DIGITAL THERAPEUTICS HAVE PROVEN STAYING POWER

Why is there still the Payer Divide with DTx Companies?

Authors: Barbara Carpenter, Alex Spencer

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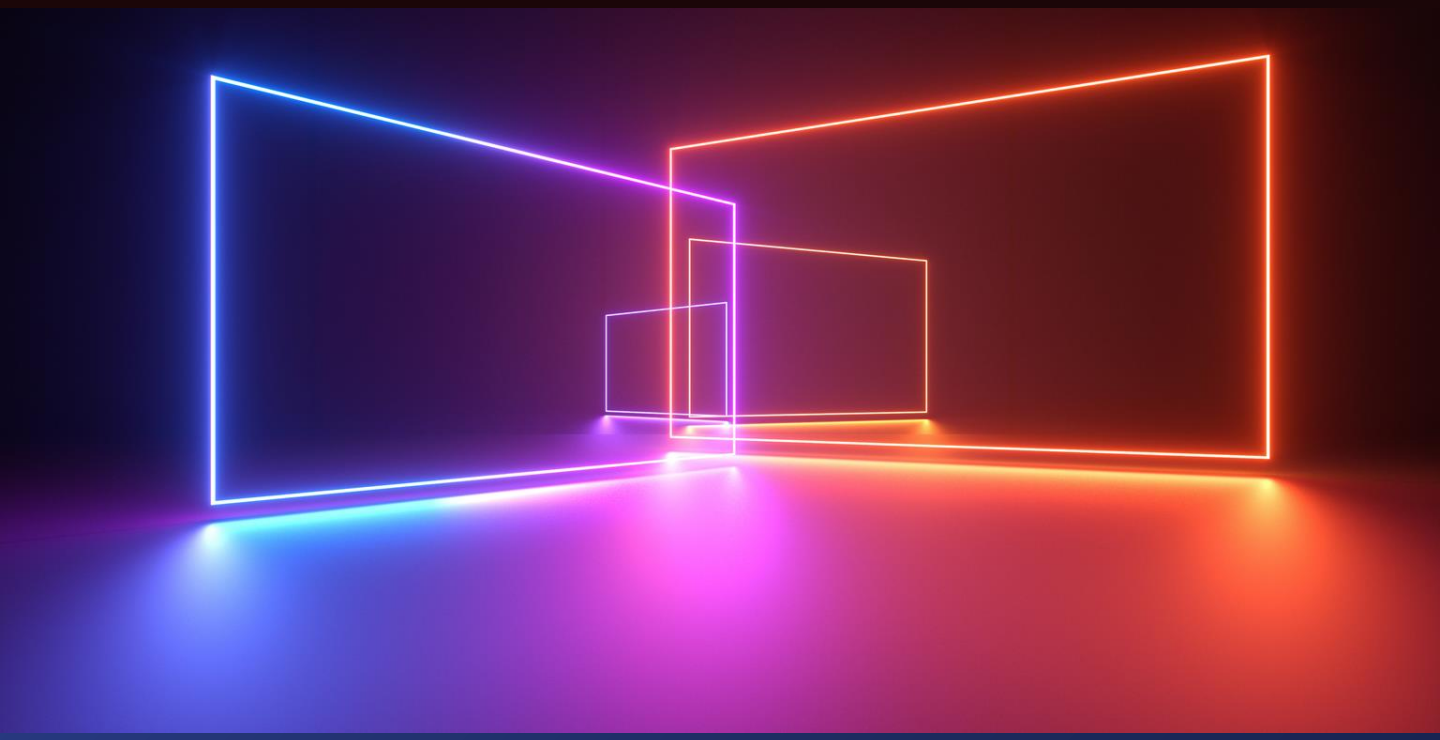

Digital Therapeutics (DTx) companies continue to struggle to get payer approval for their products, thus the divide between payers and DTx companies remain. This paper will discuss the reasons DTx companies are not getting coverage from payers for their DTx products, where they can pique payer interest and narrow the coverage gap, and consider alternative options to bring their products to market.

