A Playbook for Employers

PRESCRIPTION DIGITAL THERAPEUTICS

NCBCH
NC BUSINESS COALITION ON HEALTH

National Alliance
of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

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Part 1: An Overview of the Digital Health Space

Digital Health as an Umbrella Term

Digital health is an umbrella term for different health technologies available. These technologies are being used to:

▶ Leverage large data sources to determine which treatments are effective, for which populations, and in which scenarios to reduce inefficiencies, better apply limited resources to reduce cost, and track medical outcomes.

▶ Scale the delivery of care to patients across geographies, lowering the logistical burden of direct in-person care.

▶ Personalize and improve quality care by leveraging machine learning and artificial intelligence based on individual patient characteristics collected directly from devices and apps and from healthcare providers.
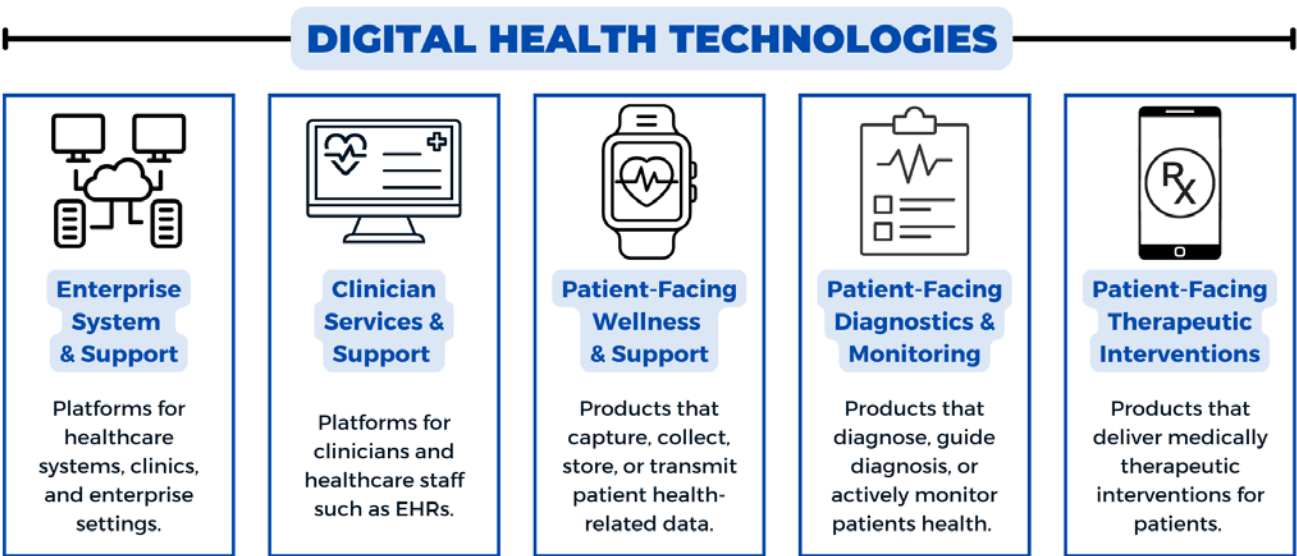
With 85% of the U.S. population now using smartphones, on-demand digital health services have become popular and accepted. Factors such as widespread internet and cellular access, cheaper technology, and the rise of analytic technologies like artificial intelligence (AI) have made this feasible. The COVID-19 pandemic accelerated this technological revolution, with many employers quickly providing innovative digital health services including health apps and telehealth services, as seen in Figure 1. Many people were exposed to digital health technologies for the first time.

The Benefits of Digital Health

The advantages of digital health adoption in employer-sponsored health benefit packages include:

▶ **Patient engagement:** Digital health technologies can facilitate tech-enabled patients with more interactions for covered plan members during the course of care. This includes reminders,

FIGURE 1: Digital Health Technologies Overview

DIGITAL HEALTH TECHNOLOGIES

Enterprise System & Support
Platforms for healthcare systems, clinics, and enterprise settings.

Clinician Services & Support
Platforms for clinicians and healthcare staff such as EHRs.

Patient-Facing Wellness & Support
Products that capture, collect, store, or transmit patient health-related data.

Patient-Facing Diagnostics & Monitoring
Products that diagnose, guide diagnosis, or actively monitor patients health.

Patient-Facing Therapeutic Interventions
Products that deliver medically therapeutic interventions for patients.

Adapted from The Digital Therapeutics Alliance
Note: EHR = Electronic Health Records

personalization, and guided user interfaces. Data can be collected to gauge the members' experience and adapt it as needed.

- **Health deserts:** Many regions of the U.S. lack sufficient primary care providers, specialists, and specialized medical services. Employers can leverage technology to provide options and lower logistical barriers of members seeking care in rural and remote areas.

