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WHITE PAPER

Reimbursement of Digital Therapeutics in the U.S.

What Is the Outlook?

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October 2022

Digital therapeutics (DTx) are impacting how patients are treated, interact with their providers and think about their own health. DTx have garnered interest from the investment community as well as pharma companies seeking an integrated digital offering. However, payers have not yet established a clear framework for integrating these technologies in their plans.

Coverage of DTx to date has been limited and the outlook for it is unclear. We spoke to four medical and pharmacy directors from large payer organizations in the U.S. to understand how the payer landscape for DTx might evolve in the future.

Introduction

The Digital Therapeutics Alliance, a digital health industry trade group, defines DTx as, "evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage or prevent a disease or disorder". DTx can be available via prescription or without a prescription: examples are Pear Therapeutics' reSET for substance use disorder (prescription) and Big Health's Sleepio for insomnia (non-prescription).

The development of DTx is coming at a time of rapidly increasing unmet need, with the COVID pandemic accelerating the importance of virtual / digital tools to engage patients. The trend to conduct remote patient treatment and monitoring is expected to accelerate in the future, with analysts estimating the U.S. DTx markets to grow from 3.2 billion USD in 2021 to up to 15 billion USD by 2028.[1] The development of DTx has accelerated particularly in the cognitive and mental health space, but also in areas such as diabetes and hypertension.

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Pharmaceutical manufacturers are noticing the potential of these technologies – with deals emerging that involve development partnerships, licensing of digital technologies and even digital device / drug combinations. A notable recent example is Sanofi's 30 million USD strategic agreement with DarioHealth in March 2022 to "accelerate commercial adoption of Dario's full suite of digital therapeutics and drive the expansion of digital health solutions on the Dario platform".[2]

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[1] Vantage Market Research, (2022, February 22). *Global Demand for Digital Therapeutics Market Will Surpass USD 14.52 Billion at 28.1% CAGR Growth*

[2] Dario Health, (2022, March 01). *Dario health enters into strategic agreement with Sanofi U.S.*

Furthermore, regulatory organizations are developing capabilities through the FDA Digital Health Software Precertification Program for more efficient oversight of DTx, reflecting expectations for a growing DTx market. However, many uncertainties lie in how these products and services will be reviewed, covered, and paid for by traditional payer bodies.

Although there is not a standard process for the review, coverage, and payment of DTx, payers have started to cover some of these products and services such as Pear's insomnia and substance use disorder products, with limited success in enabling access to patients due to concerns about clinical value vs. price.

The goal of this paper is to discuss the current status of DTx coverage, the evidence requirements for DTx coverage and payers' outlook on the future of DTx coverage – **specifically the feasibility and mechanics of a digital formulary in a future DTx market landscape.**

The Current Landscape for Digital Therapeutics

What are digital therapeutics? Are they regulated by the FDA?

The FDA defines the broad category of digital health technologies as computing platforms, connectivity, software and sensors for healthcare and related uses.[3] DTx are differentiated from other digital health technology products, like wellness apps, in that they are evidence-based therapeutic interventions that are driven by high quality software programs to treat, manage or prevent a disease or disorder. Some DTx require prescriptions, while others do not.

