Payer Perspectives on Health Insurance Coverage for Digital Therapeutics in the United States

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Background

- Over the past several years Digital Therapeutics (DTx) have been marketed in the United States
- Because of the unique nature of DTx, there is considerable uncertainty around health insurance coverage of DTx applications (apps)
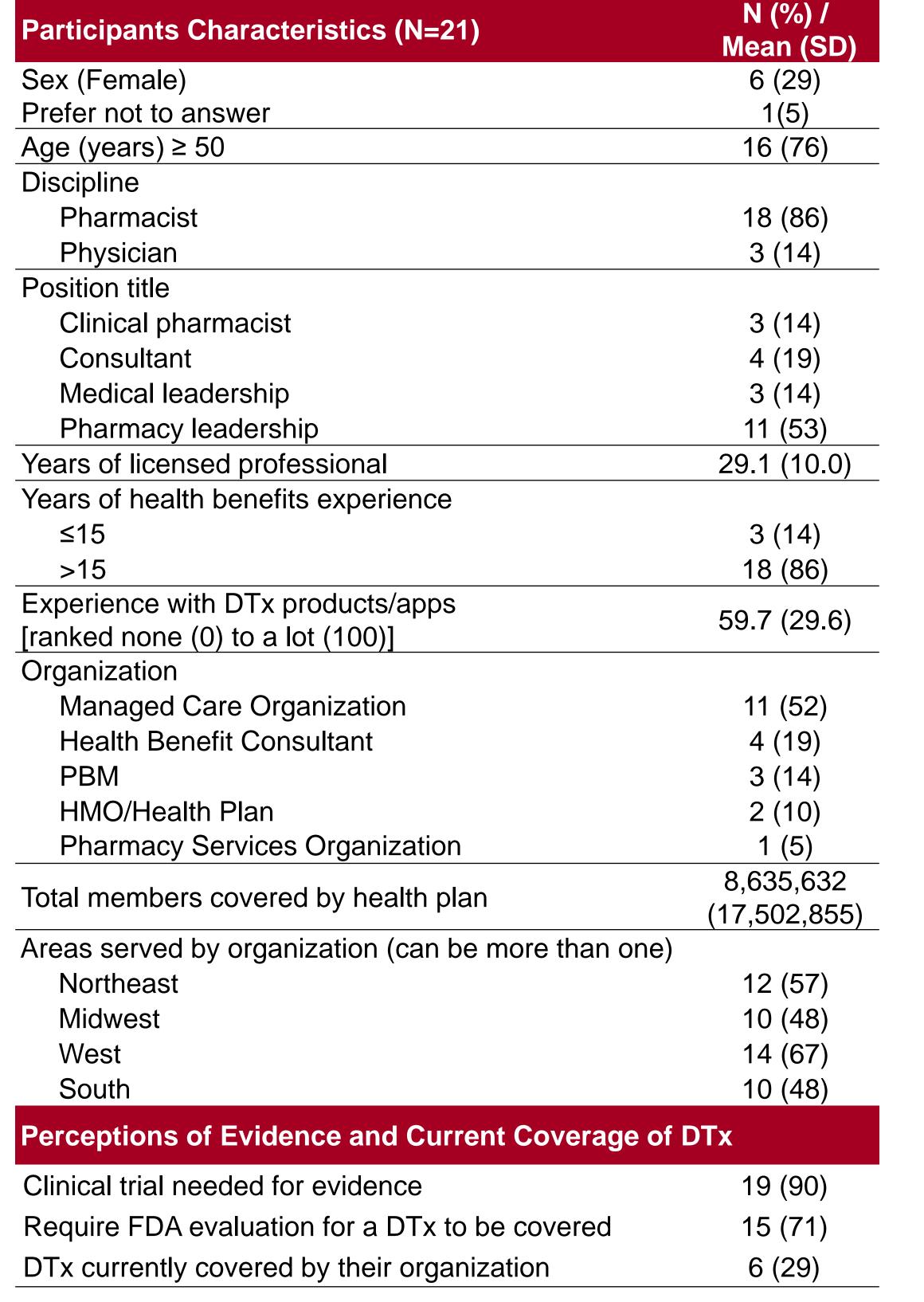
Objective

- To evaluate factors affecting health insurance coverage and reimbursement of DTx by United States payers and coverage decision-makers
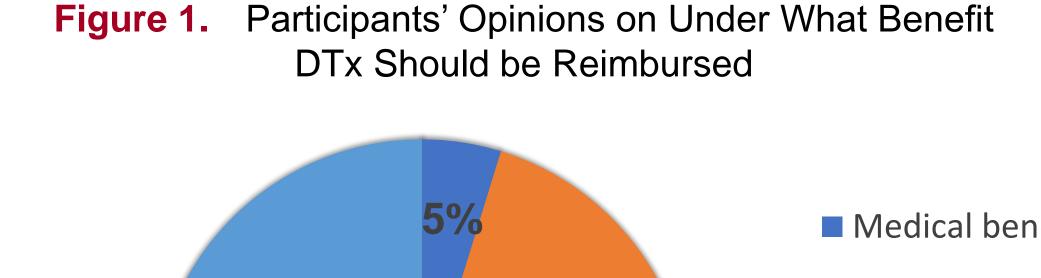
Methods