- **Lack of health specialists:** Several medical specialties, like psychiatry and primary care, are projected to have an adequate number of providers in the coming decade. Healthcare systems struggling to provide these specialties can use digital health as a means of increasing care availability.

- **Scaling chronic disease management:** Providers need digital options to more efficiently treat, manage, or monitor the growing number of chronic diseases such as diabetes, heart disease, depression and anxiety.

- **Overcoming logistical barriers to care:** Covered plan members are looking for options that reduce cost or time commitments to travel for care. The home as the "center of care" is a model growing in popularity.

- **Data interoperability:** Due to increased adoption of electronic health records (EHRs) and a push by the Centers for Medicare & Medicaid Services (CMS), data may be accessible across platforms, making it easier to monitor and track outcomes and more quickly evaluate treatment options.

- **Medical cost control:** Covered plan members are becoming more aware of medical costs. Educated consumers are seeking to reduce their cost of care through services that may be less expensive online.

- **Employee recruitment and retention:** Employers can leverage digital health technologies as a benefit option to attract and retain employees who prefer digital health services.

Digital technologies have the flexibility of being used independently, in tandem with remote or in-person clinician-delivered therapy, or paired with medications, devices, and other therapies to optimize outcomes. Employers are increasingly being exposed to new care options for covered plan members based on burgeoning digital healthcare options.

An Overview of Digital Therapeutics

Digital therapeutics (DTx) are health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has demonstrable positive therapeutic impact on a patient's health. In general, DTx products have the following characteristics:

- Care is delivered through an app, via a mobile device, tablet, personal computer, wearable device or a virtual reality (VR) headset.

- The clinical process may use data collected from the user to track the outcome.

- Services may be accessed via an app, either directly from the DTx vendor or through an employer-sponsored benefit program.

Examples of DTx products include:

- An app that provides weight-loss health information and coaching, by tracking diet and exercise and adjusting user recommendations based on weight loss over time.

- A smart inhaler to treat chronic obstructive pulmonary disease (COPD), such as asthma, that sends an alert to a provider showing trends in medication utilization or behavior suggesting risk of complications or hospitalization.

- An app that guides patients through home physical therapy sessions and is monitored remotely by a physical therapist to adjust treatment based on the user's progress.

- An app that helps with anxiety through patient-guided mindfulness training sessions and uses self-reported data to suggest other education or training sessions.

Prescription Digital Therapeutics

Prescription digital therapeutics (PDTs) are similar to DTx products with some key differences. For example:

▶ Manufacturers have submitted clinical efficacy and safety data to the Federal Drug Administration (FDA) to gain authorization as a prescription agent.

▶ FDA makes the determination if PDTs are safe and effective through review of clinical trials.

▶ PDTs are prescribed to a patient and cannot be accessed without clinical oversight. PDTs directly treat, prevent or improve the management of disease.

▶ Patient PDT usage data may enable adjustments in their overall treatment plan.

▶ PDTs are not yet commonly a covered benefit because a majority of payer plans do not have a process to evaluate their efficacy.

PDTs are similar to clinical treatments that employers currently offer in their benefit plans. However, they can be utilized virtually and after being prescribed by a provider. The patient can engage the treatment on their own time, enable the provider to remotely monitor their use of the PDT or response to treatment, and make any necessary adjustments to the treatment plan.

How PDTs May Improve Care

Patients recommended for mental health therapy often do not follow through on recommended treatment plans. They may have difficulty finding the right therapist, going to sessions, adhering to the right medication, and applying recommendations. In these cases, a PDT delivered through a prescribed app may make participation and adherence easier.

The FDA Authorization Process for PDTs

The FDA evaluation process for PDTs, as seen in Figure 2, requires clinical research showing the PDT is efficacious and safe for patients. This process is similar to processes for other medications the FDA evaluates.

FDA authorization allows a PDT to be prescribed just like other approved treatments. PDTs follow the same patient data protection and privacy rules as medical devices.

FIGURE 2: FDA Authorization Process for PDTs

Research involves risk evaluation, safety testing, an analysis of risks vs benefits, using clinical experts to align with clinical efficacy utilization.

Data collected from products is continually assessed and evaluated to modify or address safety or efficacy improvements.

RESEARCH → FDA PREP → FDA SUBMISSION → FDA REVIEW → FDA DECISION → POST MONITORING

2-Pathways for Authorization

① **510K Clearance:** Provides clinical data on efficacy and must be the same as to another marketed device

② **De Novo:** Provides pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable assurance of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device

Health Apps, DTx, and PDTs Compared

DTx and PDTs are relatively new and can be confused with health apps that are available for patients to download through their smartphones. Employers, in particular, have been exposed to many new health apps and services over the course of the COVID-19 pandemic and may find differentiating the technologies difficult.

