Pharmacy Solutions

Navigating the future of digital therapeutics

Considerations for Pharmacy Benefit Managers

gainwell

Contents

A new era of healthcare delivery: digital therapeutics

Historically, healthcare has been delivered through direct contact with a healthcare provider: physician office visits, physician-administered drugs and various outpatient and inpatient medical procedures. Healthcare products, such as self-administered drugs and durable medical equipment, have always been physically tangible. However, in recent years, healthcare delivery has expanded rapidly into the digital space, with the COVID-19 pandemic accelerating the drive to digital.

Digital health is a broad term that includes mobile health (mHealth), health information technology (HIT), telehealth, prescription drug/digital device combination products, digital therapeutics and wearable devices such as fitness trackers.[1] Digital health technology can gather large amounts of patient data to support disease management and help improve patient outcomes in a variety of disease states. Additionally, digital health technologies provide opportunities to improve access, reduce costs and produce personalized medicine for patients.

The Digital Therapeutic Alliance, a group founded by industry leaders and stakeholders in 2017, classifies digital therapeutics (DTx) as a subset of digital health products and defines them as software designed to deliver evidence-based therapeutic interventions to prevent, manage or treat a medical disorder or disease.[2] These products may deliver their clinical outcomes alone or in combination with other standard of care treatments including medication, devices or other interventions.[2]

DTx are frequently evaluated for approval by the U.S. Food and Drug Administration (FDA) for clinical efficacy and safety under similar pathways as medical devices and pharmaceuticals; however, clinical trial data requirements are typically not as rigorous.

Both prescription digital therapeutics (PDTs) and non-prescription DTx have been approved by the FDA. The first PDT for disease treatment approved by the FDA was Pear Therapeutics' reSET for the treatment of substance use disorder in 2017.[3] Since then, approximately 40 digital therapeutics have been FDA-approved.[4] The market value of digital therapeutics in 2022 is estimated at $5.09 billion with a 2030 revenue forecast of $32.51 billion.[5] In response to the accelerated growth in the digital therapeutics market, the FDA introduced a unique pathway to support more efficient and scalable regulatory oversight of these products.

Digital therapeutic software ranges from mobile applications with cognitive behavioral therapy (CBT) services to immersive action video game experiences.

PDTs have a defined treatment duration and treat a variety of chronic conditions, including but not limited to insomnia, substance use disorder, abdominal pain associated with irritable bowel syndrome (IBS) and depression. Digital therapeutic software ranges from mobile applications with CBT services to immersive action video game experiences. A list of current FDA-approved prescription digital therapeutics and their associated treated chronic conditions are listed in Table 1.

PDTs in development are aimed at treating symptoms of autism spectrum disorder, schizophrenia and depressive symptoms in people with multiple sclerosis. The pipeline also includes “generic” PDTs that are similar to recently FDA-approved PDTs or advancements to existing products (Table 2).

Table 1. FDA-approved PDTs*

Company	Product (authorization type)	Treated Disease State	Treatment Duration	Treatment Modality
Pear Therapeutics	reSET® (De Novo) € reSET-O® (510(k)) ¥	Substance use disorder (SUD) Opioid use disorder (OUD)	12 weeks 12 weeks	Mobile application
Pear Therapeutics	Somryst ® (510(k)) ¥	Chronic insomnia	9 weeks	Mobile application
Alkili	EndeavorRX (De Novo) €	Attention deficit hyperactivity disorder (ADHD)	4 weeks ±	Mobile application
Mahana Therapeutics	Mahana for IBS (De Novo) €	Abdominal pain caused by irritable bowel syndrome (IBS)	3 months	Mobile application
metaMe Health Indegene	Regulora (510(k)) ¥	Irritable bowel syndrome (IBS)	12 weeks	Mobile application
Luminopia	Luminopia One (De Novo) €	Amblyopia	12 weeks ₸	Virtual reality (VR) headset
NightWare	NightWare (De Novo) €	Post-traumatic stress disorder (PTSD)	30 days ≠	AppleWatch application
AppliedVR	RelieVRx (De Novo) €	Low back pain	8 weeks	Virtual reality (VR) headset

* This list is not meant to be exhaustive. Some FDA-approved PDTs may be excluded.

€ Classifies novel medical devices based on general or special controls that provide reasonable assurance of safety and efficacy, but for which there's no available predicate or similar device.

¥ Premarket submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent to, a legally marketed device.

± EndeavorRX was studied in 5 clinical trials in which improvement in ADHD symptoms were assessed after a four-week treatment period.

