# Current and anticipated digital therapeutics payer perspectives

**Annie Chang, PharmD[1]; Alex Kilgore, PharmD[1]; Song Lee, PharmD, MBA[1]; Barbara Carpenter[1]; Tim Frank, CPC, LPTA[1]; Benjamin Parcher, PharmD, MS[2]**

**[1]Xcenda, Carrollton, TX, USA; [2]Self-affiliated**

## Introduction

- Digital therapeutics (DTx) are evidence-based, clinically evaluated medical or non-medical device software for treating, managing, and preventing a broad spectrum of diseases and disorders.[1]
- DTx aims to eliminate gaps in healthcare by using evidence-based technologies to deliver therapies through smartphones, tablets, and similar technologies that improve patient outcomes.[2]
- These innovative therapies increase patient access to clinically safe and effective therapies, extend clinicians' abilities to care for patients, and provide meaningful results and insights on personalized goals and outcomes to patients and their clinicians.[2]
- As a new therapeutic class and modality, the DTx market is forecasted to grow significantly in market size, as measured by gross sales. In 2019, the global DTx market size was valued at $2.9 billion and is expected to reach $11.8 billion by 2027.[3]
- As digital health adoption climbs, managed care organizations face barriers around DTx management as disparate DTx coverage has led to unequal uptake and discrepancies around utilization management strategies.
- Thus, an unmet need exists for elucidating current and anticipated DTx payer policy patterns, characterizing optimal pathways of DTx coverage, and understanding evidence that shapes policy development.

## Objective

- To understand current DTx payer coverage policy patterns and anticipated future trends.

## Methods

### Policy surveillance

- DTx products were identified using Biomedtracker, Meddevicetracker, and ClinicalTrials.gov.
- Key exclusion criteria for DTx products included any digital health or digital intervention products that are solely targeted for disease detection, devices, or healthcare provider communication.
- DTx medical policy research was conducted from August to September 2020 using Canary Insights (Lakewood, CO) to inform an electronic payer survey. Canary Insights is an online platform offering up-to-date information on the current policy landscape for all major commercial and government payers.[4]
- Policies were analyzed and synthesized across key parameters, informing policy count, state and national plan coverage, DTx product coverage, coverage rationale, and coverage requirements.

### Payer survey

- Using Xcenda's Managed Care Network (MCN), an electronic payer survey containing multiple choice, open-ended, and Likert scale rating questions was fielded to payers between November 6 and 20, 2020.
  - The MCN is a proprietary research panel, representing over 275 million covered lives, with over 160 healthcare executives, medical and pharmacy directors, and other experienced individuals in managed care.
- All survey respondents were required to be part of an integrated delivery network, pharmacy benefits manager, or health plan; familiar with utilization management on digital health/therapeutics; and involved in the drug review and approval process at their respective organizations for DTx products.
- Respondents were asked to appraise their organizations' coverage of DTx products, factors and requirements for DTx product coverage, opinions and feedback regarding DTx product coverage and coverage policies, as well as DTx product policy development strategy.

## Results

### DTx policy coverage:

**Figure 1. DTx medical policy research products and policies**


[a] Parent policy count excludes matching policies from affiliate or subsidiary payer organizations.
Key: DTx – digital therapeutics.

- A total of 132 DTx products were identified, with 14 products found to have ≥1 published policy (**Table 1**).
- ≥1 unique payer covered 36% of DTx products (**Table 1**).
- Geographically, 36% of DTx products are covered under national policies, 14% are covered under regional multi-state policies, 7% are covered under regional single-state policies, and 43% are covered under regional and national policies (**Table 1**).
- Of the 5 products covered by ≥1 unique payer, 80% have specified prior authorization (PA) criteria on the coverage policy (**Table 1**).
- Coverage rationale for DTx that are not covered include lack of well-designed trials, lack of inclusion in professional guidelines, insufficient evidence documenting product efficacy, and consideration as a convenience product.

