US Payer Management of Digital Health Technologies: Recent Updates and a Glimpse into the Future

Sidhu C[1], Waththuhewa M[2], Sullivan, N[2]

[1]Value and Access Consulting, Evidera, San Diego, CA, USA; [2]Value and Access Consulting, Evidera, Boston, MA, USA

MT3

Background

Digital health refers to an array of technologies that use tracking and encouragement to prevent, diagnose, treat, and manage diseases. This includes technologies, platforms, and systems that 1) engage consumers for lifestyle, wellness, and health-related purposes; 2) capture, store, or transmit health data; and 3) support life science and clinical operations. Examples of digital health products range from lifestyle and fitness apps to telehealth to software-driven medical interventions. These innovations are valued for their ability to help people manage chronic diseases, deliver access to care when needed, improve adherence with treatment regimens, and prevent complications.

The COVID-19 pandemic significantly transformed the digital health space by accelerating acceptance and usage of digital health technologies (DHTs). As a result, DHTs have proliferated in recent years, with more than 300,000 health apps and 300 wearables now available.[1] While many DHTs hold promise, there is the common issue of poor clinical evidence to support the claims being developed to highlight their benefits. With the increase in number of options and interest for DHTs, payers are starting to feel the need to determine whether they should cover certain DHTs. However, there are challenges in how payers need to evaluate these novel products, given their coverage assessments cater to studies and evidence developed for pharmaceuticals and traditional medical technologies. Certain organizations independent from US payers are now stepping up to develop frameworks and conduct evaluations focused on assessing evidence for DHTs.

Objectives

- To review US payer coverage and assessments of approved DHTs to better understand the likely evolution of evidence needs with continued growth in the space.

Methods

Coverage information and assessments of DHTs by public payers, commercial insurers, pharmacies, Pharmacy Benefit Managers (PBMs), and independent assessment organizations was obtained through a review of websites, press releases, and public domain sources.

Table 1. Evernorth/Express Scripts Digital Health Formulary as of April 2024

Category	Sub-categories	Formulary Options	
Diabetes Care	Type 1 and Type 2 diabetes	**Preferred:**	**Omada Health**
		Alternatives:	Livongo Health, Lifescan
	Diabetes prevention and obesity	**Preferred:**	**Omada Health**
		Alternative:	Livongo Health
Cardiovascular Care	Hypertension	**Preferred:**	**Omada Health**
		Alternative:	Livongo Health
Pulmonary Care	Asthma and chronic obstructive pulmonary disease		Propeller Health
Behavioral Healthcare	Depression, anxiety, and insomnia		Learn to Live SilverCloud Health Big Health
Women's Healthcare	Family planning, pregnancy, and postpartum		Wildflower
Musculoskeletal Care	Chronic muscle and joint pain	**Preferred:**	**Hinge Health**
		Alternatives:	Omada Health RecoveryOne
Caregiver Care	Caregiver stress and emotional wellness		Prevail Health
Substance Use Disorder Care	Tobacco use disorder Alcohol use disorder Opioid use disorder		Pelago Pelago Pelago
Inflammatory Care	Treatment adherence		Health Beacon
Digestive Care	Gastrointestinal support		Vivante Health

Results

Pharmacy Benefit Managers

The first example of US payers managing DHTs came when PBM Evernorth/Express Scripts announced the introduction of its Digital Health Formulary in 2019. Since its launch, Evernorth has expanded the formulary and updated the selection of preferred products for certain therapeutic areas (**Table 1**). They also launched pilot programs to further evaluate clinical impact and user experience of additional solutions.

Evernorth highlights efficacy measures for several of its covered digital therapeutics (DTx). In diabetes care, 35% of the adult workforce participants in its Digital Diabetes Prevention Program lost 5% of their body weight after 4 months. The covered DTx for pulmonary care from Propeller Health boasts a 47% increase of days without requiring a rescue inhaler. In musculoskeletal care, a 69% average pain reduction was experienced by those enrolled in its Digital Musculoskeletal Program.[2-5]

Since 2022, Evernorth added DTx onto its formulary that target notable disease areas with the addition of Pelago in substance use disorder (SUD) including tobacco, alcohol, and opioid use disorders, Health Beacon in inflammatory care, and Vivante Health in digestive care (**Table 1**).

Our research of the public domain also found that large PBMs such as CVS Health and Walgreens have partnered with several digital health companies. However, no coverage policy was made available to better understand their decision-making rationale.

