Current and future digital therapeutics industry trends from the payer perspective

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Background

- Digital therapeutics (DTx) represent a rapidly growing and evolving market, with increasing demand for payer review and coverage.[1]
- As more DTx emerge, healthcare decision makers (HCDMs) are tasked with navigating this rapidly evolving landscape to ensure patients have access to treatment options with the potential to improve patient outcomes.
- 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.[2]

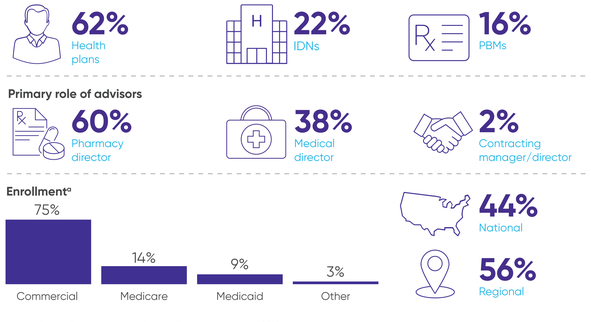
Objective

- To assess payer perceptions on the current and future state of DTx industry trends and evidence generation needs.

Methods

- A double-blind web-based survey was fielded from April 2022 to May 2022 to 50 HCDMs from Xcenda's Managed Care Network (MCN) to gather insights on existing and anticipated DTx trends (**Figure 1**).
  - MCN is a proprietary research panel of over 160 healthcare executives, medical and pharmacy directors, and other experienced individuals in managed care representing approximately 310 million covered lives in the United States (US).
  - Participation in this survey was voluntary, and a modest honorarium was paid by Xcenda to participants who completed the survey.
  - Respondents were payer HCDMs from health plans, integrated delivery networks (IDNs), or pharmacy benefit managers (PBMs).
- Survey topics included payer DTx priorities, predicted industry trends, and evidence generation preferences.

Figure 1. Advisor demographics (N=50)

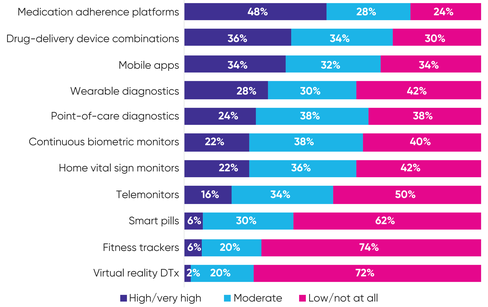


[a]Health plan enrollment estimates exclude duplicate health plans and PBMs.

Results

- Medication adherence platforms, drug-delivery device combinations, and mobile apps were rated as the highest priorities for implementation (**Figure 2**).

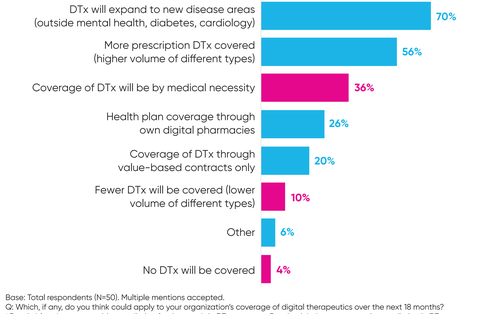
Figure 2. Current priority of implementing DTx by type



Base: Total respondents (N=50).
Q: Please rate your organization's current priority for implementing each digital health technology among your organization's member population.

- Respondents predicted that DTx will expand to new disease areas outside of mental health, diabetes, and cardiology (70%) and that more prescription DTx products will be covered (56%) over the next 18 months (**Figure 3**).

Figure 3. Predicted DTx coverage over the next 18 months[a]



Base: Total respondents (N=50). Multiple mentions accepted.
Q: Which, if any, do you think could apply to your organization's coverage of digital therapeutics over the next 18 months?
[a]Bars in blue denote a positive prediction for the trends in DTx coverage. Bars in pink denote a negative prediction in DTx coverage.

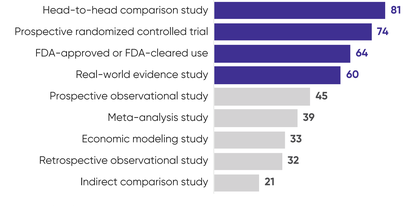
- The majority of payers are at least somewhat familiar with the FDA approval process for prescription digital therapeutics (PDTs) (**Figure 4**).

Figure 4. Payer familiarity with the FDA approval/clearance process

Base: Total respondents (N=50).
Q: How familiar are you with the FDA approval/clearance process for digital therapeutics?