**Table 1. DTx policy coverage data**

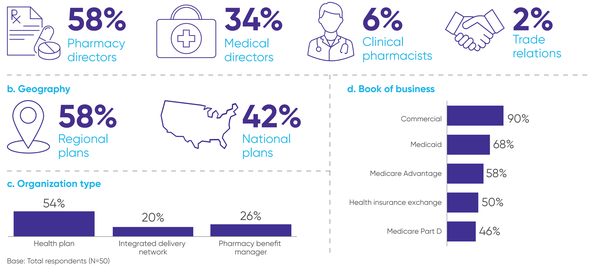
| Company | Product name(s) | Parent policy count[a] | Regional | | National | % Covered | If covered, PA criteria available? |
|---|---|---|---|---|---|---|---|
| | | | Multi-state | 1 State | | | |
| Pear Therapeutics | reSET® | 4 | 0% | 75% | 25% | 0% | N/A |
| | reSET-O® | 7 | 14% | 57% | 29% | 0% | N/A |
| Welldoc | BlueStar® | 3 | 33% | 0% | 67% | 0% | N/A |
| Palo Alto Health Sciences | Freespira® | 13 | 38% | 38% | 23% | 15% | No |
| Medtronic | MiniMed Connect® | 7 | 29% | 29% | 43% | 0% | N/A |
| Akili Interactive | EndeavorRx™ | 1 | 0% | 0% | 100% | 0% | N/A |
| Proteus Digital Health | Proteus Digital Feedback System® | 1 | 0% | 0% | 100% | 0% | N/A |
| | Proteus Discover® | 1 | 0% | 0% | 100% | 0% | N/A |
| Teva Pharmaceuticals | ProAir® Digihaler® | 4 | 50% | 50% | 0% | 100% | Yes |
| Medtronic | Sugar.IQ™ | 1 | 0% | 100% | 0% | 100% | Yes |
| Posit Science Corporation | HeartMapp® | 1 | 0% | 0% | 100% | 0% | N/A |
| Livongo Health | Insulia® | 1 | 0% | 0% | 100% | 0% | N/A |
| Teva Pharmaceuticals | ArmonAir Digihaler® | 1 | 100% | 0% | 0% | 100% | Yes |
| | AirDuo Digihaler® | 1 | 100% | 0% | 0% | 100% | Yes |

[a] Parent policy count excludes matching policies from affiliate or subsidiary payer organizations.
Key: PA – prior authorization.

### Survey demographics:

- A total of 50 respondents completed the survey, including 29 pharmacy directors (58%), 17 medical directors (34%), 3 clinical pharmacists (6%), and 1 trade relations individual (2%) (**Figure 2a**).
- 54% of respondents represented health plans, 26% represented pharmacy benefit managers, and 20% represented integrated delivery networks (**Figure 2c**).

**Figure 2. Respondent demographics**




Base: Total respondents (N=50)

### Survey results:

#### Digital health technology coverage

- 9 in 10 payers have reviewed at least 1 DTx, with mobile apps (48%) and medication adherence platforms (40%) as the most reviewed (**Table 2**).
- For top DTx product categories, the portion of products with preferred status was higher, although still below 50%. Most DTx require PA, with some requiring PA and step therapy, such as drug–delivery device combinations (35%) and smart pills (50%) (**Table 2**).
- Across all DTx product categories, medication adherence platforms and fitness trackers had the highest percentages of no coverage (35% and 50%, respectively) (**Table 2**).

**Table 2. DTx coverage by product category**

| DTx product category | Reviewed | Preferred | PA only | PA with step therapy | Not covered |
|---|---|---|---|---|---|
| Mobile apps | 48% | 48% (n=24) | 63% | 13% | 17% |
| Medication adherence platforms | 40% | 42% (n=20) | 55% | 10% | 35% |
| Drug–delivery device combinations | 34% | 41% (n=17) | 59% | 35% | 0% |
| Wearable diagnostics | 32% | 19% (n=16) | 69% | 19% | 13% |
| Continuous biometric monitors | 32% | 44% (n=16) | 81% | 6% | 6% |
| Telemonitors | 30% | 53% (n=15) | 87% | 7% | 7% |
| Home vital sign monitors | 28% | 36% (n=14) | 86% | 14% | 0% |
| Point-of-care diagnostics | 22% | 45% (n=11) | 73% | 9% | 18% |
| Smart pills | 20% | 10% (n=10) | 30% | 50% | 20% |
| Fitness trackers | 8% | 0% (n=4) | 25% | 0% | 50% |

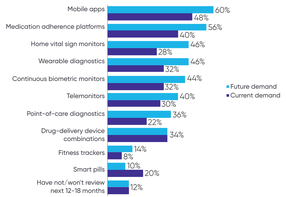
Base: Respondents who reviewed 1+ DTx technology (N=44)
Q2: In which of the following categories has your organization given one or more digital health technology products preferred status?
Q3: In general, how does your organization manage coverage for each of the following digital health technology product categories?
Key: DTx – digital therapeutics; PA – prior authorization.

