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'It's Not Going To Happen Overnight': Payors On Pear Fallout And Digital Therapeutic Coverage Prospects

by [Hannah Daniel](#)

Public and private payors at the Digital Therapeutics Alliance's 2023 Inaugural Summit weighed in on the coverage environment for prescription digital therapeutics post-Pear Therapeutics and strategic moves companies can make to position themselves advantageously.

The experience of Pear Therapeutics, Inc. – prior to its collapse – provides insight into reimbursement strategies that may be effective for others in the space, but public and private payors also note some stark realities facing prescription digital therapeutic (PDT) companies in 2023.

“The capital markets are now freezing where money was free for the last 10 years,” noted Jason Parent, director of clinical innovation at private payor Point32Health, founded by Tufts Health Plan and Harvard Pilgrim Health Care, during a 9 June panel of the Digital Therapeutics Alliance's 2023 Inaugural Summit held in Washington, D.C.

Lack of cheap funding is only going to exacerbate challenges for PDT companies that already have struggled to deliver the data needed for payors to champion coverage of the emerging technologies.

“The biggest message is just evidence, evidence, evidence,” Parent said during the panel titled, “Insights for Achieving Positive Coverage Determinations: Payors.” He added, “A strong evidence base gets you in the door.”

"From a government perspective, I can tell you this: nobody is looking actively for anything. Everyone is just trying to keep their head above water." – Ashley Peterson

Pear's agreement with Point32Health in early 2022 – roughly 15 months before the PDT trailblazer filed for Chapter 11 bankruptcy – expanded access to its FDA-approved reSET and reSET-O PDT for substance use disorders. According to Parent, Point32Health was drawn to Pear's body of real-world evidence.

While an essential piece, RWE may get PDT companies only so far. Increasingly, these companies are being asked for clinical trial data, which is costly and challenging to generate due to current regulatory constraints. In a separate panel, Marty Culjat, senior VP of regulatory innovation and digital medicine at Eversana, noted that PDT companies often balk at the notion of clinical trials because, in their view, "they already have the world's best data." (Also see "[The Frontier Of Digital Therapeutics Regulations](#)" - Medtech Insight, 16 Jun, 2023.)

Digital Therapeutics Alliance CEO Andy Molnar similarly noted at the event a conversation he had with a PDT company head, whose position boiled down to "you don't need data, it's just the smile on the patient's face that matters!"

Of course that is not the be-all and end-all, but it reflects the inexperience of the PDT sector with reimbursement and other market access hurdles with which traditional medtechs are well-acquainted.

Ashley Peterson, director of contracting and analytics at Artia Solutions and former pharmacy administrator for Florida Medicaid, provided a cold dose of reality. "From a government perspective, I can tell you this: nobody is looking actively for anything. Everyone is just trying to keep their head above water. So we're not out there looking for any solutions whatsoever. We are inundated with different products and things that people want Medicaid to cover, and they come in with such a lack of understanding – there's just a huge disconnect."

According to Peterson, Pear presented to Florida as "low hanging fruit" that did not require a massive investment. She noted that smartphones can be a "lifeline" for people on Medicaid, and Pear's mobile apps brought a solution to those patients that was unavailable before.

"I was not satisfied with the status quo" of traditional opioid abuse treatment, Peterson said. "We do have pharmaceuticals to help these individuals out. But [given] the shortage in mental

health providers, lack of transportation ... they do have that [smartphone], and that's the only thing they may have at 3 am when they might be possibly considering a relapse.”



FROM L TO R: JASON PARENT, CHARLES BROWN, ASHLEY PETERSON, TERRY COTHRAN

Terry Cothran, senior pharmacy director at Oklahoma Health Care Authority, said the Sooner State entered a value-based agreement with Pear that was designed to be low risk. “We paid [Pear] a lump sum upfront for so many prescriptions, and then we were going to measure hospital visits on the back end,” he said. The agency then would determine if the agreement had saved the state money – if not, Pear would have to make up the difference.

“That was the agreement, but that didn’t account for the bankruptcy,” Cothran quipped.

After the conference, Cothran said Oklahoma’s Medicaid agency may not be through with Pear yet, despite the firm’s dissolution and the auctioning of its digital therapeutic assets in May. (Also see "[The Afterlife Of Pear Therapeutics: Korean DTx Maker Discusses Vision For Salvaged](#)")

[Migraine Assets](#)" - Medtech Insight, 12 Jun, 2023.)

"We plan to still analyze the data, and if Pear owes us additional funds based on the outcomes, then we will follow the bankruptcy process to try to collect," he said in an email.

In addition to Florida and Oklahoma, Massachusetts' Medicaid program also granted coverage to Pear's reSET and reSET-O for substance use disorder and opioid use disorder, respectively. (Also see "[Pear Therapeutics Obtains First Medicaid Coverage For PDTs](#)" - Medtech Insight, 13 Oct, 2021.)

'Do Your Homework' And Play Nice

The overwhelming message from the panel was a sobering one that emphasized the need for quality data. For Peterson that means "peer-reviewed literature that shows at the very least budget neutrality and, even better, cost savings."

She advised companies to "do your homework" and be patient. "The Medicaid space is so complex, you get 10 million products a day. Don't give the payor a reason to tell you no," Peterson said.

She also recommended that PDT players explore public reimbursement models beyond fee for service, noting that over 85% of Florida's Medicaid population falls under managed care. "I know [fee for service] sounds good, I know it looks good, but all of the lives are out there in managed care, and there's so much more flexibility for the state," she said.

Parent stressed the importance of forging constructive partnerships with payors. "If you don't have the runway, if you barely have enough capital to get you through the next six to 12 months, especially in this market right now," companies need to evolve from an "adversarial relationship – what are you doing for me? – to how can we help each other? That's the big thing. It's about partnering," he said.

The panelists agreed that with strong partnerships, payors are more inclined to find creative reimbursement solutions or to leverage flexibilities that exist within some state systems.

Charles Brown, technical advisor to the CEO for United/Optum, suggested, "I would start by putting yourselves in the shoes of folks that are in payor organizations and recognizing the increasingly complex landscape."

Cothran remains confident that there is a future for PDTs, but Pear's demise has slowed progress in the space, and he believes the US Center for Medicare and Medicaid Services will be more cautious about covering PDTs going forward.

“It’s a new market. It's going to take behavioral change from a Medicare and Medicaid standpoint, and it's not going to happen overnight,” he said.

Currently, there is no pathway to get PDTs covered by CMS. DTA members are lobbying Congress in support of the Access to Prescription Digital Therapeutics Act, [S. 723](#), which would expand Medicare and Medicaid coverage to PDTs. (Also see "[Getting Your Point Across: Successful Lobbying Tips From The DTA Conference](#)" - Medtech Insight, 13 Jun, 2023.)