



DTx Value Assessment Dossier

DTx Product Evaluation: Economic Assessment



Step 19: Preparing for a DTx Economic Analysis

It is important for healthcare decision makers (HCDM) to develop consistent expectations for the types of economic data that digital therapeutic (DTx) manufacturers are required to develop and submit for formal review. Compared to non-digital therapies, DTx products enable HCDMs to conduct cost analyses with data that are generated in real-time by the product and provide specific insights at the individual and patient population levels.

Check all that apply.

Economic analysis is intended to be applicable for the following setting(s):

- Regional (i.e., European Union): _____
- National (i.e., country-level): _____
- Sub-national (i.e., provincial, state, local decision-making bodies): _____
- Organizational (i.e., payor, employer): _____
- Other: _____

What is the purpose of conducting a product-specific economic evaluation analysis for this product?

- Assess DTx therapy impact on costs, revenue, and other economic implications
- Compare therapy to existing alternatives and standard of care
- Enable contracting processes (i.e., outcomes, value-based arrangements)
- Gather information about healthcare system implementation costs and considerations
- Assess current gaps in care, barriers to treatment, inequalities, and resulting economic inefficiencies
- Inform decision making to enable an equitable, efficient, and high-quality health system
- Understand place of the DTx product in varied patient use settings and its impact on healthcare costs for patients, clinicians, and payors
- Other: _____

What steps should be completed in advance of this economic analysis?

- Competitive analysis to assess similar or alternative therapies/technologies available, the current standard of care, and associated costs of various treatment paradigms
- Third-party evaluations to demonstrate evidence of economic benefit and/or return on investment (ROI)
- Identifying partner organizations who share common goals and could provide additional resources to complete a study
- Other: _____

What are possible sources of economic data that should be included in DTx economic evaluations for this product?

- Product cost and how it relates to utilization (i.e., direct and indirect costs and requirements)
- Clinical trial outcomes (i.e., randomized control trials [RCT], observational studies)
- DTx-generated real-world data (RWD) (i.e., patient utilization and engagement metrics, clinical measurements and outcomes, patient-reported outcomes (PRO), dissemination speed and DTx product reach, usability)
- Real-world evidence (RWE) studies (i.e., population-level impacts, clinical setting-specific outcomes, product utilization, outcomes, healthcare costs, impact of costs through use of RWD)
- Retrospective analyses (i.e., data from chart reviews, medical and pharmacy claims, electronic medical records, or other novel sources of data)

- Demonstrated/measured financial impact (i.e., system costs and savings, impact on underserved or undertreated populations, economic modeling, incremental cost-effectiveness ratio results, resource utilization, cost offsets)
- Other: _____

Cost analysis types HCDMs may use to evaluate DTx product economic impact include:

- Budget impact model (local or regionalized data)
- Cost-utility analysis
- Cost-consequence analysis
- RWE
- Cost-effectiveness analysis
- Cost-benefit analysis
- Cost-minimization analysis
- Other: _____

Potential economic evaluation models HCDMs may consider using for this therapy include:

- Unit price-based pricing, based on the cost of the product and volume of use
- Outcomes-based contracting, where the overall price is based on product outcomes/savings
- Risk-bearing contracts, where employers/health plans bear some risk for providing high-quality care at low costs
- Average cost per member, including per member per month (PMPM)
- Subscription model, with product access for a specified number of patients
- Case rate model, including payments made per number of patients treated
- General contracting processes, where manufacturers and payors agree on mutually beneficial terms
- Patient-funded, with no third-party reimbursement
- Other: _____

Step 20: Undertaking a Formal Economic Analysis

Initial economic analysis inputs may be provided by a DTx manufacturer and include clinical trial results, RWD outcomes, RWE studies, and health economic outcomes research (HEOR). Additionally, health systems may provide setting-specific inputs to improve economic modeling, including payor-generated outcomes related to system costs and payor-generated claims data to demonstrate local product impact. Ongoing DTx-generated individual and population-level RWD are beneficial to include for long-term analyses.

Check all that apply.

Who is responsible for completing product-specific economic analyses:

For initial analyses? DTx manufacturer HCDM/payor Other: _____

For ongoing analyses? DTx manufacturer HCDM/payor Other: _____

Who is responsible for generating data for analyses:

For initial analyses? DTx manufacturer HCDM/payor Other: _____

For ongoing analyses? DTx manufacturer HCDM/payor Other: _____

What is the ideal focus of a product-specific economic analysis?