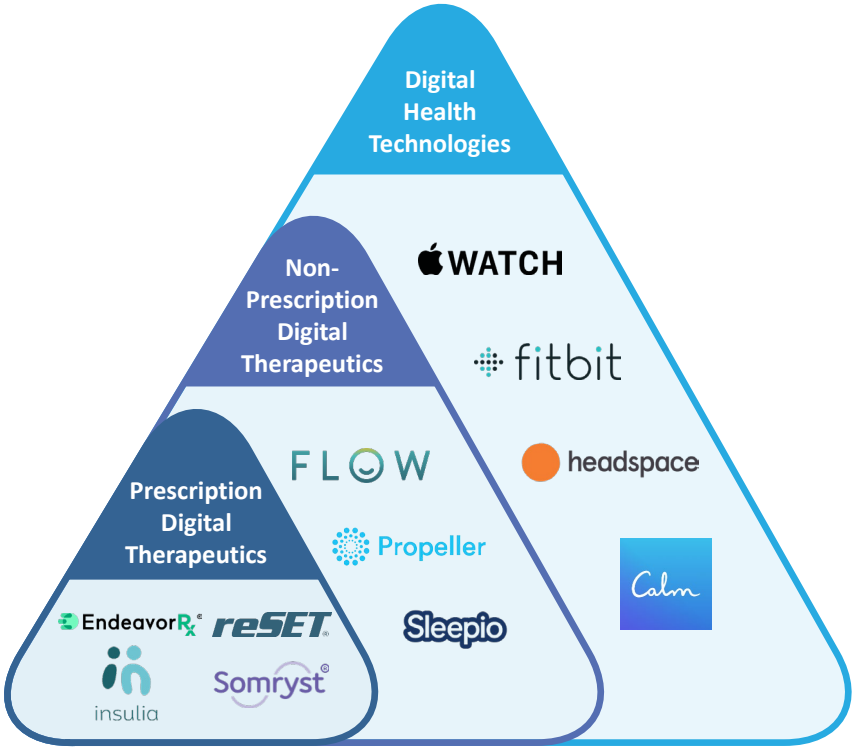

FIG 1. Examples of Digital Health Technologies and Digital Therapeutics

[3] FDA, (2020, September 22). *What is Digital Health?*

Prescription DTx are reviewed by the FDA as software as a medical device (SaMD). SAMDs are intended to be used for one or more medical purposes that perform these without being part of a hardware medical device.[4] To gain regulatory approval in the U.S., DTx can follow two pathways, 510(k) and De Novo, each of which require their own type of data.[5]

Under the 510(k) or premarket notification pathway, the FDA determines that the device is substantially equivalent to another already authorized device, called a "predicate".[5] As part of the FDA review, manufacturers are required to provide supporting data on the predicate and the new device will be considered substantially equivalent if any of the following criteria are met:

- The device has the same intended use and has similar technological characteristics
- The device has the same intended use and has different technological characterizes but has comparable safety and effectiveness to the predicate

If a DTx does not receive a substantially equivalent designation in response to a 510(k) submission or the manufacturer has determined there is no predicate, manufacturers can also opt for a De Novo Application.[5] Under this pathway, DTx seek marketing authorization as a novel Class I or II medical device, requiring efficacy and safety data, as well as labels on its intended use, OTC or prescription designation and special controls for Class II devices.[5]

It is uncertain in the future if this process will remain the same as the FDA is developing new policies and approaches to evaluating DTx with the aim of expediting approval based on the intended use and classification of the product. These initiatives indicate a growing environment for manufacturers to bring more digital health innovation to the market. The Software Pre-Cert Pilot Program is investigating a new regulatory model that prioritizes the evaluation of the product developer over the product, whereas the Breakthrough Device Designation Policy will streamline the already established regulatory pathways for DTx. Additionally, the establishment of the FDA's Digital Health Center of Excellence (DHCoE) in 2020 also signifies an increased investment of resources to expand upon the other FDA's previous forays into digital health.[6]

Are Digital Therapeutics Covered by Insurers?

While there are multiple ongoing regulatory efforts to drive DTx access, there are uncertainties from a payer and provider perspective on how to best integrate DTx in the current landscape and the current benefit assessment system. In particular, payer coverage of DTx has gained increasing relevance as more products become available. U.S. managed care payers from within Trinity's Global Health Advisory Board (GHAB) highlight that interest from employer groups in DTx is at an all-time high. However, the approach to covering DTx is still evolving, with differing views on how to administer these benefits (i.e., pharmacy vs. medical), what kinds of evidence to consider and even which products are relevant for coverage or not.

