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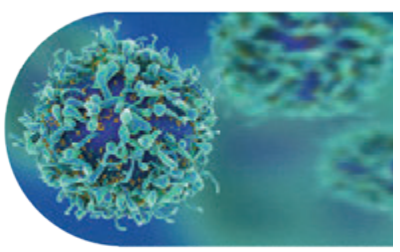

Payors Pushing Back On Digital Therapeutics

By David Bronstein

LAS VEGAS—A software program that helps clinicians diagnose autism as early as 18 months of age, versus the 3 to 4 years required by conventional workups. An interactive game for children with attention-deficit/hyperactivity disorder (ADHD) that can be a powerful adjunct to drug therapy. A phone-based app that helps patients with opioid use disorder (OUD) comply with their addiction medication.

All of these interventions, part of a burgeoning treatment class known as prescription digital therapeutics (PDTs), are approved by the FDA. They also have been a boon during COVID-19, because many of them can be used remotely and fill critical provider gaps caused by the pandemic.

However, PDTs face a major hurdle: Less than half of payors say they are willing to cover them, according to a new survey by Managed Markets Insight & Technology (MMIT) and reported at AXS22/Asembia Specialty Pharmacy Summit 2022.

Respondents cited several reasons for the resistance, according to Jayne Hornung, MMIT's chief medical officer, who presented the survey results. One insurer expressed an unwillingness to "pay for convenience" during a focus group discussion on PDTs that was part of the survey. Another payor stated that many of the PDTs it assessed "lack clinical value," which led it to decide "not to go any further" in reviewing the merits of PDTs, Ms. Hornung noted.

Such attitudes are at odds with the clinical data underpinning the current crop of

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Ohio Insurers Give Provider Status a Boost

By Karen Blum

CHICAGO—Since 2019, when Ohio legislators passed a bill allowing health plans to recognize pharmacists as care providers, several plans have established programs to recognize pharmacists in this expanded role and demonstrate their value.

Several forces converged to influence the state legislature to acknowledge pharmacists as healthcare providers who could be reimbursed for patient services, said Stuart Beatty, PharmD, BCACP, FAPhA, the director of strategy and practice transformation at the Ohio Pharmacists Association (OPA), during the AMCP 2022 annual meeting.

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Pharmacists Can Help Drive Biosimilars Growth

By Dave Doolittle

LAS VEGAS—As medication experts and some of the most accessible members of the healthcare team, pharmacists are well positioned to support the continued adoption of biosimilars.

However, several clinical, operational and financial challenges—as well as misperceptions—need to be overcome for biosimilars to reach their full potential, Sonia Oskouei, PharmD, vice president, Biosimilars, for Cardinal Health, said during a presentation at the AXS22/Asembia Specialty Pharmacy Summit 2022.

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Payor PDT Pushback

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PDTs on the market, she stressed. The ADHD therapeutic, EndeavorRx (Akili Interactive), is a case in point. The immersive video game was approved June 15, 2020, as an add-on therapy for children 8 to 12 years of age with ADHD. It uses a selective stimulus management engine to target areas of the brain that play a key role in attention function, Ms. Hornung explained.

In randomized controlled clinical trials involving more than 600 children with ADHD, EndeavorRx improved key measures of objective attention. "Not all of the results were statistically significant, but there was always a response across the five studies included in the analysis," Ms. Hornung said. "The common side effects were no different than your typical pharmaceuticals on the market, such as dizziness, frustration, etc. The point is there are peer-reviewed clinical trials demonstrating efficacy, and yet payors are still holding back on reimbursing for EndeavorRx, as well as other PDTs."

That reluctance would be easier to understand if PDTs were expensive, but that's not the case with EndeavorRx, Ms. Hornung said. "The cost for Endeavor is $150 a month for patients with no insurance. If covered, it would be less than $100 a month, and additional patient assistance is also available. Yet, Anthem says it's not considered medically necessary; Aetna says it's experimental and investigational; and UHC [United Healthcare] says it's unproven and not medically necessary."

If cost isn't the obstacle, then why the reluctance to pay for PDTs? "I keep coming back to the approval process, based on what we saw in the payor survey and anecdotally," Ms. Hornung said. "Yes, these software programs and games are approved by the FDA, but it's not via the agency's usual process for reviewing and approving drugs."