Setting-specific Multi-setting Other: _____

What components should be included in a product-specific economic analysis?

- Structured summary of objectives
- Economic analysis background
- Therapy setting of use
- Population(s) included in analysis
- Claims data
- Analysis methods (study design, inputs)
- Analysis results (plus uncertainty analyses)
- Conclusions
- Other: _____

Are results of this type of economic analysis published in peer-reviewed literature?

Yes No Other: _____

What point(s) in the product life cycle is most appropriate for conducting this economic analysis?

- Pre-market phase
- Market approval phase
- Post-market phase
- Other: _____

Suggested cadence of economic analysis reviews:

- This product does not require subsequent cost analyses following the initial evaluation
- This product should undergo periodic cost analysis updates (i.e., ongoing product iterations, product optimization)
- This product requires an annualized (or similar) cost savings assessment to understand patient utilization of services (requires use of data from the HCDM)
- Other: _____

If additional evidence for future economic analyses needs to be developed later:

Expected timelines include: _____

Anticipated costs typically include: _____

Entities generally responsible for covering new expenses: _____

Other: _____

Step 21: Key Considerations for a DTx Economic Impact Evaluation

Through their ability to generate real-world outcomes, DTx products provide accurate patient and population-level insights for economic assessments, HEOR, and long-term forecasts. The following high-level framework provides the types of direct and indirect costs that HCDMs may use to evaluate the economic impact of DTx products.

Data for the initial phases of assessing direct and indirect economic impact are typically provided by the DTx product manufacturer. Although HCDMs are encouraged to provide setting or patient-specific insights for the initial evaluation processes, these data play a key role in ongoing direct and indirect economic impact analyses.

Assessing Direct DTx Product Economic Impact

What is the cost of the DTx course of therapy vs. a traditional or comparator therapy (i.e., replacement, new costs)?

What costs may be avoided by using the DTx product vs., or in addition to, a traditional or comparator therapy (i.e., costs related to in-person/virtual or pharmaceutical therapy, medication processing, administration, monitoring, storage)?

What durability of effect is the therapy expected to provide (i.e., short-term impact, long-term impact)?

What cost savings are generated by the DTx therapy (i.e., positive overall impact on patient health condition, long-term cost avoidance, faster therapy dissemination, measurement-based care)?

What follow-on costs may be generated by the DTx therapy (i.e., booster therapies)?

What costs are incurred or covered by the payor or other entities (i.e., employer, health system, clinician, patient)?

What is the overall cost effectiveness of the DTx therapy vs. a traditional or comparator therapy?

Assessing Indirect Economic Impact

What clinical or economic benefits are derived from data generated by the DTx product (i.e., impact of DTx-generated insights on overall care, therapy optimization, patient and population-level decisions, remote data analysis by qualified non-clinician teams)?

What health system savings are generated by the DTx therapy (i.e., clinician productivity, end user work presenteeism and productivity, implementation economies of scale when multiple DTx products are integrated into a system)?

What is the impact on clinician productivity, patient reach, and workflows?

What impact will this therapy have on the patient journey and experience (i.e., available personalized care options, increased convenience, on-demand care, patient preference)?

What societal value is created (i.e., prevent productivity loss, reduce caregiver burden, improve population health, increase access to and speed of therapy dissemination)?

Step 22: Factors That Affect DTx Therapy Economic Impact

In addition to standard cost analysis inputs, HCDMs take into account the following considerations that may directly and indirectly impact economic value.

Check all that apply.

