Payer perceptions and formulary coverage trends for digital therapeutics (DTx)

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Background

- Digital therapeutics (DTx) represent a rapidly growing and evolving market with increasing demand for payer review and coverage.[1]
- Managed care organizations lack a standardized pathway to evaluate and reimburse DTx. Despite growing demand and a maturing body of evidence, the adoption rate of DTx products among healthcare decision makers (HCDMs) was only 36% according to a November 2021 Xcenda survey.[2]
- In 2022, the Centers for Medicare & Medicaid Services (CMS) established a Level II Healthcare Common Procedure Coding System (HCPCS) code for Food and Drug Administration (FDA)-cleared prescription digital behavioral therapy, potentially paving the way for more widespread coverage of DTx.[3]
- While DTx is expanding, there is still limited experience in payer evaluations, formulary coverage, and evidence exchange preferences that may influence policy decisions for DTx products.

Objective

- To assess payer perceptions and trends related to product reviews, formulary coverage, utilization management, and evidence exchange between manufacturers and HCDMs for DTx products.

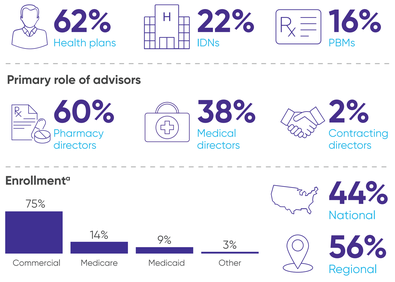
Methods

- A double-blinded, web-based survey was fielded to Xcenda's Managed Care Network (MCN) from April 22, 2022, to May 17, 2022.
  - MCN is a proprietary research panel of healthcare executives, medical and pharmacy directors, and other experienced individuals in managed care representing over 310 million covered lives.
  - Participation in this survey was voluntary, and a modest honorarium was paid by Xcenda to participants who completed the survey.
- Respondents were HCDMs from health plans, integrated delivery networks (IDNs), or pharmacy benefit managers (PBMs) who reported having a role in the formulary decision-making process for DTx products and reported being at least somewhat familiar and knowledgeable about utilization management for DTx.
- Covered survey topics included DTx product evaluations, formulary coverage and utilization management, and evidence exchange approaches.

Results

- A total of 50 respondents completed the survey. As shown in **Figure 1**, health plans represented the largest percentage of respondents' organizations, followed by IDNs.

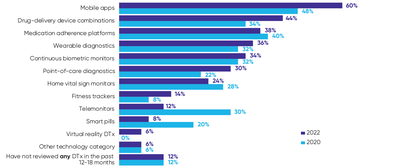
Figure 1. Respondent demographics (N=50)



[a]Health plan enrollment estimates exclude duplicate health plans and PBMs.
Key: IDN = integrated delivery network; PBM = pharmacy benefit manager.

- 88% of respondents reviewed a DTx in the past 12 to 18 months. The most often reviewed products were mobile apps (60%), drug-delivery device combinations (44%), and medication adherence platforms (38%) (**Figure 2**).
  - This is consistent with a similar survey conducted in November 2021, which showed that 90% of HCDMs had reviewed at least 1 DTx, with mobile app and medication adherence platforms being the most reviewed.[2]

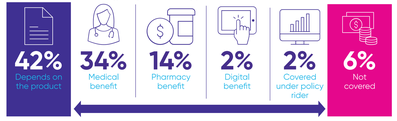
Figure 2. DTx reviewed by P&T committees in the past 12-18 months



N=50.
Q. 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?
Key: DTx = digital therapeutics; P&T = pharmacy and therapeutics.

- Coverage benefit type was primarily dependent on the product (42%) or defaulted to the medical benefit (34%). Rider policies were a small but emerging benefit category (2%) (**Figure 3**).

Figure 3. DTx coverage by benefit type



N=50.
Q. Are digital therapeutics within your organization generally covered under... ?

- Respondents noted that their organization has provided coverage for at least 1 mobile app (30%) and drug-delivery device combination (25%) with preferred status, with 37% and 50%, respectively, managing coverage with prior authorization and no step therapy (**Table 1**).
- At least 50% of respondents noted that their organization manages coverage for the following products with prior authorization and no step therapy: wearable diagnostics, home vital sign monitors, and virtual reality DTx. 50% indicated that their organization covers telemonitors with no management (**Table 1**).