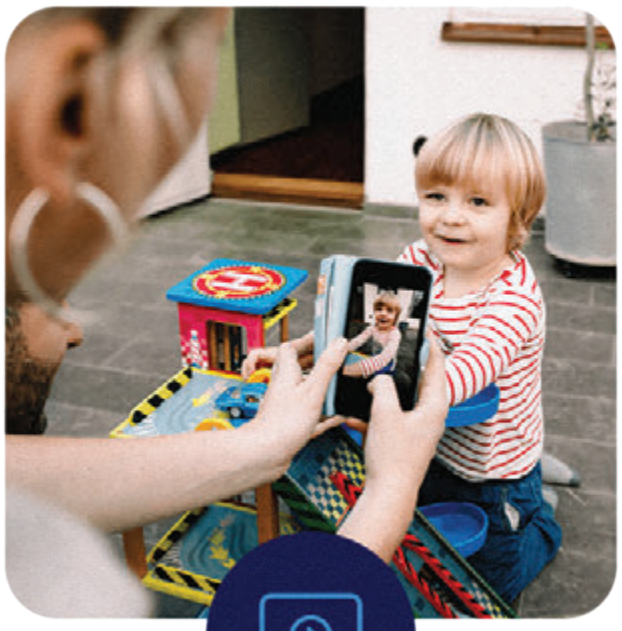
Instead, she noted, the review process for some PDTs is coordinated by the FDA's Digital Health Center of Excellence, "which is not as familiar to payors as the advisory committees that review conventional therapeutics," Ms. Hornung said. "So, the payors feel held back because they don't believe that there's a formal standard regulatory process for reviewing those studies."

Ms. Hornung added a personal account of just how much of a missed opportunity this payor resistance to covering EndeavorRx represents.

"I have a stepson who has ADHD," she said. "He has run through the gamut of pharmaceuticals that are available for him to use. He's been on combination therapies, cognitive behavioral therapy, and I'm not sure we ever hit on the ideal intervention. So, something like EndeavorRx offers hope that there is another product in our arsenal for patients with ADHD like my stepson to try. We just have to get the payors on board for this type of technology."

Unfortunately, "if you look at the national analytics database on EndeavorRx coverage, it shows exactly what we've been talking about," Ms. Hornung noted. "Only 25% of payors have coverage for it, or coverage with a prior authorization."

EndeavorRx (Akili Interactive) uses a selective stimulus management engine to target areas of the brain in children affected by attention-deficit/hyperactivity disorder.



The Canvas Dx system includes a questionnaire completed by a video analyst who reviews two videos of the child with autism spectrum disorder recorded by the parent/caregiver.

Other PDTs Facing Opposition

The PDT for autism spectrum disorder (ASD), Canvas Dx (Cognoa), is another lost opportunity to improve patient care, Ms. Hornung noted. The FDA approved the device on June 2, 2021. Also known as the Cognoa ASD Diagnosis Aid, the technology uses machine learning-based software to help healthcare providers diagnose ASD in children 18 months through 5 years of age who exhibit symptoms of the disorder.

Ms. Hornung cited a pivotal clinical trial in 425 patients that compared the assessments made by Canvas Dx with those made by a panel of clinical experts who used the current standard ASD diagnostic process. The study showed Canvas Dx provided a "Positive for ASD" or "Negative for ASD" result to aid in making a diagnosis in 32% of patients. For trial participants with a positive or negative ASD result, Canvas Dx results matched the panel's conclusions for 81% of patients who tested positive for ASD by the software and 98% of patients who tested negative for ASD by the software.

In addition, Canvas Dx made an accurate ASD determination in 98.4% of patients with the condition and 78.9% of patients without it, she noted.

"Can you imagine what we can do if more payors acknowledged these data and covered the device?" Ms. Hornung said. "If we could intervene with these kids at an early age, as the results suggest may well be possible, how much more highly functional would they be if we got them to treatment? Yet, according to our own survey as well as national payor data, insurers just aren't covering this PDT."

A closer examination of the FDA approval process for Canvas Dx offers some clues as to why payors may be reluctant to cover the software. The agency assessed it through the de novo premarket review pathway "for low- to moderate-risk devices of a new type," the FDA stated in a press release announcing the approval. "This action creates a new regulatory classification."

