WHITE PAPER

The Monetization Challenge in Digital Therapeutics

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Digital therapeutics (DTx) are poised to disrupt U.S. health care with a completely new approach to diagnosing and treating patients. These software-based interventions are expected to expand patient access, improve physician workflow, reduce payer costs, and improve clinical outcomes for patients. According to Arizton, a market research company, over the next five years, revenues are projected to grow at a compound annual growth rate of ~33%, reaching $8.9 billion by 2027, with the U.S. accounting for most of the growth.

While the future for DTx looks bright, today there's a problem: the road to revenue is still being built.

Reimbursement poses the main challenge. Public and private insurers remain slow to adopt DTx, as they are skeptical of the economic benefits, and require a restrictively large body of evidence. And because the DTx footprint is still relatively nascent, insurers have yet to feel the pressure of competition or consumer demand. Cash sales are also problematic. Patients accustomed to health insurance plans covering most of their healthcare expenses are often unwilling to pay for these products out of pocket. Other potential customers within the healthcare ecosystem include providers, employers, and pharma partners. Driving revenue from these sources, however, will likely be a shorter-term solution that bridges the immediate gap while traditional therapeutic reimbursements are being built.

Despite the longer path to traditional reimbursement, some progress has been made by DTx companies, including the first-ever DTx-focused HCPCS (Healthcare Common Procedure Coding System) code by CMS (Center for Medicare and Medicaid Services)—which was driven by Pear Therapeutics in early 2022. This code (A9291) allows HCPs to bill private payers directly for DTx, just as they would for a traditional medical device. While representing meaningful progress toward aligning DTx with more traditional reimbursement structures, the certification stopped short of presenting a clear path to revenue, at least for Medicare, as CMS did not set a benefits category for the code. In early 2023, Pear drove another positive step toward the wider adoption of DTx in the traditional healthcare payer system when its Reset and Reset-O prescription digital therapeutics were added to Florida's Medicaid preferred drug list, making them directly available to 5 million Florida-based Medicaid patients through their providers. While Pear has spurred meaningful progress from a structural standpoint, monetization from the traditional channels is still an open question, likely contributing to Pear's recent announcement that it is considering a sale. This continues to highlight the challenge of monetizing in the near term through traditional reimbursement in a slower-moving healthcare system.

Other bright spots, though, include PBM CVS Caremark, which has included several DTx products (including Big Health, Weight Watchers, and Hinge Health) on a platform to facilitate adoption and payment. Big Health has worked with the NHS (National Health Service) in Scotland to provide its suite of anxiety and insomnia solutions under the nationalized healthcare system there. Highmark Health Plan has also recently issued a positive coverage policy for FDA-approved prescription digital therapeutics.

The long-term growth of DTx hinges on establishing the traditional reimbursement pathways needed to ensure market access and sustained financial success. In the interim, digital therapeutics companies – digital health natives, established pharma and MedTech firms, and consumer tech players – will need creative go-to-market strategies to remain viable. The more creative monetization models currently being pursued include Direct to Consumer, Employer Partnerships, and Go-To-Market Partnerships. The most successful DTx companies use a combination of these pathways.

DTx Monetization Pathway Deep Dive

1. REIMBURSEMENT

While industry-wide recognition of DTx as a legitimate modality is gaining momentum, even the most successful DTx companies are not yet getting significant volume from reimbursement. Initially, other channels will be needed to generate meaningful revenue. And while reimbursement and review processes are becoming more standardized, without a formal CMS rule or process established, reimbursement decisions are likely to remain ad hoc, based on individual payer priorities.

Currently, startups are bearing the burden of breaking new ground, as larger healthcare organizations have been slower to adopt DTx. These startups need to navigate a very complex landscape characterized by many different stakeholders. Often, they lack the relationships, funding, and influence needed to overcome obstacles in an industry with many layers of bureaucracy. Progress, when made, is incremental. Larger players such as pharma companies may be able to capture strategic advantage if they adopt these new DTx technologies and then leverage their existing payer engagement infrastructure to accelerate progress to traditional reimbursement.