- Demand growth, defined as future demand exceeding current demand by more than a 10% difference, was expected in mobile apps, medication adherence programs, home vital sign monitors, wearable diagnostics, continuous biometric monitors, telemonitors, and point-of-care diagnostics (**Figure 3**).

#### Digital health technology priorities by disease state

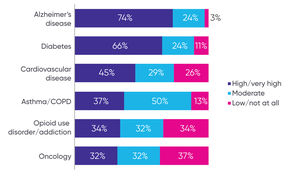
- The highest priority DTx disease areas were Alzheimer's disease and diabetes (74% and 66% rated as high/very high priority, respectively) (**Figure 4**).

**Figure 3. DTx current vs future demand in the next 12 to 18 months**




Base: Total respondents (N=50)
Q1: Digital health technology coverage: In which of the following categories has your organization's P&T committee formally reviewed at least 1 digital health technology product in the past 12–18 months? Q4c: In your opinion, in which of the following categories will your organizations see an increase in coverage demand for digital health technologies over the next 12–18 months?
Key: DTx – digital therapeutics.

**Figure 4. Current priority for managing DTx by disease state**




Base: Total respondents (N=50)
Q6: Please rate your organization's current priority for managing digital therapeutic products in the following disease states.
Note: Other disease states were included in the survey; however, only the top 6 disease states are shown in the figure above.
Key: COPD – chronic obstructive pulmonary disease; DTx – digital therapeutics.

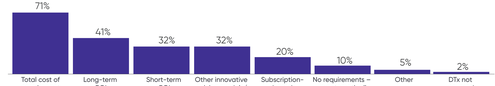
#### DTx product coverage and utilization management

- For DTx utilization management, DTx coverage typically fell under medical benefit (41%) or was product dependent (43%).
- Only 5% of DTx coverage fell under the pharmacy benefit, while 0% fell under the digital benefit.
- Payer approaches to DTx policy development varied widely; policies were developed by DTx product type, by disease area, by device, or on a case-by-case basis. Payers were split among these options, with no single approach capturing more than 25% of the total payer response.

#### Reauthorization of DTx products

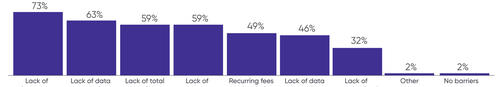
- Nearly all DTx companies have established criteria for reauthorization of DTx. The most common reauthorization criteria were documentation of positive clinical response (80%) and sustained member utilization (63%).
- The most common economic-related factors required for DTx reauthorization were total cost of care impact, long- and short-term return on investment, and innovative pricing models and risk-sharing contracts (**Figure 5**).
- The most common barriers to reauthorization were lack of long-term clinical data, data supporting long-term return on investment, re-treatment clinical data, and total cost of care data (**Figure 6**).

**Figure 5. Economic criteria required for DTx reauthorization**




Base: Payers with covered DTx (N=41)
Q11: Which of the following economic-related factors, if any, are/would also be required for reauthorization of digital therapeutic products?
Key: DTx – digital therapeutics; ROI – return on investment.

**Figure 6. Barriers to reauthorization**

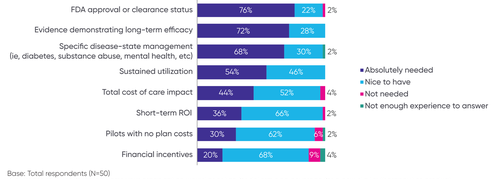



Base: Payers with covered DTx (N=41)
Q12: In your opinion, which of the following are barriers to developing reauthorization criteria with digital therapeutic products?
Key: DTx – digital therapeutics; ROI – return on investment.

