GPBCH
Greater Philadelphia
Business Coalition on Health
DRIVING INNOVATION AND VALUE IN HEALTHCARE

EMPLOYER ACTION BRIEF

Prescription Digital Therapeutics: Evidence-Based, FDA-Approved

WHAT ARE PRESCRIPTION DIGITAL THERAPEUTICS?

Prescription digital therapeutics (PDTs) are a unique class of software-based interventions used to treat, manage, and/or prevent a medical disorder or disease. These clinical interventions can be delivered through a variety of digital platforms such as smartphones, tablets, smartwatches, and virtual reality technology.

Depending on the product, PDTs are intended to be used independently or along with other therapies. Generally, PDTs are not intended to replace ongoing therapy or reduce face-to-face visits with healthcare providers, but rather to supplement and increase access to needed care. PDTs generally adapt established approaches to treatment such as cognitive behavioral therapy (CBT) for digital delivery[2]. Many current and emerging PDTs address mental health concerns such as substance use, insomnia, depression, and anxiety, in order to expand access and improve comprehensiveness of care.

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HOW ARE PDTS DIFFERENT FROM APPS & OTHER DIGITAL HEALTH TECHNOLOGIES?

There are many digital health technologies, including mobile health apps and digital therapeutics, aimed at supporting healthcare systems, clinicians and patients. The broad category of digital health includes mobile health apps that help with promoting health and wellness through tracking and monitoring parameters[3]. These apps can range from lifestyle and fitness trackers to diet and blood glucose logging for diabetes management.

What differentiates PDTs from mobile health apps is that PDTs are clinical interventions that must be FDA-authorized for a specific disease or disorder. PDTs are clinically tested and must go through FDA evaluation of efficacy and risk. In addition, PDTs are available only through prescription by a healthcare provider. PDTs are backed by clinical trial data and are evidence-based interventions whereas mobile health apps may not be supported by data or regulated by the FDA.

Prescription Digital Therapeutices

- Are evidence-based, having been assessed for efficacy through clinical trials
- Target a specific disease or disorder
- Go beyond routine patient monitoring
- Undergo FDA evaluation for authorization as medical devices
- Require prescription from a provider
- Provide 24/7 access to clinically-validated treatment

Mobile Health Apps

- Provide easy access to information related to conditions or treatments
- Help healthcare professionals improve and facilitate patient care
- Promote health and wellness
- Not FDA regulated and do not require FDA authorization
- May not be rigorously evaluated, with findings subject to external review

WHAT IS THE FDA AUTHORIZATION PROCESS FOR PDTS?

The FDA categorizes mobile health apps, in general, as Mobile Medical Applications (MMAs)[4]. These applications include software that fall under the FDA's enforcement discretion, where manufacturers are not required to submit premarket review applications or register and list their software with the FDA. Software in this category poses minimal risk to patients and consumers. Examples of software in this category include apps that help patients manage a disease without providing specific treatment suggestions.

PDTs are MMAs that do not fall under the FDA's enforcement discretion and are therefore classified and regulated as medical devices[3]. The process of approval for a new PDT requires submission of data to support safety and effectiveness for its intended use. Following FDA review and authorization, health plans and pharmacy benefits managers may decide on coverage options and utilization management, such as step therapy or prior authorization. If a PDT is covered, purchasers may then decide whether or not to offer that PDT in their benefits.

WHAT IS THE PROCESS OF OBTAINING AND USING AN FDA-AUTHORIZED PDT?

Once the FDA authorizes a PDT, a healthcare provider can prescribe that PDT in several ways. They can either register with the manufacturer's clinician-facing prescribing portal to prescribe a PDT, use an electronic prescription, or print and submit an enrollment form. After a prescription is submitted, the manufacturer will contact the patient to download and register the PDT on a device. Once a patient has acquired the PDT, they may begin using it as directed. Some manufacturers may also have clinician-facing portals where providers can monitor usage and progress. This is the general process for prescribing a PDT to a patient and there may be minor differences between manufacturers and products.