Similar to other PDTs on the market, Ms. Hornung noted, this new approval pathway may have made some payors reluctant to embrace the technology.

As for the OUD software that Ms. Hornung chose to cite as another missed PDT opportunity, she pointed to the reSET-O app (Pear Therapeutics). Approved by the FDA in December 2018, the app is intended to be used in addition to outpatient treatment from a health professional, in conjunction with buprenorphine and behavior modification therapy.

In clinical trials that led to the app's approval, 82% of people with OUD who added reSET-O to their buprenorphine stayed in treatment versus 68% who did not.

Despite those data, "UHC says the app is unproven and not medically necessary," Ms. Hornung said. Similarly, Aetna deemed the app as "experimental and investigational," and national payor data show that attitude is fairly

The Promise and Pitfalls Of PDTs in Mental Health

Prescription digital therapeutics (PDTs) hold value for patients whose conditions cannot effectively be treated by medications alone—particularly mental health disorders, according to Michael Angelini, PharmD, BCPP, a professor of pharmacy practice at Massachusetts College of Pharmacy and Health Sciences, in Boston.

Indeed, only 65% of patients respond to antidepressants, dropout rates of participants in schizophrenia trials can be as high as 66%, and drugs such as lithium can cause permanent renal impairment in up to 20% of patients treated chronically, he noted during a session on PDTs at the AMCP 2022 annual meeting.

PDTs, in contrast, offer several advantages: There are no drug interactions or pharmacologic intolerabilities, and they could increase access to care and adherence to treatment plans, Dr. Angelini said.

However, there also are several limitations, including patients who stop using the product because they get bored or don't understand how it functions. These tools can produce vast amounts of data that need interpretation. Moreover, they are not necessarily appropriate for acute crises, such as psychotic episodes.

—Karen Blum

prevalent across the board, she noted.

Ms. Hornung lamented that payor stance. "Who in this audience can say they don't know someone … who has been affected by the ongoing opioid epidemic in the United States today? This is an app that can help, based on solid clinical data. Yet, it's not being covered adequately."

Gaining Some Traction

Soumya Vishwanath, PharmD, the senior manager of formulary strategy for Magellan Rx Management, agreed that reimbursement for PDTs has been spotty, with only a "minimal number of plans" covering them. "There are some hesitations in regard to effective evaluation strategies of these products," she said during a session on PDTs at the AMCP 2022 annual meeting. "However, this space has gained a lot of traction, especially during the COVID-19 pandemic."

Payors consider several factors when deciding to cover the products, Dr. Vishwanath said:

Safety. This critical factor involves looking at the digital application's potential for harms, risks and side effects; security measures incorporated to protect information; and whether the product is cleared by the FDA. (To date, the agency has cleared 10 PDTs.)

Clinical evidence. Payors will look at what type of evidence is available, how effective the product is compared with alternative treatments, and whether there is evidence for long-term use.

Applicability. Such determinations include the patient engagement rate; the product's available platforms; whether data can be integrated into medical records; and whether the product reduces health disparities.

Reasons for Hope

As payors continue to grapple with these PDT coverage determinations, several promising developments may speed acceptance of the technology, Ms. Hornung said.

On the legislative front, the Access to Prescription Digital Therapeutics Act of 2022 (H.R. 7051 and S. 3791) has bipartisan support. The legislation includes several components that could help overcome payor reluctance, including the establishment of clearer payment codes and policies that would allow coverage by Medicare and Medicaid, she noted.

"That's huge, because payors have told us the uncertain reimbursement picture for PDTs is yet another reason for their reluctance to cover them," Ms. Hornung said.

In addition, advocacy efforts are gaining momentum, including the Digital Therapeutics Alliance, which was founded in 2017 to engage payors. "Their sole mission is to increase awareness of digital therapeutics," she said. Given the potential for PDTs to make a difference in patients' lives, "that's a huge development that hopefully will yield results soon."

These efforts are sorely needed because "digital health is becoming an essential part of how healthcare is delivered," Ms. Hornung said. "It's very likely that [PDTs are] going to grow exponentially, and we expect further research and evidence to support these technologies. Digital health and digital therapeutics are here to stay and will help support patients through their new unique healthcare journey."

—Additional reporting by Karen Blum

The sources reported no relevant financial disclosures other than their stated employment.