#### DTx information needs

- For DTx evaluation, 78% of respondents indicated FDA approval or clearance as absolutely needed. Other prospective and retrospective studies were "nice to have" but not absolutely needed.
- Clinical effectiveness (96%), safety (82%), and economic value (58%) were the top data outcomes required to adequately evaluate a new DTx as a member benefit. Humanistic outcomes (eg, health-related quality of life, work productivity, etc) were "nice to have" but not absolutely needed.
- Metrics with an extremely high level of anticipated usefulness included clinical benefit (98%), return on investment (88%), long-term adherence (82%), ease of use for patients (76%), and impact of quality metrics (66%).
- When asked to prioritize product information needed for DTx coverage determination, payers ranked FDA clearance as the top priority (76%), followed by evidence that demonstrates long-term efficacy (72%), and specific disease-state management (68%) (**Figure 7**).
- Sustained utilization, total cost of care impact, and short-term return on investment were "nice to have," with financial incentives as the lowest priority (**Figure 7**).

**Figure 7. Top criteria for DTx coverage determination**




Base: Total respondents (N=50)
Q17: Please rate the following items your organization would prioritize for determining coverage for a new digital therapeutics product.
Key: DTx – digital therapeutics; FDA – Food and Drug Administration; ROI – return on investment.

#### COVID-19 impact on coverage of DTx

- Data indicate that the COVID-19 pandemic drove uptake of digital health technology and DTx; however, survey results indicate that the pandemic did not have an impact on coverage policy decisions (58% and 46% of respondents indicated there were no DTx coverage changes and no anticipated DTx coverage changes in the next 12 to 18 months, respectively).

## Limitations

- Since the DTx medical policy research was conducted in late 2020, the fast-changing DTx policy and coverage landscape may have changed, resulting in different DTx policy coverage data.
- Not all DTx may have been accounted for as part of the DTx medical policy research, since no publicly available comprehensive DTx list exists that contains all studied and/or approved products.
- Not all DTx have publicly available coverage policies; thus, certain private coverage policies may have been excluded when the medical policy research was conducted.
- Survey results were descriptive in nature and based on a small number of respondents and thus may not be generalizable to all payer organizations or payer types.
- Respondent survey completion was voluntary, introducing potential voluntary response bias, and survey results may over-represent respondents with more knowledge and stronger interest in DTx.

## Conclusions

- Inconsistencies in DTx payer evaluation, coverage, and utilization management highlight the unmet need for establishing a standardized format for DTx appraisal.
- DTx coverage differences synthesized via DTx policies vs survey responses highlight an opportunity for improved and more frequent information exchange between DTx manufacturers and payer organizations.
- DTx demand is projected to increase across several product and disease state categories, suggesting an emerging opportunity for DTx manufacturers and payers to collaborate on determining DTx value and access.
- Financially, total cost of care is a high priority for payers when determining reauthorization, presenting opportunities for manufacturers to communicate cost offsets and highlighting the potential value in communicating health economics and outcomes research data.
- Long- and short-term return on investment, innovative pricing models/risk sharing contracts, and shorter-term subscriptions-based models are important economic criteria for DTx reauthorization, presenting opportunities to utilize and apply innovative agreements towards a newer therapeutic modality.
- The need for financial and clinical data for reauthorization is apparent, as lack of clinical and economic data is a barrier to reauthorization. DTx reauthorization criteria standardization is an unmet need where some payers may benefit from further support.
- Given the existing review and coverage of DTx and its growing demand, DTx manufacturers would benefit from generating clinical and economic evidence to support access strategies, Pharmacy & Therapeutics Committee reviews, and policy coverage development.

## References

1. Digital Therapeutics Alliance. https://dtxalliance.org/. Accessed March 19, 2021.
2. Digital Therapeutics Alliance. Understanding DTx. https://dtxalliance.org/understanding-dtx/. Accessed March 19, 2021.
3. Precedence Research. Digital therapeutics market: Global market size, trends analysis, segment forecasts, regional outlook 2020–2027. https://www.precedenceresearch.com/digital-therapeutics-market. Accessed March 19, 2021.
4. Canary Insights. https://canaryinsights.com/About. Accessed March 23, 2021.

**Please direct questions to:**
Annie Chang | AnnieChang17@gmail.com
Alex Kilgore | Alex.Kilgore@xcenda.com

**Presented at 2021 AMCP Virtual Meeting**
**April 12 – 16, 2021**

AmerisourceBergen
Xcenda