TABLE 1: Health Apps, DTx, and PDTs Compared

	MOBILE HEALTH APP	DIGITAL THERAPEUTICS	PRESCRIPTION DIGITAL THERAPEUTICS
Who makes them?	▶ Almost anybody	▶ Health technology companies	▶ Health technology companies

What are their intended purposes?	▶ Focused on health and wellness
	▶ Tracks health functions and data
	▶ Provides support for general wellness issues
	▶ Examples:
	  • Sleep tracking
	  • Weight loss tracking
	  • Medication reminder
	  • Mindfulness
	  • Exercise training
	  • Blood pressure tracking
		▶ Offer some evidence-based techniques to help users cope with a condition or disease but have not been evaluated to treat or modify disease (i.e., diabetes management, musculoskeletal, sleep disturbances, mood, mental wellbeing, etc.)	▶ Treats or manages a specific disease or medical condition, for example:
			  • Low-back pain
			  • PTSD
			  • Substance use disorder
			  • Migraines
			  • Insomnia
			  • ADHD
			  • Mental health

How do they work?	▶ Provide patient education or health coaching ▶ May have a personalized algorithm (e.g., sleep hygiene) ▶ Data may be shared by a patient with a provider	▶ May provide a digitized form of treatment (e.g., therapy) ▶ DTx may function on its own or as part of a health service combining an app and a care team (e.g., therapist, nurse, provider)	▶ Delivers disease-specific, evidence-based treatment by prescription only ▶ Provides a novel intervention using proprietary technology (e.g., as shown in Table 3) ▶ Data from treatment is reported back to a provider
Who can use them?	▶ Anyone	▶ Patients who may have access via their health plan or employer benefit program	▶ Prescribed by a patient's health provider
How do you get them?	▶ Purchased directly from an app store or provided through a third party (e.g., employer, insurance)	▶ Membership access code through a third party (e.g., employer, insurance)	▶ Prescription required for a PDT, the pharmacy then "dispenses" the PDT to the patient ▶ Patient activates the PDT and follows the treatment plan prescribed by their provider

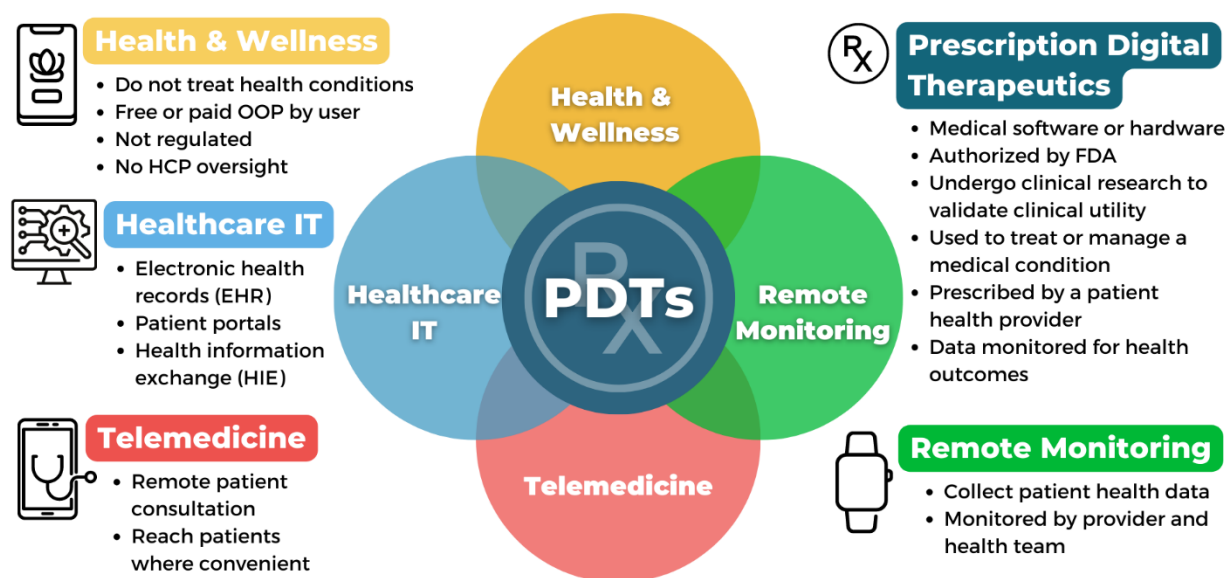|	MOBILE HEALTH APP	DIGITAL THERAPEUTICS	PRESCRIPTION DIGITAL THERAPEUTICS
Do they have evidence for use?	▶ Not required to have evidence of clinical outcome ▶ Optional to have conducted clinical research that is subject to outside review on clinical utility	▶ Research to demonstrate efficacy is optional	▶ FDA-authorized Software as a Medical Device (SaMD), evaluated and clinically validated for safety and efficacy
Are they regulated?	▶ Not regulated unless the FDA or FTC is alerted to improper use	▶ May be regulated depending on the technology (for instance, a wearable device as part of a DTx could be regulated)	▶ Regulated by the FDA as a Software as a Medical Device (SaMD)
Does the FDA evaluate them?	▶ No	▶ Some components of a DTx may be evaluated, depending on the acuity of condition addressed	▶ Yes, they are authorized/ cleared by the FDA, usually through a *de novo* or 510(K) clearance pathway
Do they have technical or clinical support systems in place?	▶ Individual apps may vary on support they offer	▶ Individual DTx vary on support they may offer	▶ Yes, either through company technical support, pharmacy, or clinical team
Who pays for them?	▶ Users may elect to purchase and use a health app on their own through the app store ▶ Users may get access through their health insurance that is covered on a Per member per month (PMPM) fee	▶ User may get access through self-pay or through health plan	▶ Employers may elect to cover a PDT on terms set forth in the benefit plan ▶ Cost is determined between health plan, PBM, or health exchange, similar to how current medications are covered