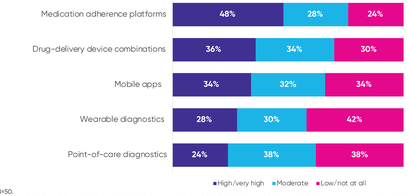
Table 1. DTx coverage management by product

DTx	Provided coverage with preferred status	Coverage with no management	PA and no step therapy	PA with step therapy	Not covered	Not enough experience with DTx
Mobile apps	30%	17%	37%	10%	30%	7%
Drug-delivery device combinations	25%	23%	50%	23%	0%	5%
Point-of-care diagnostics	20%	33%	40%	13%	7%	7%
Medication adherence platforms	18%	37%	21%	11%	26%	5%
Continuous biometric monitors	18%	29%	47%	12%	12%	0%
Wearable diagnostics	16%	6%	50%	6%	33%	6%
Home vital sign monitors	11%	33%	58%	0%	8%	0%
Telemonitors	9%	50%	17%	17%	17%	0%
Fitness tracker	5%	29%	29%	14%	29%	0%
Smart pills	2%	0%	25%	0%	75%	0%
Virtual reality DTx	0%	0%	67%	0%	33%	0%
Category average	14%	23%	40%	10%	25%	3%

Respondents who reviewed 1+ DTx technologies (N=44).
Q. In which of the following categories has your organization provided coverage for 1 or more digital health technology products with preferred status?
Q. In general, how does your organization manage coverage for each of the following digital health technology product categories?
Key: DTx = digital therapeutic; PA = prior authorization.

- Based on respondent feedback, DTx types with the highest priority for formulary management are medication adherence platforms (40%), drug-delivery device combinations (28%), and mobile apps (34%) (**Figure 4**).

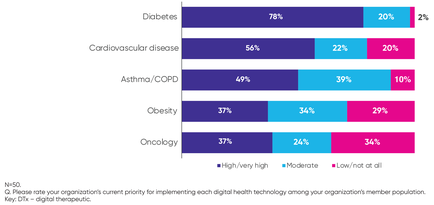
Figure 4. Management priority of DTx by product type



N=50.
Q. Please rate your organization's current priority for implementing each digital health technology among your organization's member population.
Key: DTx = digital therapeutic.

- Diabetes (78%), cardiovascular disease (56%), and asthma/chronic obstructive pulmonary disease (COPD) (49%) were the disease states with the highest priority for management (**Figure 5**).
  - Respondents also identified these disease states as high-impact areas for DTx regarding the potential to address unmet needs.

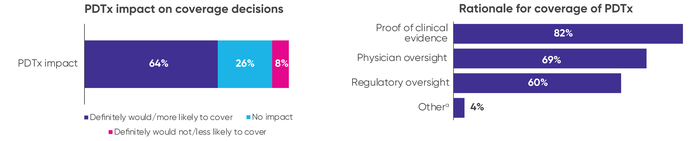
Figure 5. Management priority of DTx by disease state



N=50.
Q. Please rate your organization's current priority for implementing each digital health technology among your organization's member population.
Key: DTx = digital therapeutic.

- The majority of respondents (64%) noted that they were more likely to cover a DTx if it was available by prescription only. Key rationale for prescription-based coverage included the requirement for clinical evidence (82%) and physician (69%) and regulatory (eg, FDA) (60%) oversight (**Figure 6**).

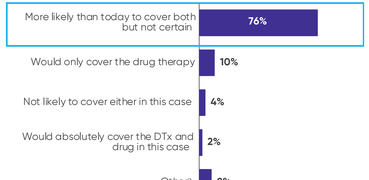
Figure 6. Prescription impact on DTx coverage decisions



[a]"Other" responses included: "Easy to adapt coverage policy to existing benefit design" and "not necessarily true...we may cover if OTC if backed by [key opinion leaders] or guidelines."
N=50.
Q. If a DTx is a prescription-only product, how would that impact coverage decisions? Those definitely/more likely to cover PDTx (N=45).
Q. Why is your organization more likely to cover a product if it is prescription-only?
Key: DTx = digital therapeutic; PDTx = prescription drug therapeutic.

- 76% of respondents indicated that coverage would also be more likely if DTx was paired with a drug therapy by the manufacturer (**Figure 7**).

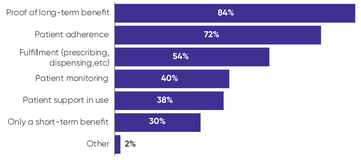
Figure 7. Likelihood of coverage if paired with a drug therapy



[a]"Other" responses included: "we will separate this decision," "would consider covering both if there were data of improved outcome vs the drug alone;" "maybe, it depends," and "would look at each separately based on medical necessity and member adherence needs."
N=50.
Q. How much more likely would your organization be to cover a digital therapeutic if it was automatically paired with a drug therapy by the manufacturer?