> "DTx are good for anything that requires a lifestyle change because they engage the member on multiple fronts and push through barriers of adherence."
>
> **National MCO Pharmacy Director**

[4] FDA, (2018, April 12). *Software as a Medical Device (SaMD)*

[5] FDA, (2022, March 10). *Premarket Submissions: Selecting and Preparing the Correct Submission*

[6] FDA, (2022, September 27). *Digital Health Center of Excellence*

Currently, across most U.S. health plans, DTx, including prescription and non-prescription DTx, are not broadly covered under the standard health plan benefits offered by managed care organizations (MCOs) or pharmacy benefit managers (PBMs). Though large MCOs and PBMs may have digital formularies of covered DTx products, this benefit is fully funded by employer groups that opt into coverage. Payers that provide access to DTx products highlight that covered products mostly consist of non-prescription products, like Trelstar, Propeller Health and Sleepio, among others, rather than products that require a prescription (e.g., reset-O, Somryst).

> "Just because it's not FDA approved doesn't mean it can't have good data."
>
> **National MCO Pharmacy Director**

Payers view non-prescription DTx as easier to manage, given there is no provider interaction or oversight required. They highlight that the currently available clinical evidence for prescription DTx is not convincing enough to consider coverage given the price of the prescription DTx (vs. non-prescription). Up-front payment models, more akin to drug payments, are viewed unfavorably given higher pricing (>1,000 USD per app access), while payment of non-prescription DTx is based on a per-member-per-month that is considerably lower than prescription DTx. Payers favor this simple model given the fees are nominal and there is cost consistency.

> "It does not help to be FDA approved interestingly enough - we feel that prescription DTx do not offer clinically meaningful value relative to their price."
>
> **National MCO Pharmacy Director**

Other payers are more skeptical and have taken other approaches to adopting DTx. Some payers may also be more inclined to manage DTx under the medical benefit, viewing these kinds of products more similarly to medical devices. Others have included prescription products, like Pear Therapeutics' suite of DTx, as covered benefits (though still employee-funded), while not considering non-prescription DTx and wellness-focused apps. These payers believe that non-prescription DTx products are not relevant to health plans, and should be fully patient funded.

> "These are nice tools for people who like using tools; these don't belong on a formulary, they belong at an app store."
>
> **PBM Representative**

Importantly, these payers still recognize the utility of DTx and propose other methods for implementation – for example: a shared wellness benefit where patients are rewarded for meeting endpoints associated with improved health outcomes (e.g., weight loss, medication adherence, HbA1C [glycated hemoglobin] reduction, etc.) while using a DTx. However, they still view DTx as a "fringe" benefit that will be driven by employers rather than a new distinct benefit category to be managed.

Current trends among payers raise questions for the potential of DTx, especially prescription products, to achieve broad coverage until wider use is shown. While there is no guidance, Pear Therapeutics seems to be at the forefront of development; please refer to the Pear Therapeutics Case Study on the next page for more details.

PEAR THERAPEUTICS

Case Study

Pear Therapeutics has positioned itself as a leader in developing and commercializing prescription DTx; but how have they managed to do so? And, most importantly, how has this affected the coverage and reimbursement of Pear's products, and their financial situation?

Pear's strategy stems in "be everywhere" and "convince everyone": active involvement with physicians in the field (gaining physician trust), providing remote prescriptions for patients within their targeted indications (facilitating patient access), the set-up of clinical trials to track outcomes relevant to patient monitoring (especially healthcare resource utilization) and building strong relationships with individual payer networks to enable coverage (building trust within the payer community) have been strategies to their current position in the DTx space.[7-14]

To date, Pear has been the only DTx manufacturer to justify long-term reductions in healthcare resource utilization (12 months for reSET-O and 24 months for Somryst). This data includes demonstrating reductions in in-patient stays and emergency department visits with their substance (opioid) use disorder DTx reSET-O, and reductions in emergency department visits, hospitalizations, hospital outpatient visits, and treatment with their chronic insomnia product, Somryst, in combination with sleep aid and medication.[7-9]

However, coverage and reimbursement of Pear's products remains limited. Pear's products are only available through some Blues plans, PBMs and regional payers or as a covered benefit for employees at Fortune 500 companies. From a government perspective, patients across multiple states have access to Pear's products, and they are pursuing Medicaid coverage in five states. The negotiation process with insurers has been slower than Pear had originally anticipated. By Q2 2022, Pear had 11,000 prescriptions, a little over half of which were fulfilled; of those, only 45% were paid for.[10-12]