Patient and Caregiver Clinical Outcome Considerations

DTx therapy economic evaluation should take into account:

- Clinical, behavioral, and health impact of the therapy for the targeted disease
- Cost savings related to product impact on other health conditions
- Cost savings related to product impact on or avoidance of adverse events, side effects, or comorbidities
- Patient and caregiver improved quality of life, satisfaction, and fulfilled expectations
- Convenience of and remote access to the active interventions provided by the DTx product, including:
 - Increased number of settings for care delivery (i.e., home, school, work, clinical environment)
 - Increased frequency of active care delivery (i.e., nights, weekends, between traditional care visits)
 - Societal impact and improved access to underserved populations (i.e., rural, urban, undertreated)
- Other: _____

Clinician and Health System Administrative Considerations

DTx therapy economic evaluation should take into account:

- Resources necessary to educate and enable clinicians to authorize and use DTx products in practice
- Short- and long-term impact on clinician workflow efficiencies and productivity
- Economies of scale achieved through the implementation of multiple DTx or digital health products into a single health system or platform
- Financial and administrative resources that may be freed up to create further capacity in the system
- Alignment with long-term digitization trends in the health ecosystem (i.e., compatibility with telehealth, virtual care)
- Product impact on national or local health system performance and quality ratings
- Clinical and financial value of applying insights generated by product back into patient-care settings
- Overall economic impact on the clinical practice or health system (positive, neutral, or negative budget impact)
- Other: _____

Payor Considerations

DTx therapy economic evaluation should take into account:

- Potential impact of DTx product on disease incidence, prevalence, target population, and current cost of care (i.e., increased therapy opportunities, forecasted rate of disease state improvement, estimated magnitude of disease state resolution)
- Measures that may be derived from DTx products (i.e., therapy utilization, magnitude of outcomes)
- Review of results from other types of studies such as pharmacoeconomic modeling, healthcare utilization, comparative effectiveness, and productivity studies
- Savings related to the deployment of value and outcomes-based payment models
- Billing codes and processes that apply to the use and delivery of the DTx product
- Other: _____

Employer Considerations

DTx therapy economic evaluation should take into account:

- Employee retention and satisfaction
- Employee presenteeism/absenteeism and productivity at work
- Ability to address disparities and critical social determinants of health
- Therapy impact on costs and outcomes vs. current standard of care
- Expanded benefits and non-traditional therapy options for mental, behavioral health, and chronic conditions
- Market differentiation and recognition
- Other: _____

Step 23: Health Technology Assessment (HTA) Considerations

Existing HTA frameworks¹ in Europe related to DTx already share a certain set of requirements (i.e., CE marking as a medical device), but requirements still vary related to interoperability and evidence.

HTA frameworks for evaluating DTx products are increasingly being established across Asia, Australia, and Europe. Current HTA examples include the mHealth Belgium Validation Pyramid Framework, the German DiGA Fast Track framework, the UK National Institute for Health and Care Excellence (NICE) Evidence Standards Framework for Digital Health Technologies and Digital Technology Assessment Criteria (DTAC) frameworks, and the French PECAN Fast Track Framework. Many countries are now embarking on their own efforts to develop DTx and digital health frameworks, so it is important for them to have access to best practices established at the country and industry level.

Check all that apply.

- The following HTA evaluations have already been conducted for this product:

- The following HTA evaluations are underway for this product:

Forthcoming and renewed HTA evaluations for this product should include the following costs and economic evaluation considerations:

Resource Utilization

- Types of resources used when delivering the assessed technology (vs. comparators, if applicable):

- Amounts of resources used when delivering the assessed technology (vs. comparators, if applicable):

- Measured and/or estimated costs of the assessed technology (vs. comparators, if applicable):

- How the technology modifies the need for other technologies and use of resources (vs. comparators, if applicable):

- Likely budget impacts of implementing the technologies (vs. comparators, if applicable):

- Other: _____

Measurement and Estimation of Outcomes

- Primary measured and/or estimated health-related outcome(s) of the assessed technology (outcome identification, measurement, and valuation):

- Other: _____

¹ HTA Core Model source: <https://eunetha.eu/wp-content/uploads/2018/03/HTACoreModel3.0-1.pdf> (page 205)

Examination of Costs and Outcomes

- Estimated differences in costs and outcomes between the technology and its comparator(s):

- Other:

Characterizing Uncertainty

- Possible uncertainties surrounding the costs and economic evaluation(s) of the technology:

- Other:

Characterizing Heterogeneity

- Extent that differences in costs, outcomes, or cost-effectiveness can be explained by variations between subgroups using the technology:

- Other:

Validity of the Model(s)

- Methodological assumptions that can be made in relation to the technology:

- Extent that estimates of costs, outcomes, or economic evaluation(s) should be considered as providing valid descriptions of the technology:

- Other:

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.