It remains to be seen which players – smaller, more disruptive startups, or larger incumbents that are moving into the DTx space – will be the primary drivers of health ecosystem change around DTx and reimbursement. Regardless of who ultimately leads in the space, breaking the "glass ceiling" of DTx reimbursement will require pushing multiple products through the reimbursement system to establish a repeatable framework for DTx. At that point, the floodgates will open for other companies to take advantage of the paths carved by these first movers.

Within the reimbursement framework, there are three main routes to payer coverage:

- **Purpose-built reimbursement codes:** This is a slow process (~2 years) but provides pricing flexibility for the treatment. Challenges include highly manual processes and layers of administrative speedbumps, compounded by lack of familiarity with the DTx category. Smaller DTx companies in the space are resource-constrained and lack the relationships and institutional knowledge to break down barriers at CMS, health authorities, and large payers. Purpose-built reimbursement codes include:
    - CPT codes (allow an HCP to bill for time), which is administered by the AMA and leverages the Medical Benefit of insurance
    - A HCPCS code (for Durable Medical Equipment (DME), usually attributable to physical devices), which is administered by CMS. In the case of Pear Therapeutics, the creation of a code though CMS unlocks the ability of Pear to negotiate a rate with payers, even though CMS did not provide a reimbursement rate*
    - For prescription DTx, the manufacturer could previously obtain a National Drug Code (NDC), which served as a unique identifier to facilitate easier negotiations with payers*, but this was replaced in 2021 by unique codes for software as a medical service (SaMD) products

*For HCPCS codes or NDC codes, the DTx solution can be on *formulary* or *off formulary.* On formulary drives higher adherence rates and an increase in trust, but is a more cumbersome process.

- **Retrofitted reimbursement codes:** This approach applies pre-existing codes to a DTx product (e.g., Remote Patient Monitoring [RPM] codes) to enhance speed to market. The downside is minimal value. While allowing HCPs to bill for time spent with setup and monitoring, a significant amount of time is required for non-billable activities such as collecting and analyzing the data beyond the maximum billable limits. With this approach, each patient is worth hundreds of dollars over their lifetime, versus potentially multiple thousands with purpose-built codes. RTM (Remote Therapeutic Monitoring) codes may also be used; these open new avenues of payment for companies like Propeller, but face the same difficulties. Both RPM and RTM codes provide some revenue but are low value relative to the complex technology development and services costs they are reimbursing. As a result, companies that exclusively use retrofitted reimbursement codes often see negative operating margins, without a path to profitability.

- **No reimbursement code:** Under this model, DTx companies contract directly with payers, usually using licensing-like payment terms. This allows the payer to reimburse the DTx company directly for providing the product to its installed base, and relies on the DTx company's ability to prove its economic value. Pricing is flexible, but payers have limited programmatic spend budgets, which presents a challenge regardless of pricing flexibility.

In pursuing reimbursement from payers, DTx companies also need to increase their appeal by generating substantial evidence of benefits well beyond what Health Authorities require for regulatory approval. Three types of evidence that payers seek include:

- **Clinical value:** Quantifiable evidence of improved efficacy or safety associated with use of the DTx. The level of sophistication of payers is increasing, as they look for Randomized Control Trials (RCTs) and Real-World Evidence (RWE) to validate the clinical efficacy of a product. Payers prefer to focus on quantifiable endpoints, e.g., "x days reduction in hospital stay," "symptom score improvement of y," etc., that allows them to price value delivered by a DTx solution accordingly.

- **User demand and engagement:** This is a largely foreign concept to traditional MedTech and Pharma companies. To operate here, DTx pilot programs must capture user demand data as evidence. Payers look for usage analytics such as user adoption and retention, both of which are common metrics for digital companies. In cases of disease management, payers are interested in the long-term engagement of their base to manage these chronic conditions. DTx companies that can show evidence of bottom-up demand from enrollees have a better chance at persuading payers to reimburse. This requires spend on marketing and user education, even when the DTx is prescribed.

