Paying for Digital Therapeutics: What Evidence is Needed

Issue Panel  Annual Conference May 17th 2022
Moderator and Speakers

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Zachary A Zalewski, MChem, MBA
CEO
Digital Medicine Society (DiMe)
Poll Question

• What word(s) come to mind when you think of DTx?
Zachary A Zalewski, PhD, JD
Enterprise Strategy Director
US Pharmacopeia
DTx Contemplates a Large (and Growing!) and Overlapping Medical Device Universe

SaMD: Software as a Medical Device; CT: computed tomography; EHR: Electronic Health Records
PDT: Prescription Digital Therapeutics; DTx: Digital Therapeutics;
Medical Devices are Subject to FDA Regulation, Which Includes Evidentiary Requirements

• “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or... intended to affect the structure or any function of the body of man or other animals”*

• “the effectiveness of a device is... determined... on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate...”**

*Federal Food, Drug & Cosmetic Act Section 201(h)(1)(b), (c)
**Federal Food, Drug & Cosmetic Act Section 513(a)(3)(A)
Sponsors Provide FDA with Safety & Efficacy Evidence; FDA Authorization Gives Payers Certainty

- Evidence (including clinical) of safety and efficacy
- FDA-authorizes label (indications, patient populations, etc.)
- Payer reimburses based on FDA authorization and in-house evidentiary review
Vyishali Dharbhamalla, PharmD
Senior Manager, Professional Affairs
Academy of Managed Care Pharmacy
67% of payers require FDA approval

**PAYER RESPONDENTS**

**Requirement for FDA approval of DTx***
- Clinical trial evidence
  - Yes, will require FDA approval 67%
  - Not sure 14%
  - No, it's not important to have FDA approval 19%

**Requirement for pilot program†**
- Real-world evidence
  - Yes 55%
  - No 22%
  - I don’t know 25%

*AMCP/Cyan Health Survey: August 2021
*N=21 Payer Respondents
†N=20 Payer Respondents
FDA = U.S. Food and Drug Administration.
86% of payers have (or plan to have) a defined approach for covering DTx

PAYER RESPONDENTS
% of payers with a defined approach for covering DTx

- Yes: 30%
- No, but my organization is interested in formalizing an approach to coverage in the future: 30%
- No, but an approach is in development: 26%
- No, my organization is not interested in DTx: 9%
- Not sure/I don’t know: 4%

AMCP/Cyan Health Survey: August 2021 N=23 Payer Respondents
DTx = digital therapeutics.
Evidentiary, benefit inclusion, education, and IT infrastructure challenges exist

**Factors adversely impacting the likelihood of coverage for a DTx***

<table>
<thead>
<tr>
<th>Factor</th>
<th>Payer Respondents</th>
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<tr>
<td>Cost or other barriers to implementing the technology to collect data</td>
<td>71%</td>
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<td>Lack of experience with or knowledge of DTx</td>
<td>38%</td>
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<td>Low patient/prescriber education</td>
<td>43%</td>
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<tr>
<td>Low patient acceptance/engagement</td>
<td>43%</td>
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<td>Inadequate level of evidence for coverage determinations</td>
<td>71%</td>
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<td>Lack of coverage by Medicare or State Medicaid</td>
<td>43%</td>
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<td>Perceived issues with clinical trial design (e.g., observations or open-label trials)</td>
<td>48%</td>
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<td>Small size of clinical trials</td>
<td>62%</td>
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<tr>
<td>Number of clinical trials</td>
<td>24%</td>
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*This was a “select all that apply” question.
What we need:

- More and better evidence
- Evidence Framework
- P&T Committee Supplementation
- Education
- IT Integration
Payers are moving towards coverage of prescription DTx, but need clinically meaningful evidence, benefit inclusion, education, and IT infrastructure changes.
Jennifer Goldsack
CEO
Digital Medicine Society (DiMe)
Advancing digital health applications
Advancing digital health applications

Global priorities for innovation in real-world evidence (RWE) generation

Topic areas where precompetitive collaboration, research, and the development of best practices will speed broad acceptance of high-quality evidence to support digital health applications

- Missing data
- Study endpoints
- Comparator group
- Multimodal interventions
- Study question
- Equity
- Generalizability
- Confounders
- Fit-for-purpose
European digital health regulatory landscape is soaring

- In Oct’21, France’s President announced plans to replicate the DiGA reimbursement scheme.
- In Nov’21, European Council agreed on a new, harmonised regulation on health technology assessments across EU.
- In partnership between ORCHA and 7 ICS, now 5.6 million people in England will have access to digital health libraries.
- Belgium, Denmark, Finland, Scotland, Ireland, Luxemburg, Spain and Sweden are discussing market access for reimbursable medical apps.

Source: PalmHealth.co
In Mar’20 Australia’s TGA released a comprehensive overview of software products qualifications and selection requirements. In Feb’21, they also released their SaMD classification.

Japan’s MHLW and PMDA launched a process called “SAKIGAKE”, which allows for accelerated regulatory pathways for products designated as breakthrough devices addressing high, unmet medical needs.

Singapore’s Health Sciences Authority (HSA) has published guidelines on software medical devices with intentions to

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So is Asia-pacific region making strides...

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Source: APACmed
Regulatory process aren't the limiting factor for digital innovation. Rather an optimal regulatory strategy is critical part of successful digital product strategy.
Poll Question

• What do you think is the most challenging aspect for DTx uptake?

A) Trial data does not exist for DTx
B) Lack of RWE for DTx
C) Manufacturer ability to articulate value proposition
D) Payer readiness to evaluate DTx