The Value of Prescription Digital Therapies

Employers, realizing PDTs have the potential to expand access to care for covered plan members and possibly reduce costs, are looking to add digital health technologies and prescription digital therapies in their health benefits.

Employers understand several value-add benefits of PDTs:

▶ **Treatment & Disease Management:** PDTs may complement a patient's current treatment and management of chronic conditions remote from traditional care settings which may enhance patient engagement for improved treatment outcomes.

▶ **Increased Patient Adherence & Engagement:** Patients can be set up for treatment from the convenience of their home without missing any appointments. PDTs can prompt reminder notifications to ensure adherence to dosing guidelines and create an online community of patients and families to provide ongoing support during and after treatment.

▶ **Improved Care Delivery:** Medical professionals can deliver patient-centric care through interactive and customized therapy delivered at the patient's convenience. The healthcare provider may have access to data from the PDT to see how the patient is engaging and fulfilling therapy and can elect to intervene if necessary.

▶ **Reduced Logistical Hurdles:** Patients can get care services where they want it and when they want it.

▶ **Reduced Gaps in Care:** PDTs target conditions that are poorly addressed by the healthcare system today, such as chronic diseases, mental health, and neurological disorders.

▶ **Expanded Patient Care Tools:** Patients have access to increased care options and may elect to use a PDT over other traditional treatment if it better fits their ability to fulfill the treatment. For example, if a patient cannot for logistical reasons attend in-person therapy, a PDT may allow for remote therapy that is more convenient.

FIGURE 3: Why Cover PDTs?

WHERE DO PDTS FIT INTO HEALTHCARE?

Health & Wellness
- Do not treat health conditions
- Free or paid OOP by user
- Not regulated
- No HCP oversight

Healthcare IT
- Electronic health records (EHR)
- Patient portals
- Health information exchange (HIE)

Telemedicine
- Remote patient consultation
- Reach patients where convenient

Prescription Digital Therapeutics
- Medical software or hardware
- Authorized by FDA
- Undergo clinical research to validate clinical utility
- Used to treat or manage a medical condition
- Prescribed by a patient health provider
- Data monitored for health outcomes

Remote Monitoring
- Collect patient health data
- Monitored by provider and health team

Note: HCP = Health Care Provider

- ▶ **More Non-Pharmacological Options:**
  PDTs may offer treatment options without the side effects of medications.

- ▶ **Increased Data to Assess Outcomes:**
  Data from PDTs may be useful to health plans and employers as they assess treatment protocols.

The Diseases PDTs Can Treat

There are 13 PDTs are authorized by the FDA and available. These are listed in Table 3.

Currently, PDTs treat:

- ▶ Central nervous system and psychiatric conditions (e.g., pain, depression, SUD, PTSD)
- ▶ Gastrointestinal conditions (e.g., irritable bowel syndrome, Crohn's disease)
- ▶ Women's health (e.g., incontinence)
- ▶ Ophthalmology
- ▶ ADHD