PDTs currently authorized by the FDA

PDT Product	Manufacturer	Therapeutic Area	Website
reSET	Pear Therapeutics	Substance Use Disorder (SUD)	resetforrecovery.com
reSET-O		Opioid Use Disorder (OUD)	
Somryst		Chronic Insomnia	www.somryst.com
Nightware	Nightware	PTSD Driven Traumatic Nightmares	nightware.com
EndeavorRX	Akili Interactive	ADHD in children ages 8-12 years old	endeavorrx.com
Mehana IBS	Mahana Therapeutics	Irritable Bowel Syndrome (IBS)	mahanatx.com
EaseVRx	AppliedVR	Chronic lower back pain	easevrx.com
Luminopia One	Luminopia	Amblyopia in children ages 4-7 years old	luminopia.com
Regulora	metaMe	IBS-related abdominal pain	regulora.com

HOW ARE PDTS COVERED BY HEALTH PLANS?

PDTs increasingly are being covered by commercial and Medicaid plans, as real-world evidence of their effectiveness builds. Coverage of PDTs can occur through either the pharmacy or medical benefit, at the discretion of the plan sponsor. PBMs may be better able to manage this benefit, given the alignment with other prescribed therapies and ability to track utilization, spending, and outcomes. PDTs can also fit into tiered medication formularies as they are usually used in conjunction with other medication therapy. Depending on plan structure, patient out-of-pocket payments for PDTs may be significantly higher through the medical benefit than the pharmacy benefit. Also, because billing and reimbursement typically occur post-administration, tracking utilization under the medical benefit could be more challenging.

A value-based reimbursement arrangement may help to reduce costs for employers and payers, where payment occurs only when certain outcomes or treatment milestones are achieved. For example, an outcome that can be measured for a patient on the reSET-O program for opioid use disorder is if the patient continues medication-assisted treatment or is abstinent 12 or more months. Another coverage option can be a subscription model, which is common for software in technology industries. Here, the cost of a PDT is set up as a recurring fee (weekly, monthly, etc.) and payment occurs only when the PDT is used. These payment models may help to promote adherence to this new class of prescribed therapies.

EXAMPLES OF EMPLOYER-RELEVANT PDT'S: A CLOSER LOOK AT TWO FDA-AUTHORIZED PDTS

reSET-O for Opioid Use Disorder

reSET-O is a PDT approved for treating opioid use disorder (OUD) in patients 18 years of age and older undergoing buprenorphine treatment. reSET-O is not intended to replace ongoing buprenorphine therapy or replace care by a medical provider. The intervention is a 12-week community reinforcement approach and contingency management program that consists of 31 core lessons on CBT and relapse prevention, with 36 maintenance lessons on managing relationships, communication skills and time management. The clinical data submitted for FDA-approval showed an increased retention in outpatient opioid use disorder treatment, from 68.4% with buprenorphine alone to 82.4% when reSET-O was added to buprenorphine treatment[5,6]. No significant adverse effects compared to usual treatment.

Economic Value

From 2015 to 2018, the employer costs of OUD include increased healthcare spending, lost productivity, and increased disability and workers' compensation claims, which total nearly $150 billion[7]. This cost is an underestimation, as it does not include presenteeism, difficulty hiring and retaining a sufficient workforce, or lost economic opportunities due to inability to meet demand for services. The same study also estimated that individuals with OUD experienced $22,000 in additional annual healthcare costs compared to individuals without OUD. The list price of reSET-O, before applicable plan-dependent rebates and discounts is approximately $1,800. While the economic value of PDTs continues to be analyzed, early claims data show that reSET-O has the potential to lower the cost of OUD through reduced healthcare resource utilization[8,9].

Somryst for Chronic Insomnia

Somryst is a PDT approved for treating chronic insomnia in patients 22 years of age and older. Somryst is not intended to replace ongoing treatment medication and requires supervision of a healthcare provider for use. The intervention is a 6 to 9-week cognitive behavioral therapy for insomnia (CBT-I) program, with 6 core lessons on behavioral, educational and cognitive techniques to improve sleep health. Results from a web-based CBT-I study showed reductions of 45-52% of insomnia symptoms, such as the amount of time it took to fall asleep and the amount of time spent awake at night[10]. Improvement in insomnia symptoms persisted at 6-month and 12-month follow-ups.