- **Unmet need:** A gap analysis of unmet needs includes clinical and broader coverage driving to quantifiable decreases in overall costs. This evidence drives the payer's decision to cover a DTx, as it ties back to the ROI calculation. Mental health and high-cost chronic diseases are prime targets for DTx, which can have outsized impact on "unmet needs."

While the hill to traditional reimbursement pathways is steep, ongoing industry efforts are improving adoption of DTx by payers. Industry groups like Digital Therapeutics Alliance are creating processes and frameworks to streamline evaluations of DTx for both providers and payers. AdvaMed is working to enhance collaboration between the FDA and CMS to increase transparency, parallel processing, and better access for innovative new technologies. Digital formularies and PBMs like CVS Caremark are working to further simplify contracting, pricing, and navigating patient needs. Payers are reevaluating their models, and regulatory pathways are becoming more and more defined as guidance is issued.

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2. DIRECT TO CONSUMER

When considering DTC within the healthcare space, the most engaged stakeholders managing health conditions are frequently the most willing to pay out of pocket for a digital solution. A direct-to-consumer approach to monetization has higher success for indications characterized by high patient involvement. Furthermore, DTC success is more pronounced in higher income segments, where patients have more time, money, and support available to manage the healthcare journey. To date, the DTC approach has been most successful in weight loss management tools (e.g., Noom, which had $400 million in revenue in 2020, predominantly from user subscriptions). In these use cases, patients have been willing to pay as much as $60/month for a proven digital solution. Willingness to pay across indications that have historically been reimbursed through traditional payers is more challenging. Oncology, for example, has substantial coverage across the privatized healthcare system and patients are not accustomed to paying out of pocket in that space. However, weight loss has historically had few well-developed medical treatment paths (excluding more invasive procedures), opening the opportunity for DTC solutions to establish traction where gaps exist across the traditional care spectrum.

The structure of a DTC healthcare offering commonly replicates monetization models associated with traditional tech products such as Duolingo (education tech) and Whoop (fitness and health coaching).

Monetization models include:

- Free to user: This model utilizes ad revenue, or monetizes user data to provide cash flow.

- Freemium: In this model, core features of app are free, but paid in-app upgrades significantly enhance the functionality. This retains the wide reach of free download, but offers some direct revenue streams. Success relies on how useful the core features are versus the premium features. Ultimately, the DTx needs to drive behavioral engagement from patients that encourages the upgrade to premium membership. Premium membership may include upgraded features and additional value propositions such as community engagement, co-creation/authorship of content, social interaction, etc.

- Pay per use: Applicable to some DTx use cases such as diagnostic tests, the patient pays each time they use the product (e.g., takes a test). This model often creates a poor user experience with incorporated payment flows that can deter long-term usage for individual patients.

- Pay per download: Here, patients pay a fixed amount to download the app, allowing for unlimited use thereafter. The payment process creates a high barrier to download, resulting in lower initial reach. However, free perpetual use after payment increases product stickiness over time.

- Subscription: In this model, patients enroll in a monthly or annual subscription that may be an individual or a family plan. The approach is well-suited for DTx, especially in the mental health or chronic disease management spaces where the product can become a core part of the patient's ongoing treatment. In addition to decreasing the upfront cost, the subscription model provides an incentive for patients to keep using the product diligently over time. It's important to note that the subscription monetization model does not structurally preclude a reimbursement component. For example, the DTx treatment may include eight weeks of reimbursable use, followed by OOP subscription for long-term use, behavioral maintenance, and ongoing engagement.

A DTC monetization pathway requires a lower burden of providing evidence to show improved outcomes than does the payer reimbursement approach. However, that advantage is offset by the fact that clinical validation is still extremely important for brand reputation, achieving physician endorsement, creating a barrier for others, and enhancing marketing messaging and positioning. DTC also typically requires a heavier marketing initiative, complete with branding, ad spots, etc. And while not as regulated as pharmaceuticals, DTx advertising does differ from country to country, creating some complexity when scaling products across geographies.