TABLE 3: FDA-Cleared PDTs as of Q3 2023

PRODUCT	MANUFACTURER	DESCRIPTION	INDICATION
AspyreRx	Better Therapeutics	CBT (Cognitive Behavioral Therapy) program to help improve diabetes management and lead to A1c reduction	Diabetes
CureSight	NovaSight	Eye-tracking technology to help the user strengthen vision	Amblyopia
EndeavorRx	Akili Interactive	Adaptive-algorithm game platform to help children 8–12 years of age train attention function	ADHD
Freespira	Freespira	Provides training for individuals to manage PTSD through breathing exercises with a CO_2 sensor to track progress	PTSD
InTandem	MedRhythm Inc	Rhythmic auditory stimulation (RAS), the mechanism of auditory-motor entrainment through music to help improve ambulation in adults post-stroke	Post-stroke ambulation difficulty
Leva	Renovia	Pelvic floor training system using a sensor wand to track Kegel muscle movement	Urinary incontinence
Luminopia One	Luminopia	Uses head-mounted display to improve visual acuity in patients 4-7 years of age	Amblyopia
Parallel	Mahana Therapeutics	3-month CBT treatment	Irritable bowel syndrome
Nerivio	Theranica Bio-Electronics Ltd	Wireless remote electromodulation device that attaches to the upper arm to help treat migraines in those 12 years or older.	Migraines with or without aura
Nightware	Nightware	Uses wearable biometric sensors (like an Apple Smartwatch) to track sleep and determine when nightmares are occurring, then delivers vibrations to interrupt nightmares without waking the patient	PTSD nightmares

PRODUCT	MANUFACTURER	DESCRIPTION	INDICATION
RelievVRx	AppliedVR	Home-based VR system for adjunctive treatment using patient-guided pain management techniques	Chronic low-back pain
Regulora	metaMe Health	Uses gut directed hypnotherapy to help the patient manage pain	Irritable bowel syndrome pain
Stanza	Swing Therapeutics	Provides Acceptance and Commitment Therapy (ACT), a type of CBT, through an app to help psychological symptoms (e.g., depression, anxiety) affiliated with fibromyalgia	Fibromyalgia Psychological symptoms

While this current class of PDTs focuses primarily on psychological aspects of diseases, there is a growing effort to address other conditions. These include PDTs for oncology to help with general supportive measures; pulmonary conditions; genitourinary conditions such as urinary incontinence; women's health issues such as pregnancy, postpartum care, and menopause; and cardiometabolic diseases like diabetes and weight management. The subsequent section lists current PDTs undergoing research.

Current PDT Pipeline

There are more than 20 PDTs currently in late-stage development with more coming to market in the next five years. Several are available under emergency use authorization (EUA) from the FDA due to the COVID-19 pandemic and may be cleared depending on FDA actions in 2023. While there is no central database of PDTs under development, a sample is in Table 4.

TABLE 4: PDTs in Development

NAME	MANUFACTURER	INDICATION
Modia*	Orexo/GAIA Therapeutics	Opioid use disorder (OUD)
Ensemble*	Happify Health/Twill	Anxiety or depression
Attune*	Bluenote Therapeutics	Anxiety in cancer
Skylar's Run*	ATENTIV Health	ADHD
Deprexis*	Orexo/GAIA Therapeutics	Depression
Vorvida*	Orexo/GAIA Therapeutics	Alcohol use disorder
Cerena*	Bluenote Therapeutics	Wellbeing
SparkRx*	Limbix	Depression
DTHR-ALZ	Dthera Sciences	Alzheimer's
Autism Therapeutic	Cognoa	Autism
CT-152	Click Therapeutics/Otsuka	Major depressive disorder
BiovitalsHF	Biofourmis	Heart failure

NAME	MANUFACTURER	INDICATION
Tempo	Swing Therapeutics	Fibromyalgia
BNT-200	Bluenote Therapeutics	Anxiety in AML
WB001	Woebot Health	Depression
MR-001	MedRhythms	Stroke
TLC-001	Constant Therapy	Stroke
CT-155	Click Therapeutics/Boehringer Ingelheim	Cognitive impairment associated with schizophrenia
AKL-T02	Akili Interactive/Shionogi	Autism
AKL-T04	Akili Interactive	Major depressive disorder
FemmeRhythm	Biofourmis/Chugai	Endometriosis
CT-132	Click Therapeutics	Episodic migraines

*Available under COVID-19 Emergency Use Authorization until November 2023

How Does a PDT Work?

PDTs are intended to help manage or treat a disease. They may follow a digitized version of current care processes, like using CBT through an app that provides automatous treatment under a provider's oversight. Other PDTs may use digital health technologies to provide treatment, such as through wearable sensors that can detect a symptom which the device then treats.

The process to prescribe treatment with a PDT is similar to how a provider would select a standard medication or therapy for a patient to use, as seen in the following figure. A key difference is the PDT gives feedback to the provider, who can adjust treatment as needed to achieve the desired clinical outcome.