The first digital therapeutic (DTx) was FDA cleared and came to market in the 2000s[1]. Since then, there is still a disconnect between DTx companies and payers. Pear Therapeutics is the best example, to date, of "commercial success" and failure of a company that was too commercially advanced to fail. So, is it the instability of DTx startup companies that is causing a lack of coverage among payers? Not likely. Payers are familiar with drugs from biotech startups - some drugs get FDA approval and get coverage, while others fail trials, never to be heard from again. Payers are still open to biotech drug evaluations.

> *"It's (Pear downfall) not that big of a deal. Potentially opens the door for others." - National payer*

> *"(Pear's downfall) No impact really. I think that most products will go through same process as Reset-O, a pilot required for coverage. I see these treatments as augmented & supplemental." – Regional payer*

A SMALL FISH IN A BIG SEA of pharma, medtech and digital health companies

DTx are not top of mind for health payers even if their products are FDA-cleared and have active members using them. In a survey of 12 mid-sized to large payer organizations, DTx were thought to be important, even offering time and cost savings, but there was little to no DTx specific strategy nor was it a part of an overall business strategy. So why don't payers have a corporate vision for DTx, despite their importance?

- **Lack of predictability—**It's hard to see future success without volume forecasts and a per member cost savings model.
- **Lack of familiarity—**DTx do not follow the traditional drug model with rebates and discounted pricing. Many DTx use subscription models, which are less familiar for payers.
- **Lack of provider buy-in—**Healthcare providers need to have the awareness and buy-in to prescribe the product and only a minority of them, depending on the specialty, are aware and comfortable in prescribing DTx.

> *"I think the payer isn't the problem, I think it is lack of volume at the healthcare provider, so a big hurdle in the next 3-5 years is if they don't get providers to start driving to use these products and requiring payers to pay for them, it will just sit still."- National payer*

- **Lack of CMS support—**While changes are underway, DTx are currently lacking CMS coverage under the Medicare benefits, creating hesitation among payers.

WHERE DTx COMPANIES HAVE STRENGTH

What helps a DTx's chances for coverage with payers?

POPULATION NEEDS

Addressing a high cost or high prevalence therapy area like diabetes, substance abuse, mental health, pain management, or heart health, just to name a few, is still a pressing issue for payers. Payers are open to solutions in cost-draining areas of

PRIOR AUTHORIZATION

Requiring prior authorizations may further reduce risk to payers allowing them to maintain control over DTx adoption and allowing for closer monitoring and data collection during initial uptake periods.

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FDA CLEARANCE

Obtaining FDA clearance shows payers the DTx is scientifically vetted and reliable, removing some risk to the payers.

CLINICAL DATA

Having clinical data of any sort, which shows improved efficacy with DTx plus Standard of Care vs. Standard of Care alone, validates that DTx can provide a benefit to members with minimal risks.

HEALTHCARE PROVIDER INVOLVEMENT

Requiring a prescription denotes healthcare providers' oversight and monitoring, reducing risk of wrong or improper use.

REAL WORLD EVIDENCE (RWE)

Providing RWE that shows improvement in health outcomes and cost savings, specifically in the member population, further supports the use and coverage of DTx.

> *"I think obviously the robustness of the randomized trial is critical. I think what I haven't seen as of late is the interaction between this product and real standard of care. Nobody's generally comparing themselves to the standard care; no one else is also comparing themselves in the conjunction of a drug therapy, for instance, or a medical therapy. I want to know the incremental value you're bringing to this therapy, so this thing's really doing what it says it's doing, or if they're (patients) actually just being more adherent to their GLP-1 medication than they are on this therapeutic."*
>
> *-National provider*

UNFAIRLY, A HIGHER BAR IS SET WHEN IT COMES TO RWE.