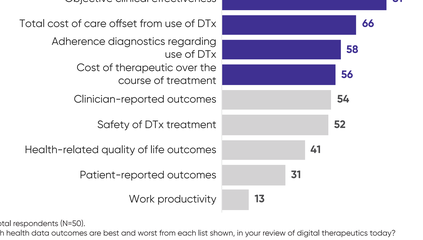
- A max-diff trade-off exercise showed that, from an evidentiary-needs perspective, head-to-head comparison studies (81), followed by prospective randomized controlled trials (74), were considered the best evidence options in terms of usefulness for DTx review (**Figure 5**). Objective clinical effectiveness (81) and total cost of care offset (66) were priorities for health outcomes data (**Figure 6**).

Figure 5. The usefulness of evidence options to review DTx today (point scale of 0-100)



Base: Total respondents (N=50).
Q: Please tell me which of these evidence options are best and worst from each list shown, in terms of usefulness to you in your review of digital therapeutics today.

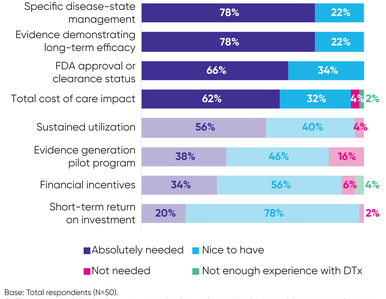
Figure 6. The usefulness of health outcomes to review DTx today (point scale of 0-100)



Base: Total respondents (N=50).
Q: Which health data outcomes are best and worst from each list shown, in your review of digital therapeutics today?

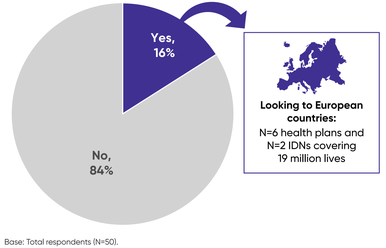
- Most respondents (78%) noted that evidence demonstrating long-term efficacy and specific disease-state management were absolutely needed to determine coverage for new DTx (**Figure 7**).
- While other countries are also developing innovative ways to manage PDTs, the majority of respondents (84%), which were all US payers, reported that they do not look to other countries for information on coverage strategies for PDTs (**Figure 8**).

Figure 7. Items prioritized by payers when determining coverage for new PDTs



Base: Total respondents (N=50).
Q: Please rate the following items your organization would prioritize for determining coverage for a new digital therapeutics product.

Figure 8. Do payer organizations look to other countries for information on DTx approval, utilization, and reimbursement?



Base: Total respondents (N=50).
Q: Germany has introduced the Digital Healthcare Act with the goal to accelerate the implementation of digital solutions. This allows for oversight and regulation of digital technologies while creating a clear and defined path for approval, utilization, and reimbursement. Does your organization look to other countries outside the US for information on reimbursement strategies for digital therapeutics?

Limitations

- 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.
- 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.

Conclusions

- As the development of DTx continues to increase, stakeholder alignment across the industry is necessary to shape the future of DTx and facilitate appropriate patient access.
  - This research summarizes payer HCDM viewpoints on product reviews and evidence generation priorities, which are key pieces of the puzzle for DTx manufacturers looking to gain coverage and reimbursement of their products.
- The results indicate that HCDMs may prioritize adherence platforms, drug-delivery device combinations, and mobile apps for coverage among their populations.
- Payer respondents expect the market to continue to expand into new therapeutic areas and that more prescription DTx will obtain coverage.
- Although most respondents were at least somewhat familiar with the FDA approval process for PDTs, improving awareness of the approval process and evidence standards may improve payer receptivity to coverage of PDTs.
- Payer respondents prioritized head-to-head comparison studies, randomized controlled trials, and real-world evidence studies as the most useful evidence options, indicating that these may be important study types to prioritize for manufacturers.
- Evidence generation around comparative clinical effectiveness and long-term outcomes are valued most highly by payers and may optimize DTx approval, reimbursement, and market uptake.

References

1. Parcher B, Coder M. Decision makers need an approach to determine digital therapeutic product quality, access, and appropriate use. *J Manag Care Spec Pharm*. 2021;27(4):536-538.
2. CMS. Centers for Medicare & Medicaid Services (CMS) Healthcare Common Procedure Coding System (HCPCS) Application Summaries and Coding Recommendations Second Biannual, 2021 HCPCS Coding Cycle. December 2021 Meeting Notes. Accessed April 25, 2022. https://www.cms.gov/files/document/2021-hcpcs-application-summary-biannual-2-2021-non-drug-and-non-biological-items-and-services.pdf

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