Health Plans

The review identified two policies from Managed Care Organizations (MCOs), which included Aetna and Highmark (**Table 2**). Aetna considers FDA-approved or FDA-cleared DTx for contraception based on fertility awareness (e.g., Natural Cycles) to be medically necessary, per federal preventive care mandates, when prescribed by a treating provider. Interestingly, this is the only DTx Aetna currently covers. Aetna lists 21 other DTx not covered as they were deemed to be experimental and investigational, with insufficient evidence in published, peer-reviewed literature to support their effectiveness.[6]

Highmark covers eight FDA-approved DTx under specific conditions: 1) the DTx must be prescribed by a licensed healthcare professional (HCP); 2) it must be used within its approved indications and prescribed by a provider for whom the condition is within the scope of their practice; 3) the member must be age ≥18, unless the DTx is specifically designed and approved for pediatric use and the member is within the age range for which the DTx is recommended; 4) the DTx is used for outpatient care; and 5) the member must be able to reasonably interact with the software to receive a prescription for any DTx treatment or intervention. Furthermore, Natural Cycles is covered as an FDA-approved digital app for contraceptive use with prescription, which may be considered medically necessary when used as contraception only. [7]

A more recent entrant into the landscape includes health insurer UnitedHealthcare, with its UHC Hub initiated in 2023. While UHC Hub lists on its website 23 preferred vendors, no rationale for decision-making was found in the public domain.[8]

Table 2. MCO Policies for DTx *(Not Exhaustive)*

Health Plan	Policy	Coverage Decision and Rationale
Aetna	Prescription Digital Therapeutics (2023)	▪ Natural Cycles: medically necessary per federal preventive care mandates ▪ Lists 21 DTx not covered, considered investigational and experimental
Highmark	Prescription Digital Therapeutics (2022)	▪ Eight DTx covered considered medically necessary if FDA approved and prescribed by a HCP within scope of practice, for outpatient care ▪ Natural Cycles: medically necessary when used as contraception only

Abbreviations: DTx = Digital therapeutics; HCP = Healthcare professional

DHT Assessments by US Organizations

In 2020, the Institute for Clinical and Economic Review (ICER) assessed three DTx developed to treat opioid use disorder: reSET-O (Pear Therapeutics), Connections (Chess Health), and DynamiCare (DynamiCare Health). After a review of the evidence base, ICER noted the key source of uncertainty was a lack of peer-reviewed data. None of the three DTx had direct randomized trial evidence demonstrating how well it may enhance abstinence or retention in medication-assisted treatment for people with opioid use disorder. Furthermore, it flagged key differences between studies and real-life utilization of the DTx: reSET-O was approved based on its similarity to application of the same educational modules in earlier studies, but the modules were delivered on a computer in the clinic rather than for a smart phone app, and contingency management incentives included as part of the intervention were fundamentally different. Despite those criticisms, ICER acknowledged a moderate certainty of a comparable or small net health benefit, with high certainty of at least a comparable net health benefit for all three DTx. [9]

Beyond well-run clinical trials to demonstrate safety and effectiveness across patient-relevant outcomes, ICER defined the need for robust data on components of value as: durability of effect, impact on healthcare utilization and clinician productivity, patient experience, information technology security and patient privacy, and generalizability to a large and diverse population. With the maturation of the DTx industry, ICER anticipated that the entire health system will demand the same level of evidence and rigor that it currently does from the biopharmaceutical industry. [9] We noted that for its first and unique review of DTx products, ICER used its value assessment framework, which mainly focuses on a review of the clinical and economic evidence. While ICER almost exclusively appraises pharmaceutical interventions, it did not highlight adaptation of their framework to DTx.[9,10]

In 2023, the Peterson Health Technology Institute (PHTI), an independent non-profit, was created to analyze the clinical benefits and economic impact of DHTs, as well as their effects on health equity, privacy, and security.[11] Its assessment framework has been specifically tailored for DHT appraisals and was developed in partnership with ICER. It outlines the key questions PHTI aims to answer during its evidence review: DHT context (history and role in care, competitive landscape, privacy and security, developer history and funding), clinical impact (user experience, safety, effectiveness, and health equity), and economic impact (budget impact).[12]

PHTI ranks DHTs within three broad functional categories that are tiered to their potential risk to patients. Tier 1 "Self-directed health management" may include DHTs collecting personalized health information for use by the end user and not intended for professional consideration. Tier 2 "Professionally directed diagnostic and prognostic health management" may include DHTs that diagnose a specific clinical condition and/or guide diagnosis or management decisions through diagnosis or prognosis. Tier 3 "Professionally-directed preventative and therapeutic health management" is divided into two sub tiers: Tier 3a DHTs for preventative health behavior management with professional involvement that are low-to-moderate risk, and Tier 3b DHTs that directly provide treatment or act as an adjunct to other interventions for a diagnosed clinical condition that are moderate-to-high risk. Using this tiering, PHTI defines minimum and best evidence requirements for each tier.[12]

DHT Assessments by US Organizations (cont.)