Why are DTx companies being asked to provide RWE when drug manufacturers can receive approval without this? The risk factor feels higher for payers when stepping outside of traditional drug models. In a perfect world, payers would want to see a wish list of data including RWE that shows:

- Efficacy
- Safety
- Engagement
- Compliance beyond 12 weeks
- Longer term durability of effect
- Cost of product
- Cost savings/offset to plan (medication reduction, reduced doctor visits, reduced healthcare utilization)

In addition, peer-reviewed journal articles on the success rate, along with KOL endorsements, increases the chances for coverage. The lack of historical efficacy with DTx is a barrier that DTx companies must overcome, and generating RWE provides DTx companies with an opportunity to show payers the benefits without the cost and time of large clinical trials.

> *"Currently I'm underwhelmed on how DTx companies are using that data to articulate the situation. The real-world evidence is a good thing and a huge differentiator. These products are generating mountains of data on these patients on a minute-to-minute basis, but I'm underwhelmed by how these DTx companies are using that data to articulate the situation."-National payer*

> *"I want to see a 15% to 20% reduction in the cost of care. If they don't demonstrate an ROI in their clinical trial, we're not even going to talk to them. But there is RWE so that you can calculate the ROI to a specific member population and obviously with our population it is much more important that they get the benefit" -National payer*

THE REALITY OF OVERCOMING PAYER BARRIERS

Consumers still expect DTx affordability like a traditional drug payer coverage model can provide (insurance covers all or part of a drug through prescription benefit). It may be years before payers jump onboard and provide a similar model for DTx. In the meantime, DTx companies have alternatives to overcome barriers in seeking payer coverage.

OVERCOMING PAYER BARRIERS TO COVERAGE

Insurance Member Model

Individuals or employees get a DTx product through their insurance providers at a discounted rate, if adherence metrics are met. This takes the decision out of the hands of P&T (Pharmacy and Therapeutics) committee payers and puts the decision in the hands of executives who will champion the DTx for their member base.

- One option is to utilize a pilot program with payers—by providing discounted pricing to insurance providers in exchange for claims, adherence, and other financial data, DTx companies can use the data to model cost savings which can help refine their value stories, while establishing a valuable partnership with payers.

This model works best when the insurer has a population need to treat a particular condition, the DTx company can afford to offer their product at a significant discount or at cost to the insurance company for a period of time, and the DTx company has the capabilities for financial modeling – collecting and analyzing data on claims, adherence and other financial data to show return on investment in terms of health outcomes and financially. Outcomes and financial data can then be used to develop a value story for partnerships with additional insurance companies.

OVERCOMING PAYER BARRIERS TO COVERAGE

Direct-to-Consumer Model (DTC)

A DTC model is where DTx companies go straight to the patient, allowing use without a prescription to build a value story with RWE. Here, efforts shift from influencing the payer to influencing prescribers and patients on the value of the DTx.

- E.g., Akili Interactive made their *Endeavor for ADHD* app for children available through the app stores, without a prescription, and saw a boost in revenue from the prior 3-month period.[2]

This model is best applied when the indication doesn't require high HCP involvement, there is high patient awareness and autonomy about the indication. The DTx solution must prove valuable to patients who are intrinsically interested in finding a solution. Not only is it important to have superb end-to-end user experience, it is critical to have a well-funded and strong marketing strategy.

OVERCOMING PAYER BARRIERS TO COVERAGE

Employer Model

Collaborating with employer benefits may have a lower barrier to entry for DTx companies, allowing them to provide their products to patients, collect additional data, and continue to build out their value story. In this model, the payer and prescriber are not a factor. The company must convince employees to use the therapeutic based on their own self-assessment of health.

For this model, the employer needs to have a good handle on the health of their employee population and where patients could benefit from additional treatment to reduce absenteeism, promote safety and performance (e.g. a sleep apnea solution for truck drivers). The DTx company needs strong sales and marketing teams to convince employers the DTx solution is valuable and worth offering to their employees to ultimately keep employees at work with fewer sick days and better overall health, which translates to better performance. This implies the value story that is told has "proof of its claims" and can be replicated. It also poses a competitive advantage for the employer in a tight market where benefits are a means to attract top talent over other companies.