FIGURE 3: PDT Process
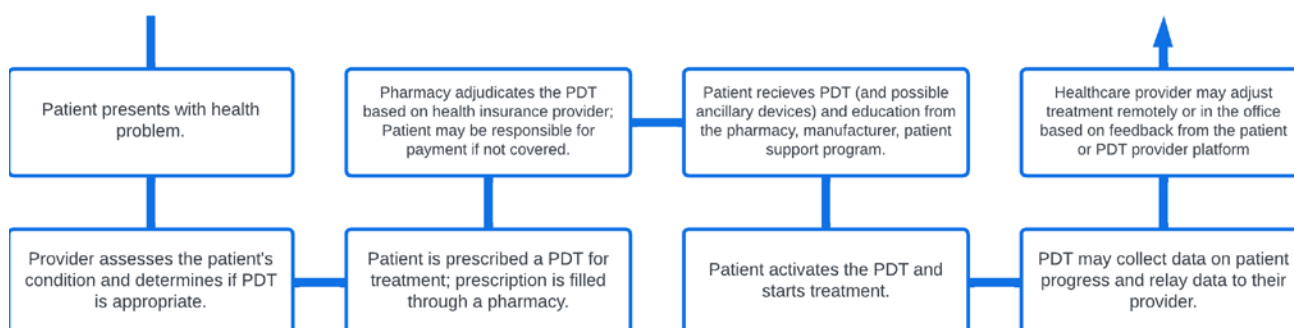
Part 2: How Employers Can Evaluate and Implement a PDT Strategy

With the development of digital health options, PDTs are becoming a new area employers need to consider in their health benefit plans. This section helps employers:

▶ Use health data to determine PDT needs

▶ Use PDTs to expand health equity and access

▶ Structure PDTs into the benefit plan

Evaluate Employee Health Data to Determine PDT Coverage

Health data will suggest whether and how PDT coverage should be considered. The following four steps can be taken by employers to determine how to create access for plan members (as shown in illustration below):

1. **Why does adding PDT coverage address employee needs?** The treatment provided by PDTs offers employers the potential to help plan members prevent, manage and treat physical, mental, and behavioral conditions. In reviewing claims, employers can determine PDT coverage areas, such as smoking cessation, weight loss, mental health services, musculoskeletal issues, or chronic pain management.
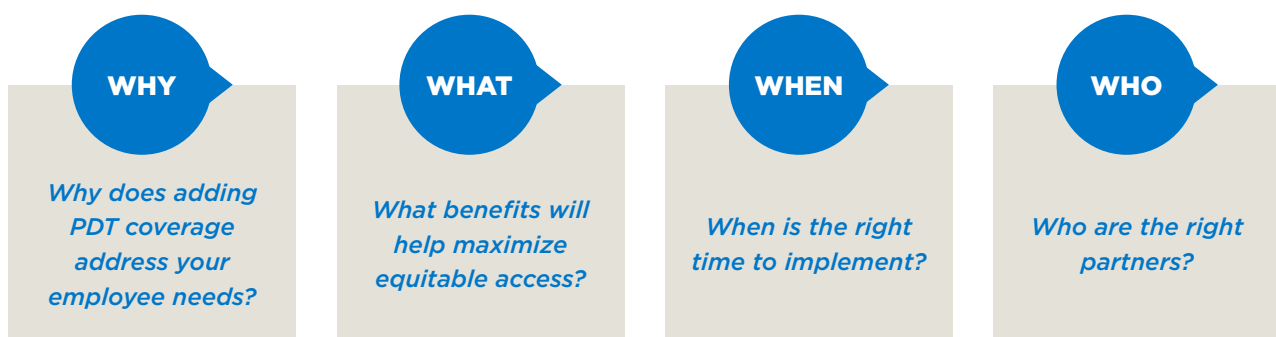
2. **What benefits will help maximize equitable access?** Reviewing employee absenteeism, presenteeism and retention also gives clues about a PDT strategy. PDTs may lead to higher utilization, adherence and health management, which would reduce absenteeism, increase productivity, and have the added benefit of providing more equitable access.

3. **When is the right time to implement?** PDTs may be added to the benefit plan at any time or at the beginning of the plan year. If an employer identifies an accelerating health usage trend that can be better addressed by a PDT, the employer may not want to wait until the plan year anniversary.

4. **Who are the right partners?** Once an employer decides to offer PDTs, the next step is to identify the best reimbursement and implementation strategy. The coverage pathway can be through the employers' medical plan or the pharmacy plan. In determining the right partner, it is important to ask three questions to guide decision making: (1) What partner will optimize

FIGURE 4: The 4-Ws Decision Tree: Creating Value & Access for Your Plan Members

WHY

Why does adding PDT coverage address your employee needs?

WHAT

What benefits will help maximize equitable access?

WHEN

When is the right time to implement?

WHO

Who are the right partners?

adoption and access to the PDT for a specific population? (2) Which partner has an effective communication strategy to increase patient awareness and utilization? (3) Which partner will best track outcomes and effectiveness? Ideal PDT partners help promote access and adoption, have communication strategies that target diverse populations, and can best demonstrate positive adoption and effectiveness.

Benefit Coverage of PDTs in Pharmacy vs. Medical

As yet, there is no standard benefit coverage model for PDTs in the U.S. Other countries, such as Germany, the UK, and Korea, have adopted different models for PDT coverage that favor a national model for select conditions. In comparison, in the U.S, PDTs either fall under medical or pharmacy benefit coverage. However, there is a growing preference for pharmacy coverage as the default for PDTs.