- While respondents were more likely to cover prescription DTx, proof of long-term benefit (84%), patient adherence (72%), and fulfillment considerations (54%) were identified as challenges (**Figure 8**).
- Proof of long-term effectiveness on patient outcomes/return on investment (ROI) (38%), clinical evidence (28%), and inclusion in treatment guidelines (18%) were identified by respondents as some of the top needs to improve DTx coverage.

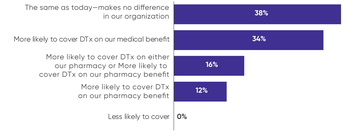
Figure 8. Challenges with PDTx



N=50.
Q. What challenges are present with PDTx products?

- While some respondents (38%) indicated that the establishment of the HCPCS code A9291 would have no impact their organization's coverage of DTx, 34% responded that it is likely to shift coverage to the medical benefit (**Figure 9**).

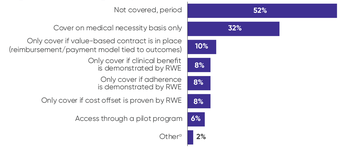
Figure 9. HCPCS code A9291 coverage impact after April 1, 2022



N=50.
Q. How would the availability of this code impact your coverage decision of digital therapeutics after April 1, 2022?
Key: DTx = digital therapeutic; HCPCS = Healthcare Common Procedure Coding System.

- Among those who do not cover DTx, over half (52%) handle coverage requests by not covering DTx period, regardless of other factors. 32% indicated that they cover DTx on a medical necessity basis only (**Figure 10**).
  - Respondents noted that the most common rationales for non-coverage included no proof of long-term clinical efficacy (72%), uncertainty in ROI (56%), and lack of standardized evidence assessment (50%).

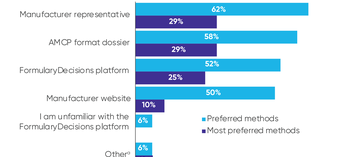
Figure 10. Coverage requests when DTx is not covered



[a]"Other" responses included: "appeal process."
N=50.
Q. How do you handle coverage requests for typically non-covered digital therapeutics?
Key: DTx = digital therapeutic; RWE = real-world evidence.

- Most respondents (82%) indicated that they would require or at least value an AMCP dossier to support their evaluation of DTx.
- Manufacturer representatives, AMCP Format dossiers, and FormularyDecisions® were the preferred communication methods when receiving DTx information (**Figure 11**).

Figure 11. Preferred methods of communication for DTx information



[a]"Other responses included; "Through the PBM if prescription," "we use validation institute for alot of digital tools," and "internal research and write up."
N=50.
Q. (Multiple mentions allowed.) Which of the following methods/approaches do you prefer for the communication of information for digital therapeutics?

Conclusions

- The results indicate that HCDMs are continuing to review DTx products entering the market, particularly mobile apps and drug-device delivery combinations. Medication adherence platforms and products for diabetes and cardiovascular disease are high priorities for management among managed care organizations.
- Of the products evaluated, managed care organizations are providing coverage for a very limited number of DTx with no management. Mobile apps and drug-device delivery combinations are among DTx that have received preferred status, and most covered products, including wearable diagnostics and home vital sign monitors, are managed with prior authorization.
- Among HCDMs who do not cover DTx, most are not covering under any circumstance, while some are covering on a medical necessity basis only. To improve future coverage, HCDMs desire proof of long-term efficacy/ROI and inclusion in treatment guidelines.
- Coverage appears to be more likely for prescription-only DTx and drug therapy combinations; however, challenges with proof of long-term benefit, patient adherence, and fulfillment remain.
- While benefit type for DTx coverage is primarily product-specific, the establishment of the HCPCS code by CMS may provide a more standardized pathway for reimbursment and lead to greater DTx coverage under the medical benefit.
- Manufacturer representatives, AMCP dossiers, and FormularyDecisions® are highly valued among HCDMs and should be leveraged for the exchange of DTx information.
- Current and anticipated HCDMs' approaches should be considered when developing policies to facilitate informed formulary decisions and appropriate patient access for DTx. Future research will determine how DTx coverage strategies may influence patient access.

Limitations

- This research reflects the perspectives of managed care professionals identified from Xcenda's MCN research panel; other user types (eg, healthcare providers, patients, manufacturers) were not represented in this subset.
- 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.
- Because all respondents voluntarily completed the survey, voluntary response bias may exist, and survey results may over-represent respondents with stronger interest in payer-manufacturer partnerships.

References

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