These issues with obtaining coverage and reimbursement for their products has led to Pear having to lower their revenue forecasts from 22 million USD to 14-16 million USD for 2022 (fulfilling 35,000-45,000 prescriptions vs. the projected 50,000-60,000). Additionally, the updated projections have led to a restructure of the Pear Therapeutics workforce.[13, 14]

While the promise and potential of DTx have been well covered by Pear Therapeutics, only time will tell whether DTx can turn into a profitable business, or it will have to stay one step behind pharma and medical equipment. Pear Therapeutics is eager to continue breaking the barriers to DTx access and their clinical value in the shape of patient-relevant outcomes and HCRU.

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7 Pear Therapeutics, (2022, June 6). *Pear Therapeutics Announces New Analysis Showing Reduction In Healthcare Resource Utilization And Associated Costs In Patients Using Reset® At Six Months*

8 Pear Therapeutics (2022, June 8). *Pear Presents Interim Real-World Data Showing Significant Reductions In Symptoms Of Chronic Insomnia, Anxiety And Depression With Somryst® At Sleep 2022*

9 Pear Therapeutics (2022, June 14). *Pear Therapeutics Announces New 12-Month Analysis Showing Reduction In Healthcare Resource Utilization And Associated Costs In Patients Treated With Reset-O®*

10 Pear Therapeutics (2022, April 4). *Pear Therapeutics Announces Program To Bring Prescription Digital Therapeutics To Patients In Recovery Through A Telehealth Provider Experience*

11 Pear Therapeutics (2022, February 10). *Pear Therapeutics Announces State Of Michigan To Fund Access To Prescription Digital Therapeutics For Substance Use And Opioid Use Disorders*

12 Pear Therapeutics (2022, February 24). *Pear Therapeutics Announces New CMS HCPCS Code For Prescription Digital Behavioral Therapy Inclusive Of All Of Its Commercial Products*

13 Pear Therapeutics (2022, March 28). *Pear Therapeutics Reports Fourth Quarter And Full Year 2021 Financial Results*

14 Pear Therapeutics (2022, August 11). *Pear Therapeutics Reports Second Quarter 2022 Results*

The Future Landscape for Digital Therapeutics

Although payers may not agree on what coverage of digital therapeutics may look like, they acknowledge the importance of creating a framework for their evaluation, as the number of DTx developed is increasing and interest from doctors, employers and patients continues to grow.

A subset of payers envision a sub-committee within the P&T committee that has medical benefit representation and can therefore assess DTx as their own category in the future. This process would allow for the evaluation of novel DTx in comparison with other products within the same class instead of other drugs within the same therapeutic area.

> "We want to see the same type of clinical benefit that we'd see with drugs."
>
> **National MCO**

Review of DTx would contain the key clinical and economic components payers currently use in the evaluation of DTx. Rigorous clinical study designs such as trials with an active comparator arm (other available apps) are still seen as the gold standard when assessing DTx and would still be preferred over other weaker clinical evidence (single-arm, or open-label studies). Other types of evidence such as health economics, including HCRU data, are expected to be critical for DTx, as concerns around their high cost vs. limited perceived clinical benefit in patient-relevant outcomes remain (please refer to Pear Therapeutics case study for further details on how they are using these to justify the real-world value of reSET, reSET-O and Somryst).

While there is a general skepticism around the use of health economic models to justify the product's economic value, given the lack of long-term experience with the use of DTx, payers anticipate an increasing acceptance of this type of evidence. This is further strengthened as plans become more comfortable with recommendations from third parties like ICER that develop these economic models.

Most payers view DTx as **moving into a digital formulary** with a **similar structure to current pharmacy benefit formularies**, given that they are technologies that do not require HCP administration. There is already beginning to be a shift toward having a separate digital health formulary.