Medical Coverage

Under medical coverage, PDTs are treated as a medical service where PDTs are an extension of clinical care targeting a specific condition. Inclusion under the medical benefit allows integration into a disease management program which could be accompanied by a case manager to assist with providing patient support. In this scenario:

▶ The PDT is prescribed by a clinician who then uses a variety of Current Procedural Terminology (CPT) medical codes to get reimbursement from payers.

▶ The model involves using remote patient or therapeutic monitoring codes to increase overall compensation.

▶ A portion of the reimbursement is shared with the PDT company.

Pharmacy Coverage

Under pharmacy coverage, PDTs are treated similarly to a medication, and are billed in accordance with current practices related to a medication pathway. This coverage pathways provides the opportunity to leverage pre-existing controls built into the pharmacy benefit program such as formulary and utilization management as well as cost controls and reporting.

▶ The provider prescribes the PDT product. The prescription is sent to a pharmacy that verifies the prescription, submits a claim to the insurer, then transmits message with access code to the patient or dispenses the product to the patient.

▶ A portion of the reimbursement may be shared with the PDT company.

As of now, since they are prescribed, PDTs align to pharmacy coverage with traditional claims adjudication processes. However, this approach raises new concerns, since existing PBM reimbursement pathways are not designed to accommodate the administration of a therapeutic intervention being delivered by software.

Leveraging PDTs to Address Access & Equity Issues

PDTs have many treatment advantages, including improving health access and health equity. Health access is improved by care that can be delivered outside a clinical setting and in the convenience of the patient's home and at a convenient time. Health equity is improved because PDTs can be adjusted to meet the economic, social and other needs of diverse populations.

Access and equity are directly tied to treatment compliance, health engagement and positive outcomes.

Why PDTs?

PDTs may be easier for the patient to administer, boosting compliance. PDT costs can be lower than current pharmaceutical treatments, especially if PDTs achieve treatment objectives faster than current treatments.

Part 3: The Employer's Role in Promoting PDTs

PDTs are relatively new. Many insurers and PBMs are hesitant to reimburse for them. Some health plans have promised coverage, but employers, for now, are looking for ways to integrate PDTs into health plans. Here is a look at the current state and actions that employers can take.

Current Insurance and PBM PDT Reimbursement

Reimbursement for PDTs will vary depending on the insurance plan's understanding of PDTs and willingness to cover them. Currently, several health plans and PBMs have investigated the coverage of PDTs and have issued statements regarding how they will cover and reimburse PDTs.

Health Plans Coverage Decisions*

▶ **Highmark Blue Cross Blue Shield:** Covers Nightware, Mahana IBS, RelieVRx, EndeavorRx, Luminopia One (covered through medical)

▶ **Cigna:** Limited coverage of digital health products through Evernorth Digital Health Formulary (no covered PDTs)

▶ **Elevance Health (previously Anthem):** Allows coverage when medically necessary but all PDTs are considered "Not Medically Necessary"

▶ **Paramount:** PDTs are considered experimental/investigational due to lack of evidence

▶ **UnitedHealthcare:** Not medically necessary and unproven

▶ **Molina:** DTx/PDTs not medically necessary due to lack of evidence

▶ **Humana:** DTx/PDTs are excluded from coverage

▶ **Aetna:** Considers FDA approved apps for contraception to be medically necessary per federal preventative care mandates when prescribed. This covers Natural Cycles. All other PDTs are considered experimental or investigational.

PBM Coverage Decisions*

▶ **Express Scripts:** Limited coverage of digital health products through Evernorth Digital Health Formulary (no PDTs on formulary, but PDTs have been covered for employer clients upon request)

▶ **Ingenio Rx:** No mention of PDTs covered under formulary

▶ **Optum Rx:** No PDTs on formulary, but covered for employers upon request

▶ **CVS Health:** No PDTs on formulary, but covered for employers upon request

▶ **Elixir:** No mention of coverage at this time

This is not a complete list of coverage decisions as of 1Q23.

As payers, **employers play an instrumental role in driving PDT product adoption** and growth of PDT products as many insurance companies to date have shown little interest in moving these products into mainstream. Highmark's Policy Position (see sidebar) is a prime example of how others can address medical necessity with guidance provided by the USFDA. To start initiating coverage, employers need to integrate the request for coverage into their benefit plan design.

Insider Look
Highmark Blue Cross Blue Shield's PDT Policy Position as of August 1, 2022

This Insider Look is an example other administrators might use to cover PDTs. Highmark BCBS is supporting PDTs that meet their policy requirements.