Traditional Med Tech and Pharma companies also face challenges modeling DTC asset revenue effectively. For example, selling through an app store requires paying a significant share of revenue to the platform host (i.e., Apple or Google). Properly pricing a DTx product can also be difficult when approaching an unfamiliar market. Unlike traditional reimbursement negotiations with payers that focus on the value delivered by a DTx product, DTC pricing is set by patient willingness to pay and patient market perception. Beyond these challenges, DTC pricing may become problematic if a company is also considering longer-term plans for traditional medical reimbursement through payers. A DTx company that eventually wants to achieve a reimbursement strategy for monetization cannot charge a low price in a DTC channel initially and later request payers to reimburse a higher cost for the same product.

3. EMPLOYER PARTNERSHIPS

Similarly to direct negotiation with payers through the reimbursement pathway, DTx companies can build B2B relationships with self-insured employers to provide DTx products to their employees as a benefit negotiated with the DTx company. Companies pursuing this model typically use a B2B licensing agreement and negotiate a flat rate or a cost structure tied to number of active users on the platform. This approach relies on standard B2B sales and marketing efforts by the DTx company, which can be significant with channels becoming crowded by health and wellness offerings across different treatment areas. To drive efficiency, some companies employ a rollup strategy, offering a range of products for mental health, mindfulness, musculoskeletal, weight loss, etc., as a package to consolidate selling and negotiation efforts.

The DTx company must consider additional costs associated with selling and managing a relationship-oriented business, including the need for account managers, customer success managers, dedicated sales reps, dedicated technical support, etc. Furthermore, the company must maintain a provocative dual-value proposition that proves value for both the patient (employee) from a care and quality of health position, as well as the “provider” (employer) from an employee engagement position. The DTx must be worth using, and adequately engaged with by an employee population.

Headspace Health, for example, partners with companies to provide its meditation app to employees as part of their HR benefits. Headspace tells companies that employees who use its product will be happier and more productive. To support this claim, Headspace provides HR and other company leaders with access to analytics dashboards showing aggregated, de-identified statistics around app usage and satisfaction scores over time. Sustaining this model requires continually adding features and focusing on user privacy, which translates to additional development effort, larger internal product and engineering teams, and additional costs to the DTx company. More specifically, providing regular feature updates to drive high utilization over time is more difficult with a free offering than with subscription models, and requires close collaboration with customers to promote usage through marketing pushes such as company-wide challenges.

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4. GO-TO-MARKET PARTNERSHIPS

DTx companies should be assessing the full value chain to identify partnerships that may provide avenues to product improvement and monetization. This commonly lands in two spaces: connected devices and drug companions.

Connected Devices:

Connected devices that remotely monitor pulse rate, blood pressure, temperature, blood glucose and more offer consumer benefits such as, for diabetes patients, requiring fewer finger stick tests. Devices also offer a clear reimbursement pathway by virtue of their classification as Durable Medical Equipment (DME). Furthermore, the growth of wearable adoption – driven by the prevalence of chronic disease and a growing consumer focus on health and fitness – creates a less ominous adoption barrier for partnering DTx companies than an independent software offering would face. Hardware drives stickiness among users, and payers are more comfortable reimbursing for a physical device that is utilized versus a software-only value proposition.

In most cases, the commercial model of a connected device/DTx partnership centers around selling the physical device. The device may be sold to end users in a variety of ways, including DTC. Under this scenario, the DTx company then negotiates a deal for a percentage of wearable device revenues or a flat fee from their GTM wearable partner.

External hardware/software partnerships may be complicated by the fact that a fixed percentage of sales or a flat fee must be negotiated pre-launch to avoid disagreements about attribution. However, that challenge can be addressed if the same entity provides both hardware and software. A few years ago, Apple's ECG software was approved as a class 2 medical device to be used exclusively on the iWatch platform. In this instance, consumers don't pay for the ECG (DTx software), they pay for the iWatch (hardware). But the ECG adds critical functionality to the platform and can lead to an increased percentage of sales. In a case like this, where the lift in sales due to a software feature may be hard to measure independently of other features, an external partnership between a DTx company and a hardware manufacturer would be less likely to succeed.