Express Scripts is seen as one of the early adopters of a digital products / apps, having introduced a digital health formulary in 2019.[15] Although these benefits are likely to remain employer funded for the time being, payers believe that having a separate benefit will help to increase access to these products by standardizing review process and available evidence.

[15] Cision PR Newswire (2019, May 16). *Express Scripts Simplifies Digital Health Technology Marketplace for Consumers and Payers*

Although most payers do not currently place high importance on FDA review of DTx, some believe that regulatory clearance could drive their willingness to cover DTx in the future if their pricing and evidence become more attractive. However, payers may not necessarily be impressed by efforts made by the FDA to improve the regulatory process and the relevance of FDA approval is still in question, especially with use of direct-to-consumer style non-prescription DTx as compared to prescription DTx.

As digital formularies are carved out and established within health plans, payers believe they will allow for increased access to DTx as there will be a standardized process for review. In addition, similar utilization management and cost-savings tools are likely to be applied, with a separate digital formulary allowing payers to manage benefit design as they do with drugs, including tiering and contracting.

> "I think that one of the things to be considered will be is there the ability to move data back to the health plan or the PBM for instance; if these DTx are cloud-based and there is data coming in that can let us know how a person is doing and how the disease is being treated."
>
> **PBM Representative**

	Pharma-like [current approach]	Consumer Health	Digital Formulary
Responsible Committee	P&T Committee	None – paid for through OOP payments	Combination of different payers (such as P&T Committee, Medical Technologies Committee)
Evidence Requirements	Patient-relevant outcomes measured over a long-term period, economic impact (i.e. healthcare resource utilization, cost offsets)	Sufficient to drive prescription/utilization by patients	Requirements adjusted from pharma-like model to enable data collection over time (through the introduction of value-based contracts [VBCs])
Reimbursement Considerations	Payments limited to app, limited reimbursement for HCP time in assessing results, limited price vs. pharma products	None – paid for through OOP payments	Coverage for app use and physician time, additional flexibility around app pricing, especially if VBCs introduced

TABLE 1. Potential Commercialization Pathways for Digital Therapeutics

Conclusion

To date, U.S. payers have evaluated and covered DTx on a case-by-case basis, using the same standards and processes used for pharmacological products. Given the lack of awareness around the potential value of DTx in patient relevant outcomes, DTx developers have faced the pressure of producing evidence at par with pharmaceutical manufacturers (e.g., robust clinical trials with large sizes, long durations and comparative evidence, economic outcomes), which may not be sustainable for a still developing industry without substantial economic support.

As more DTx options become available in the market and more patients become aware of their value, payers and manufacturers need to collaborate to find a middle ground where appropriate pricing, together with clinical and economic evidence, can be balanced with standardized product reviews and payer coverage, budget and contracting considerations. Refer to Table 1 for a summary of the potential commercialization pathways for DTx in the future.

Continue reading for key implications for various stakeholders and author information

Key Implications for DTx Manufacturers

The limited utilization of prescription DTx and the lack of defined pathways for approval, coding and reimbursement result in a challenging payer landscape for DTx

- There is a lack of clarity in clinical evidence standards for these technologies, though payers are clear that RCT data will be needed for consideration of any prescription DTx
- Most payers view non-prescription DTx and wellness apps more favorably than prescription DTx due to their ease of implementation with employer groups and data sharing
- Access and reimbursement for DTx will need to be driven first by demand from the key distributors of these products (e.g., employers for non-prescription DTx and wellness apps and providers for prescription DTx)

Key Implications for Pharma Manufacturers

Despite greater experience and familiarity with the regulatory and commercialization pathways for drugs, past drug-DTx partnerships have not shown to be successful in driving drug utilization

- Payers could be open to non-prescription DTx that can boost adherence of medications and provide patient support and education, requiring data (e.g., clinical outcomes, HCRU data) to support their utilization
- While DTx is still in its infancy, there are a number of potential opportunities in the future for innovation and collaboration across traditional pharma and digital products to improve patient outcomes

Key Implications for Providers & Patients

Providers and patients can expect a self-pay market until these products gain greater traction, though advocacy to employers could help to drive coverage.

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