- Cross-sectional qualitative study
- Online questionnaire and focus group sessions from August to October 2022
- Participants: managed care pharmacy and medical directors, health benefit consultants, and pharmacy benefit managers were recruited by snowball and convenience sampling
- Participants completed a pre-focus group questionnaire on their opinions on DTx products and their coverage
- The focus group evaluated the following topics: (1) evidence to evaluate DTx, (2) circumstances/attributes needed for DTx coverage, (3) barriers to DTx coverage, (4) coding issues and other factors influencing coverage as pharmacy or medical benefit, (5) benefit designs of DTx coverage, (6) indication and duration for DTx coverage, (7) reimbursement issues of DTx, (8) Food and Drug Administration (FDA) approval/policies associated with DTx
- Recorded transcriptions were analyzed by Atlas.ti software to determine frequency of topics mentioned by participants

Results

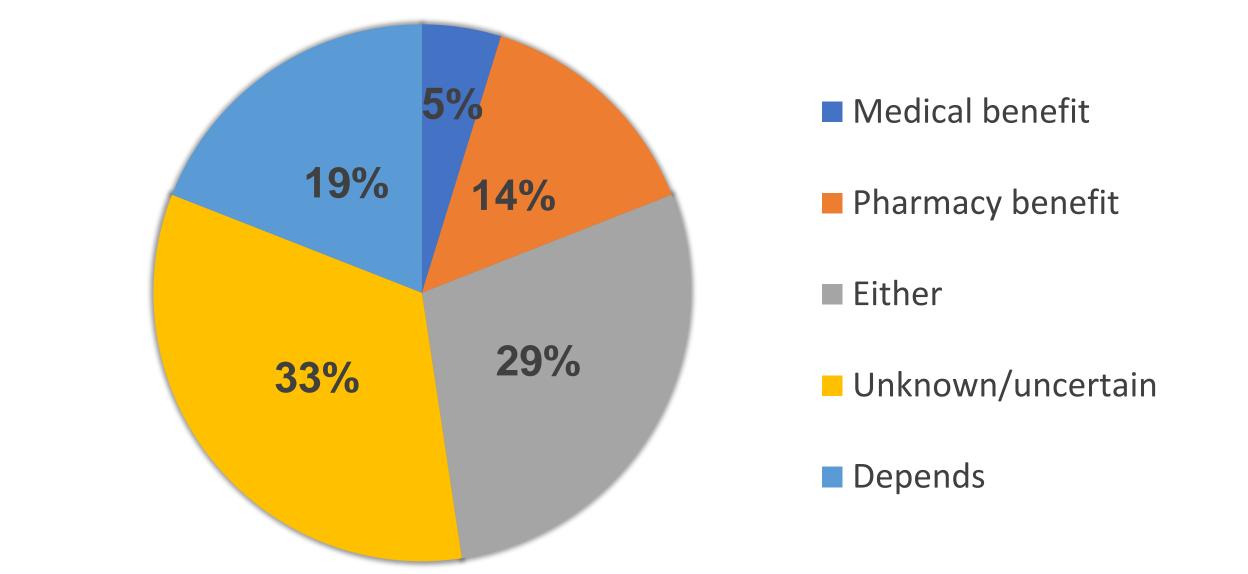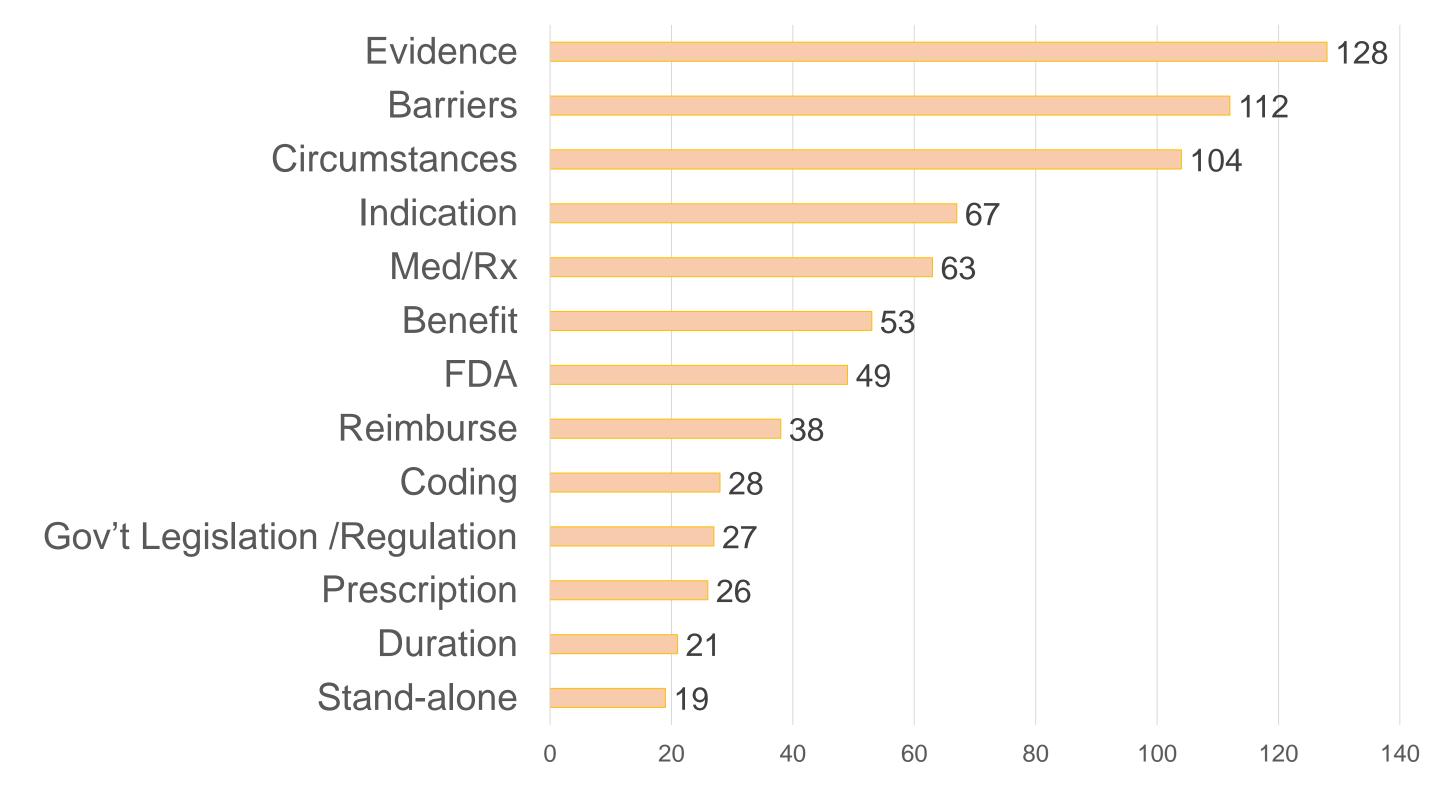**Table 1.** Participants Characteristics and Perceptions of DTx