OVERCOMING PAYER BARRIERS TO COVERAGE

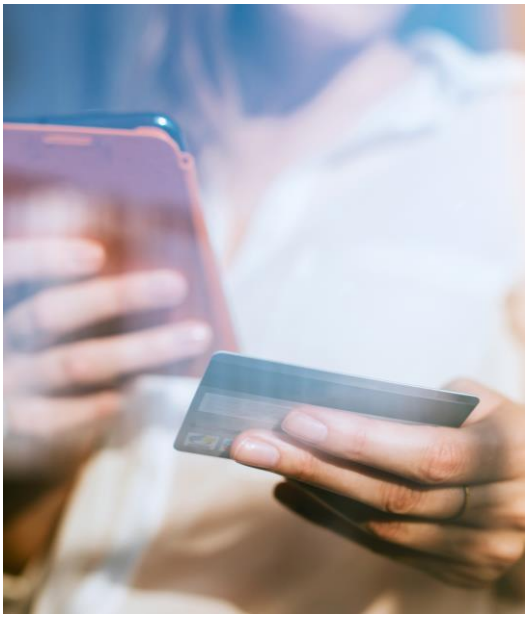
Health Systems

Health systems are leveraging DTx relationships to equip their systems to maximize HCP and patient relationships by integrating innovative technologies to enhance data collection and analysis to support improved health outcomes for patients. In this scenario, the prescriber drives the use of therapeutics available through the health system, removing the payer as a factor. In exchange, the DTx provider (health system) and prescriber mutually benefit from data exchange to improve the overall health of the patient population.

For this model to work, it's critical the DTx company has a compelling solution prescribers can get behind, along with the analytical capabilities to help embed prescribing into the natural workflow, collect and analyze data, and offer reporting to both prescribers and DTx providers (health system). Additionally, this strategy may help alleviate pressures from HCP burnout and labor shortages.

OVERCOMING PAYER BARRIERS TO COVERAGE

Payviders Model



Partnering with payviders (organization offering health insurance and hospital/health system care) can streamline the process for securing coverage and encourage use among healthcare providers. Additionally, since payviders are already set up in a system that incentivizes value-based care, they could serve as natural partners for evidence generation. Payviders offer a strategy where the prescriber is entitled to suggest a DTx to patients and the payvider in return receives outcome data to continue to build its value story and improve the health of patients, enticing other payviders.

Here, payviders already understand their member population and are in need of a specific solution to manage a condition or reach a specific sub population and are highly invested in preventative care. DTx companies can offer value through tailored solutions that meet these needs and in return gain RWE from a partner that puts a high emphasis on value-based care and reduced use of hospital services (ER visits, readmissions, etc.)

HOW IPSOS CAN HELP

Ipsos' Digital Health Center of Excellence has partnered with nearly 90 digital health startups with bespoke solutions to answer key business questions. Ipsos has a deep understanding of the health insurance landscape and robust access to provider, insurer, and patient insights. Example engagements include:

Develop a commercialization roadmap…

of key actions and milestones to understand who are the right decision-makers for your offering, what evidence you need to generate for partnership and how to develop a compelling value story that fits your organization's business needs. Whether it is pursing an alternative solution or approaching insurers directly, we will partner with you to develop the best roadmap for your company.