Pharma Partnerships:

DTx and pharma companies may form partnerships to create joint-GTM approaches. Here, the pharma company provides the drug, and the DTx helps drive drug adoption, drug compliance, and patient retention. The pharma product generates revenue directly, and the DTx provides an uplift to that revenue stream or eliminates future declines due to non-adherence. A deal is negotiated whereby the pharma company reimburses the DTx company for use of the device; the terms may be arranged based on the volume of patients taking a drug who are also utilizing the DTx. The DTx company negotiates based on value delivered through use of the DTx product, relying on quantifiable metrics such as measured increases in patient adoption of a drug, retention on a specific drug, or utilization of a drug when prescribed. Anti-kickback legislation creates barriers for a DTx attempting to claim percentage increases in drug sales as a result of DTx availability, as the DTx cannot be seen as unfairly funneling users to a specific drug.

This restriction can make it difficult for pharma companies to evaluate the ROI of the partnership, since standard success metrics and KPIs cannot directly attribute any drug uplift to the DTx product. There is an exception, under which a DTx product *IS ABLE* to provide references to a specific drug therapy IF the software is a drug companion that has been validated *WITH the drug through clinical trials* and is established as part of the drug label. In this case, the DTx is a digital arm of a specific drug rather than an independent product. This has driven awareness around the potential upside of driving the conception, build, and integration of digital therapies *early in the R&D process* to be tested and validated alongside a drug therapy.

An example of the pharma partnership model is Propeller Health. Propeller used a two-prong strategy to monetize its respiratory device for asthma and COPD. First, Propeller negotiated directly with payers to reimburse for plan members using the DTx by showing evidence of long-term cost savings. Next, Propeller negotiated directly with manufacturers of asthma and COPD drugs (e.g., inhaled medicines) to receive payment based on evidence of improved drug adherence when utilizing the DTx. Recently, Propeller has augmented this model with reimbursement using RTM codes.

5. DATA MONETIZATION

One of the more creative monetization strategies is to sell the data that a DTx generates. In this approach, adoption is generally not encumbered by cost barriers to end users that would otherwise constrain adoption. Note that the pathway to monetization is longer term, since the DTx needs to collect enough data to enable meaningful analytics. Data around clinical and patient-reported outcomes is highly attractive, especially with proper metadata tagging and when packaged as a RWE product. Patients are often willing to share their data when it leads to better health outcomes in a novel new product, but data privacy must always be closely managed.

At present, no DTx companies have used this as their primary source of revenue. However, the prospect of data monetization is generating keen interest, especially as the demand for reliable RWE increases for pharma trials. And while a full, accessible infrastructure does not yet exist for a large-scale data marketplace, smaller solutions such as Komodo Health are emerging. In the future, we may see a one-stop-shop where data sellers (DTx companies, providers, etc.) and data purchases (researchers, Pharma, etc.) come together and exchange information.

CONCLUSION

The digital therapeutics industry is focused simultaneously on two time horizons. The long-term goal of scalable reimbursement pathways, once achieved, will enable the transformation of digital therapeutics. In the meantime, companies are exploring sustainable commercial models in the near term. Unfortunately, the allocation of resources to these near-term commercial objectives will inevitably slow industry progress towards a truly scaled reimbursement model.

Near-term options range from DTC applications to creative GTM partnerships, but no clear winners emerge across the space at this point. The “right model” depends heavily on the nature of the DTx and its position along the patient journey. As such, DTx companies should explore all options thoroughly, and find the right fit based on their offering, their longer-term strategic goals, and immediate monetization needs.

In the long term, we recommend that DTx companies focus their monetization strategies to progressive Payers and integrated Payer/Provider networks to drive momentum and demonstrate value in the reimbursement category. In parallel, the industry needs to continue to work with the CMS on updated policies and definitions to establish widespread reimbursement pathways. This vision requires cooperation across DTx companies, including supporting the tenacity of disruptive startups, as well as piggybacking on the capabilities and relationships of large corporations.

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