specifically: _____

Level of network connection required for product use:

- Does not require a sustained network connection (offline-capable)
- Requires ongoing basic network connection
- Requires ongoing broadband or high data connection
- Other: _____

Product software is compatible with: iOS Android Web Other: _____**Form(s) of technical assistance available to patients and clinicians:** In-product support Product demonstrations, videos, on-demand content Dedicated product website (+/- chat functionality) Phone service line Virtual or video "in home" support Clinic or pharmacy in-person support Other: _____

Commentary: DTx products have varying levels of technical requirements depending on the disease state being addressed and the type of intervention delivered to the patient. Understanding the product's technical requirements will assist HCDMs and information technology (IT) teams in enabling optimal use of the DTx therapy.

Step 5: Product Usability

Product appropriateness and usability are critical to ensuring that the DTx product's full therapeutic value is delivered to the patient. The following considerations can help HCDMs determine which end users may benefit from the specific DTx therapy. Correctly identifying patient populations who will benefit from a DTx therapy and ensuring that all necessary technical requirements are accounted for will increase the likelihood of successful clinical outcomes and reduce unnecessary costs.

Check all that apply.

DTx product accounts for the following:

- Language(s): _____
- Health literacy levels: _____
- Digital health literacy levels: _____
- Cultural considerations: _____
- Disability considerations: _____
- Special patient circumstances, abilities, and needs: _____
- Patient age considerations: _____
- Other: _____

Product Usability

DTx product includes the following:

- End user-centric design (i.e., understandable user interface and display)
- Patient-centric instructions (i.e., directions, time commitment)
- Clearly identified patient and clinician product access points (i.e., initial, ongoing)
- Technical considerations (i.e., hardware interoperability, battery drain)
- End user usability testing
- Other: _____

Patient Protection

DTx product includes the following:

- Product provides necessary device and information security [further insight provided in Step 10]
- Patient data is protected [further insight provided in Step 11]
- Other: _____

End User Support

DTx product includes the following:

- Reliable and consistent product performance
- End user-centric technical support (i.e., FAQs, call center, virtual, in-person)
- Regular software updates for ongoing user friendliness and patient applicability
- Other: _____

Product Design Process

DTx product includes the following:

- Human factors testing, physiological tracking methods
- Qualitative research (i.e., focus groups, observational sessions, user interviews)
- Other: _____

Step 6: Patient Centricity

Digital therapeutics exist for the benefit of patients and other end users. As such, they need to be designed to meet patient needs, address current gaps in care, and improve health outcomes. Given the diversity of patient experiences and needs, the following considerations provide HCDMs with a guide to optimize product appropriateness:

Check all that apply.

To use this product appropriately, individual patients should:

- Have access to host technologies (i.e., smartphone, tablet, headset)
- Have access to related product components (i.e., hardware, sensors, medications, in-person therapy)
- Have access to WiFi or cellular internet (i.e., sustained or intermittent connection, broadband)
- Display a sufficient level of literacy, digital health literacy, numeracy
- Be informed of available cost-sharing or product coverage options
- Other: _____

Patient financial considerations for this product include (varies by use setting, payor):

- This product may be fully covered by a health plan, in-network provider, payor, or employer, with no patient cost
- This product may be partially covered, with some patient out-of-pocket costs (i.e., deductible, co-insurance)
- This product may be patient-covered, with no third-party coverage
- Other: _____

Typical patient costs for this product may be: _____

This product may provide patients with the following clinical benefits:

- Reliable insights and resources as patients manage and navigate their care
- New treatment modality for patients if other therapy options are insufficient, inappropriate, or already exhausted
- Equitable access to high-quality therapies through the product's ability to scale
- Delivery of reliable clinical insights to relevant clinical care teams
- Other: _____

This product may provide patients with the following environmental and social benefits:

- Expanding patients' ability to receive active clinical care in and beyond traditional settings (i.e., in-home settings, asynchronous care, remote/digital care)
- Providing novel therapy options for patients in underserved settings (i.e., low-income, rural, urban settings)
- Providing technical support services for patients, caregivers, and other end users (i.e., in-product support, product support center, multilingual support)
- Addressing existing disparities (i.e., social determinants of health, accessibility, socioeconomic status)
- Other: _____

Additional consumer friction points this product may address include:

- _____
- _____

Step 7: DTx Product Technical Considerations

Digital therapeutics are recognized as medical devices and therefore are subject to a variety of internationally recognized standards, national, and local regulations. Understanding the product's technical requirements will assist HCDMs and IT teams in enabling optimal use of the DTx therapy.