Economic Value

Chronic insomnia has substantial negative effects on employees, such as reduced work performance, workplace accidents and errors, absenteeism and presenteeism. An analysis from 2012 of lost productivity resulting from insomnia in the US workforce was estimated to be $63.2 billion per year[11]. Healthcare costs of untreated insomnia, including inpatient admissions, ED visits, days hospitalized and outpatient provider visits, are estimated to be as high as $100 billion per year[11]. An analysis of healthcare utilization in Medicare patients found that those with insomnia showed approximately $64,000 higher all-cause costs over an 11-month period, driven by inpatient care, compared to controls[12]. The list price of Somryst, prior to any plan-level rebates or discounts, is approximately $900. Compared with medications, CBT-I has fewer adverse effects and is also recommended as the first-line intervention for chronic insomnia by the American College of Physicians and the American Academy of Sleep Medicine[13]. Given the benefit in improving sleep health in insomnia, Somryst has the potential to reduce healthcare utilization, as well as absenteeism and presenteeism.

RECOMMENDED ACTIONS FOR EMPLOYERS

PDTs may significantly improve outcomes and reduce total costs of care. Since coverage of PDTs is more likely to fit within the pharmacy benefit, employers should speak with their PBMs and benefits consultants to determine which, if any, FDA-authorized PDTs are currently available. If FDA-authorized PDTs which support care for high-volume and high-cost conditions are not available (covered) through the PBM or health plan, employers should further discuss whether and how the plan reviewed evidence and made a coverage determination. PBMs also may be willing to begin covering a specific PDT at the employer client's request.

Coverage decisions should be based on value, so it is important to recognize that PDTs are not equivalent in terms of effectiveness and outcomes. Eligibility and utilization management should also be considered, as well as a plan to monitor utilization and outcomes. While PDTs have the potential to reduce healthcare costs, current economic data is limited and new data should be evaluated when made available.

Questions to Guide Coverage:

- What is the prevalence of the medical disorder or disease in your population? (if not known, ask your consultant and/or plan for this information)
- What is the health impact and economic impact of the problem being addressed, based on your data and/or literature?
- How familiar is your population with utilizing technology (smartphone, wearables, etc.)?
- What is the value proposition for the PDT as communicated by the manufacturer?
- What is the cost to the plan for the PDT (net any applicable rebates or discounts)?
- What concomitant therapies need to be used with the PDT, and how will the PBM or health plan monitor this comprehensiveness of treatment?
- How will clinical and economic outcomes be monitored to track utilization and value?

Employer Perspective: Why Cover PDT's?

Over the last three years, 2019 to 2021, the Teamsters Health and Welfare Fund of Philadelphia and Vicinity has seen a significant increase in members seeking overall mental and behavioral health services. There has also been a growing concern about new or increased substance use due to COVID-19 pandemic related stress as utilization in the Employee Assistance Program has increased by 15% just for substance use disorder. Due to the rise in substance use disorder and an increasing need for accessible behavioral health services during the pandemic, the Fund recognized that it needed another tool to support its members. This need led to the seeking out of prescribed digital therapeutics (PDTs) and the 24/7 support they could provide to those members in need. If a prescribed phone application could increase a member's odds of success when in treatment for substance use disorder, then the Fund needed to make this option available. After seeing the published clinical data that demonstrated the success of PDTs in conjunction with therapy, it only made sense that the Fund add them to its pharmacy benefits plan. The goal here with PDTs is to provide members who have substance use disorder another opportunity to be successful in their treatment. Not only are PDTs shown to be successful they are cost-efficient in the overall course of care.

– Tanika Smith, Director of Communications, Teamsters Health and Welfare Fund of Philadelphia and Vicinity

RESOURCES FOR MORE INFORMATION

Digital Therapeutics Alliance:
https://dtxalliance.org/

Pear Therapeutics:
General information: Pear PDT Digest: https://peartherapeutics.com/news/pdt-digest/, website www.peartherapeutics.com, and video https://vimeo.com/user101786366/resetandreset-o2021

reSET-O resources:
www.resetforrecovery.com and https://vimeo.com/user101786366/reset-oproduct

U.S. Food and Drug Administration (FDA):
https://www.fda.gov/medical-devices/digital-health-center-excellence/device-software-functions-including-mobile-medical-applications

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The Greater Philadelphia Business Coalition on Health (GPBCH) seeks to increase the value of health benefit spending for the region's employers. We do this by improving workforce and community health, increasing healthcare quality and safety, and reducing healthcare costs. The Coalition represents employer interests in working with health plans, healthcare providers, benefits consultants, suppliers and other system stakeholders to address population health priorities and to ensure that when healthcare is needed it is accessible, affordable, equitable, high-quality, and safe.

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