Assess demand…

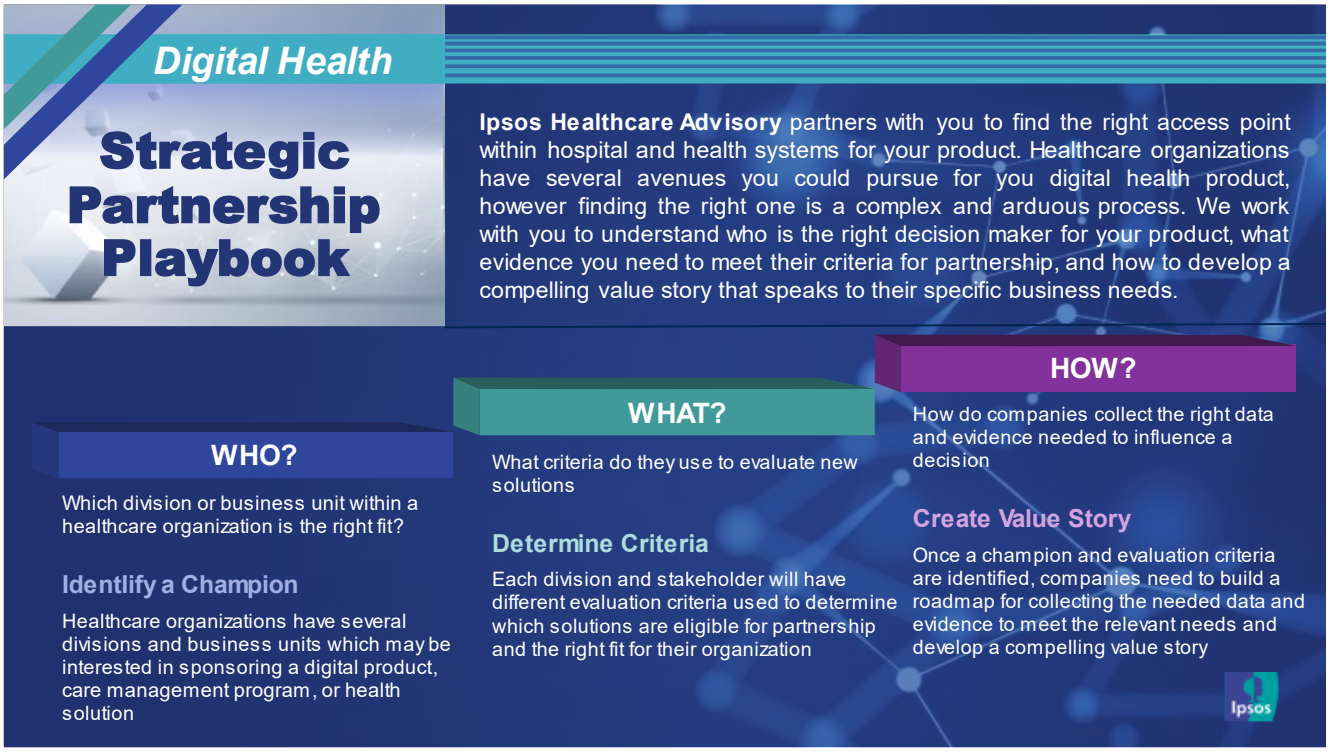
through forecasting to develop a clear picture of potential market size, a worthwhile exploration before bringing a DTx to market

Refine user engagement strategy…

to ensure seamless integration into users' lives, promote user retention, and drive beneficial health outcomes, using the alternative partnership models noted above for uptake of DTx products

Analyze ROI…

to begin building a value story highlighting cost savings and market reach, valuable to payviders & insurers



For more information

Please contact:
Email: Ashley.Lumpkin@ipsos.com
Email: Barbara.Carpenter@ipsos.com
Email: Alex.Spencer@ipsos.com

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[1] https://en.wikipedia.org/wiki/Digital_therapeutics#:~:text=7%20References,Definitions,as%20far%20back%20as%202000.

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*Capobianco E (10 November 2015). "On Digital Therapeutics". Frontiers in Digital Humanities. **2** (6). doi:10.3389/fdigh.2015.00006.*

[2] Akili says OT https://pharmaphorum.com/news/akili-says-otc-switch-adhd-dtx-leads-sales-rise?utm_source=pharmaphorum+Daily+Newsletter&utm_campaign=3dee9b438b-EMAIL_CAMPAIGN_2019_09_24_10_10_COPY_01&utm_medium=email&utm_term=0_a54496134b-3dee9b438b-445553043C switch for ADHD DTx leads to sales rise | pharmaphorum