PHTI released its first report in 2024 on diabetes care DHTs. Its key findings are available in **Table 3**. Overall, these tools fail to deliver meaningful health benefits to patients while increasing spending.[13] PHTI found that patients using those DHTs achieve only small reductions in hemoglobin A1c (HbA1c) compared with those who do not, and these reductions are not sufficient or sustained enough to change the trajectory of their health, care, or long-term prognosis, including cardiovascular risks. PHTI made three key recommendations for purchasers. First is to require data and analysis of the DHT performance in their own member population at regular intervals, including methods of reviewing evidence in key areas of clinical impact (e.g., HbA1c), user engagement, program completion rates, key predefined clinical outcomes, or utilization changes. Second is to use performance data to ensure payments are tied to successful results. This may include increasing the portion of contracts at risk and/or including claw back clauses for overpayments. The final recommendation is to define meaningful clinical and economic impact targets that emphasize success in important subpopulations who may be more likely to benefit from the solution.

Table 3. PHTI Ratings for DHTs in Diabetes Management

	Clinical effectiveness	Economic impact	Summary rating
Remote patient monitoring *Glooko*	Small but not clinically meaningful reduction in hemoglobin A1c Evidence certainty: Higher	Net increase in spending. Current provider reimbursement exceeds cost savings from avoided care	**Current evidence does not support broader adoption**
Behavior and lifestyle modification *DarioHealth, Omada, Perry Health, Teladoc (Livongo), Verily (Onduo), Vida*	Small but not clinically meaningful reduction in hemoglobin A1c Evidence certainty: Higher	Net increase in spending. Current provider reimbursement exceeds cost savings from avoided care	**Current evidence does not support broader adoption**
Nutritional ketosis *Virta*	Clinically meaningful reduction sufficient to achieve remission in some patients Evidence certainty: Lower	Initial net increase in spending with potential for long-term savings	**Evidence supports broader adoption with ongoing evidence generation**

Key: Positive, Moderate, Negative; Higher evidence certainty, Lower evidence certainty

Conclusions

- Health plans have been slow to develop policies for assessing DHTs.
- PHTI's assessment framework and category reviews provide health plans and PBMs with a valuable resource to support their decision-making.
- It will be important to follow the impact of PHTI on payer assessments as this can help guide evidence requirements for DHTs.

References

1. Silberman, J., Wicks, P., Patel, S. et al. Rigorous and rapid evidence assessment in digital health with the evidence DEFINED framework. npj *Digit. Med.* 6, 101 (2023). https://doi.org/10.1038/s41746-023-00836-5
2. Evernorth. Evernorth Digital Health Formulary. Available at: https://www.evernorth.com/our-solutions/digital-health-formulary.
3. Castro Sweet C, Bradner Jasik C, Diebold A, DuPuis A, Jendretzke B. Cost Savings and Reduced Health Care Utilization Associated with Participation in a Digital Diabetes Prevention Program in an Adult Workforce Population. *JHEOR*. 2020;7(2):139-147.
4. Express Scripts 2019 Data
5. Bailey. J., et al. (2020) Digital Care for Chronic Musculoskeletal Pain: 10,000 Participant Longitudinal Cohort Study. JMIR
6. Aetna. Prescription Digital Therapeutics. Available at: https://es.aetna.com/cpb/medical/data/900_999/0999.html
7. Highmark. Highmark commercial medical policy - Pennsylvania. Available at: https://securecms.highmark.com/content/medpolicy/en/highmark/pa/commercial/policies/Miscellaneous/Z-105/Z-105-001.html
8. UHC Hub. UHC Hub: A curated network of vendors. Available at: https://www.uhc.com/employer/products-solutions/uhc-hub.
9. ICER. ICER Publishes Final Evidence Report and Policy Recommendations for Digital Health Therapeutics for Opioid Use Disorder. Available at: https://icer.org/news-insights/press-releases/icer-publishes-final-evidence-report-and-policy-recommendations-for-digital-health-therapeutics-for-opioid-use-disorder/
10. ICER. Value Assessment Framework. Available at: https://icer.org/our-approach/methods-process/value-assessment-framework/
11. PHTI website. Available at: https://phti.com/
12. ICER-PHTI Assessment Framework for Digital Health Technologies. Available at: https://phti.com/wp-content/uploads/sites/3/2023/09/ICER-PHTI-Assessment-Framework-for-Digital-Health-Technologies.pdf
13. PHTI. Digital Diabetes Management Solutions. Available at: https://phti.com/wp-content/uploads/sites/3/2024/04/PHTI-Digital-Diabetes-Mgmt-Assessment-Report-v1.1.pdf

Presented at ISPOR—The Professional Society for Health Economics and Outcomes Research ● 5–8 May 2024 ● Atlanta, GA, USA

Funding provided by Evidera Inc., a business unit of PPD, part of Thermo Fisher Scientific