Participants Characteristics (N=21)	N (%) / Mean (SD)
Sex (Female)	6 (29)
Prefer not to answer	1 (5)
Age (years) ≥ 50	16 (76)
Discipline	
Pharmacist	18 (86)
Physician	3 (14)
Position title	
Clinical pharmacist	3 (14)
Consultant	4 (19)
Medical leadership	3 (14)
Pharmacy leadership	11 (53)
Years of licensed professional	29.1 (10.0)
Years of health benefits experience	
≤15	3 (14)
>15	18 (86)
Experience with DTx products/apps [ranked none (0) to a lot (100)]	59.7 (29.6)
Organization	
Managed Care Organization	11 (52)
Health Benefit Consultant	4 (19)
PBM	3 (14)
HMO/Health Plan	2 (10)
Pharmacy Services Organization	1 (5)
Total members covered by health plan	8,635,632 (17,502,855)
Areas served by organization (can be more than one)	
Northeast	12 (57)
Midwest	10 (48)
West	14 (67)
South	10 (48)
Perceptions of Evidence and Current Coverage of DTx	
Clinical trial needed for evidence	19 (90)
Require FDA evaluation for a DTx to be covered	15 (71)
DTx currently covered by their organization	6 (29)

Figure 1. Participants' Opinions on Under What Benefit DTx Should be Reimbursed

- Medical benefit: 5%
- Pharmacy benefit: 14%
- Either: 29%
- Unknown/uncertain: 33%
- Depends: 19%

Figure 2. Topics Mentioned by Participants in Focus Groups

Topic	Count
Evidence	128
Barriers	112
Circumstances	104
Indication	67
Med/Rx	63
Benefit	53
FDA	49
Reimburse	38
Coding	28
Gov't Legislation /Regulation	27
Prescription	26
Duration	21
Stand-alone	19

Med/Rx: Medical or Pharmacy Benefit

Figure 3. Word Cloud from Focus Group Transcripts

Quotes

- **Evidence**: "…with the limited published evidence that's out there, we're not seeing long-term value proposition and long-term effectiveness or cost-effectiveness assessments…"

- **Gov't Legislation /Regulation:** "I think Medicare covering it would probably, you know, urge payer to be able to covered under the commercial plan"

- **Pharmacy/medical benefits**: "It just depends on the disease"

- **Barriers**: "In what populations? How long? Do they use technology? What's the durability or the stickiness of the effect and to gain insights from pilots before we figure out? Is there an ROI and how do we deploy it?"

Conclusions

Health insurance coverage of DTx is not yet common, but most participants believe that:
- FDA review/approval will be required by most organizations to include DTx as a covered benefit
- Payers expect high-quality evidence as a condition of coverage
- Prescription apps (circumstances) were preferred over non-prescription apps from a coverage perspective
- Benefit policies will need to be modified to accommodate DTx products