USFDA approved digital therapeutics prescribed by a licensed health care professional for therapeutic intervention may be considered medically necessary when the following criteria are met:

▶ The digital therapeutic is used within its approved indications; **and**

▶ The therapeutic is prescribed by a provider for whom the condition is within the scope of their practice. Eligible prescribers include medical doctors, psychologists, licensed mental health social workers, licensed professional mental health counselors, licensed marriage and family therapists, and advanced practice providers (nurse practitioners or physician assistants) working in the relevant field; **and**

▶ The member must be at least 18 years of age, unless the digital therapeutic is specifically designed and approved for pediatric use and the member is within the age range for which the digital therapeutic is recommended; **and**

▶ The digital therapeutic is only used for outpatient care; **and**

▶ The member must be able to reasonably interact with the software in order to receive a prescription for any digital therapeutic treatment or intervention.

Digital therapeutics not meeting the criteria as indicated in this policy are considered not medically necessary.

How Employers Can Promote PDTs

Below is a list of points employers can use in addressing the health insurance industry's hesitancy.

INDUSTRY STATEMENTS	COUNTERPOINT ARGUMENT
Allows coverage when medically necessary but all PDTs are considered "not medically necessary"	The medical necessity criteria show that many PDTs indeed meet the criteria Continue to request a review of emerging data as PDTs gain real-world evidence
PDTs are considered experimental/ investigational due to lack of evidence	Similar to pharmaceutical drugs, PDTs conduct randomized clinical trials, offer real-world evidence, and are FDA authorized
DTx/PDTs are excluded from coverage due to lack of demand by physicians	Request physician education on PDTs be included
No real-world evidence that these therapies work	The FDA has authorized many PDTs similar to standard pharmaceuticals

The other areas employers say have hindered adoption and uptake with PDTs are:

▶ **Contracting with PDT companies.** To implement PDT coverage, employers may have to contract directly with PDT companies when the health plan and/or PBM does not manage the contracting process.

▶ **Provider adoption and education.** Provider education has not been sufficient to lead to discussions with patients. Because PDTs do not have widespread coverage yet, providers are hesitant to write prescriptions for a patient that may not have coverage available.

▶ **Patient awareness.** As of now, communications about PDTs are not consistent in the market. Employers have an opportunity to ensure this type of education is available to improve awareness.

Promising Strategies that Impact Benefit Design Decisions

Coverage for PDTs will evolve over time as further products come to market, regulators establish more guidance, and coverage expansion occurs by insurance companies and PBMs. In the meantime, here is a process to keep employers current:

Employer Checklist to Evaluate

PDT ACTION ITEM	PLAYBOOK SECTION	CHECKLIST
Identify what digital solutions are currently being offered, and if they are a general health app, DTx product, or a PDT. Consider the following: ▶ Is a singular option being offered? Or is there an overlap of options with multiple products? ▶ What is the desired outcome and is it being met?	Table comparing apps and DTx and PDTs	
Assess the needs of the employee population to determine which PDT company addresses the greatest need. Consider the following: ▶ Is the PDT a good fit for your population? ▶ Can population health improvement be monitored? ▶ Is other therapy needed, and how will the plan monitor the comprehensiveness of treatment?	Section on the 4Ws	
Create a process to add new PDTs to your formulary as they are released into the market. Consider the following: ▶ Cover PDTs at the drug class/therapy level as they are approved. ▶ Establish timeline and responsibility with partners to establish formulary development with technological changes. ▶ Obtain cost information from the manufacturer to monitor additional service fees.	4Ws and section on PDTs approved and upcoming	
Select a PBM/health plan that are willing to manage individual PDT company contracts on your behalf.	4Ws and section 3	
Ensure your PBM, health plan, EAP, healthcare navigation tool, and other vendors integrate PDT coverage and availability into their existing communication strategy as a potential low-cost alternative therapy.	4Ws and section 3	
Validate how reporting of PDT utilization, denials, and therapy outcomes is shared, what information is provided, and the frequency of the reporting.	4Ws and section 3	
Monitor user engagement with PDTs and if continuation or contract changes are needed based on outcomes.	4Ws and section 3	
Work with vendors to educate members, providers, disease management programs and other related entities that PDTs are a covered option under their plan benefit.	Section on the 4Ws	

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10130 Mallard Creek Rd, Suite 300 · Charlotte, NC 28262

704-944-3135 · ncbch.net

in **www.linkedin.com/company/north-carolina-business-coalition-on-health**

NCBCH
NC BUSINESS COALITION ON HEALTH

National Alliance of Healthcare Purchaser Coalitions
1015 18th Street, NW, Suite 705
Washington, DC 20036
(202) 775-9300 (phone)
(202) 775-1569 (fax)

nationalalliancehealth.org
twitter.com/ntlalliancehlth
https://www.linkedin.com/company/national-alliance/

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