Check all that apply.

Technical Considerations

DTx product typically functions:

- As a standalone product
- With built-in capacity to integrate data streams and outputs with other products
- As part of a multi-product platform
- Other: _____

To generate therapeutic interventions, the product uses:

- Static algorithms
- Artificial Intelligence (AI) functionalities
- Machine Learning (ML) functionalities
- Other: _____

DTx manufacturer has taken the following steps to prevent biases in therapeutic algorithms:

Product has notification, recovery, and resolution plans in the event of a(n):

- Software malfunction
- Hardware malfunction
- Integration malfunction
- Affiliated product malfunction
- Other: _____

Data Infrastructure and Storage

The following entities are typically responsible for:

- Data storage/hosting: _____
- Data access: _____
- Data ownership: _____
- Data upkeep/deletion: _____
- Other: _____

Typical frequency of:

- Software patches: _____
- Operating system updates: _____
- Cybersecurity improvements: _____
- Other: _____

Measures tracked for DTx product uptime availability: _____

Measures tracked for DTx product reliability: _____

Data storage is hosted on:

- Private cloud, in the following country(ies): _____
- Public cloud, in the following country(ies): _____
- Hybrid cloud, in the following country(ies): _____
- Multicloud, in the following country(ies): _____
- Other: _____

Step 8: DTx Manufacturer Evaluation

Equally important to ensuring DTx product quality is the confidence HCDMs must have in the manufacturers that develop and support each product. The following criteria provide HCDMs with a high-level overview of a manufacturer's reliability, governance, and services.

Check all that apply.

What is the company's approach to ensuring product quality?

The manufacturer:

- Ensures safe, effective, and secure products during all life cycle phases
- Uses good development practices that incorporate appropriate review activities such as code review, peer review, and self-review
- Conducts verification and validation processes to ensure conformity to requirements and confidence the software meets its intended use, user needs, and operational requirements
- Other: _____

Will the company have the ability to launch, scale, and maintain this product long-term?

The manufacturer:

- Has a history of strong internal leadership and organization tenure
- Is well-managed across key pillars
- Openly shares relevant information with stakeholders to build confidence in the organization and its products
- Has the appropriate resources necessary to ensure effectiveness across all life cycle processes and activities in meeting user requirements
- Demonstrates the ability to meet the scale required with a reproducible impact
- Possesses the ability to enable smooth product rollouts and provide ongoing maintenance
- Prioritizes a patient safety focus to monitor and manage risks
- Other: _____

How does the company approach data generation and management?

The manufacturer:

- Optimizes product use through real-world performance monitoring
- Provides patients with clear and concise information related to data access and use
- Protects and stores data according to local, national, and regional requirements
- Other: _____

How will the company support customers?

The manufacturer:

- Provides customer support services (i.e., health systems, employers, clinicians, patients)
- Has a history of pursuing partnerships with relevant stakeholders
- Demonstrated success with previous product lines, launches, or pre-market pilots
- Other: _____

Commentary: Companies that develop and manufacture DTx products must be dedicated to scientific, rigorous product development and maintenance processes that undergo clinical evaluations and are subject to regulatory oversight. These factors enable increased product trustworthiness and integrity.

Digital Therapeutics Alliance

Founded in 2017, the Digital Therapeutics Alliance (DTA) is a non-profit trade association of industry leaders and stakeholders engaged in the evidence-driven advancement of digital therapeutics. As the leading international organization on digital therapeutic thought leadership and education, DTA provides patients, clinicians, payors, and policy makers with the necessary tools to evaluate and utilize DTx products.

DTA's members—including organizations dedicated to manufacturing, evaluating, supporting, and utilizing DTx products—work to transform global healthcare by advancing high-quality, clinically validated digital therapeutics to improve clinical and health economic outcomes.