₸ Luminopia was evaluated in a phase 3 clinical trial with primary endpoints evaluated at week 12 of therapy.

≠ Multiple clinical trials evaluated primary efficacy endpoints at day 30 of use.

Table 2. Pipeline PDTs*[6]

Company	Product Line	Treated Disease State ±
Happify Health	Ensemble (investigational) +	Major depressive disorder (MDD), generalized anxiety disorder (GAD)
Click Therapeutics; Boehringer Ingelheim	CT-155	Cognitive impairment associated with schizophrenia (CIAS)
Akili Interactive; Shionogi	AKL-T02	Autism spectrum disorder
Cognoa	Autism therapeutic	Autism spectrum disorder
Click Therapeutics; Otsuka	CT-152	Major depressive disorder (MDD)
Akili Interactive	AKL-T03	Major depressive disorder (MDD)
Pear Therapeutics	Pear-004	Schizophrenia
Pear Therapeutics	Pear-006	Depressive symptoms in multiple sclerosis
Orexo	Modia	Opioid dependence
Biofourmis; Chugai	FemmeRhythm	Endometriosis
Swing Therapeutics	Tempo	Fibromyalgia
MedRhythms	MR-001	Motor deficits post-ischemic stroke

***** This list is not meant to be exhaustive. Some pipeline PDTs may be excluded. **±** Treatment duration for therapies listed are TBD. **+** Investigational product created under the Enforcement Policy for Digital Health Devices for Treating Psychiatric Disorders. During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

Keeping pace with evolving regulations

The regulatory pathway for medical devices was established in section 513 of the Federal Food, Drug and Cosmetic Act. Devices are classified in three categories based on the level of control required to ensure safety and efficacy (Class I, II and III).[7] Regulatory pathways include premarket notification 510(k), premarket approval (PMA) and de novo (Table 3). PMA is used frequently in the evaluation of Class III medical devices to determine safety and efficacy by reviewing scientific evidence of their benefit to a large portion of the target population. In order to market a Class I, II or III medical device in which a PMA is not required for human use in the United States, a 510(k) must be submitted to the FDA unless a 510(k) exemption has been issued. A 510(k) requires evidence of “substantial equivalence” to an already marketed device. The De Novo pathway is utilized to market a device of low to moderate risk that does not have a “predicate” or similar device already marketed.[7]

Table 3. Current FDA approval pathways for digital therapeutics

Pathway	Description	Determination	Details
510(k) [1]	Premarket submission made to FDA to demonstrate the device to be marketed is as safe and effective as a legally marketed device	Clears device	• Submitters must demonstrate device is substantially equivalent to a predicate (approved through De Novo) or existing device • Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalence claims • Clinical trial data not required
Premarket approval (PMA) [2]	Scientific and regulatory review necessary for a Class III device or device found not equivalent to a Class I or II predicate through 510(k) process	Approves device	Involved process to determine reasonable safety and efficacy of device and requires scientific evidence that: • The possible benefits outweigh the possible risks • The device will significantly help a large portion of the target population
de novo [3]	Classifies novel medical devices based on general or special controls that provide reasonable assurance of safety and efficacy, but for which there's no available predicate or similar device	Grants marketing rights	• Clinical trial data required • Testing to demonstrate a reasonable assurance of safety and effectiveness required

≠ Clinical trial data required not as rigorous as data required for pharmaceutical approval

1. Premarket Submissions: Selecting and Preparing the Correct Submission-Premarket Notification 510(k). U.S. Food & Drug Administration. March 13, 2020. Accessed May 22, 2022. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/premarket-notification-510k
2. The Device Development Process-Step 3: Pathway to Approval. U.S. Food & Drug Administration. February 9, 2018. Accessed May 24, 2022. https://www.fda.gov/patients/device-development-process/step-3-pathway-approval
3. Premarket Submissions: Selecting and Preparing the Correct Submission-de novo Classification Request. US Food & Drug Administration. November 29, 2021. Accessed May 22,2022. https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/de-novo-classification-request

Regulatory review of medical devices does not always translate to appropriate review of digital therapeutics. Key components needed for evaluation of DTx are excluded under traditional pathways due to the unique software offerings and risks associated with digital therapeutic use. In 2017, the FDA published the Digital Health Innovation Action Plan, which provided details for digital health developers on certification requirements, guidance on modernizing FDA policies and increasing staff with digital health expertise within the FDA.

In September 2020, the FDA announced the launch of a new unit within the Center for Devices and Radiological Health (CDRH) called the Digital Health Center of Excellence (DHCoE), which is intended to provide regulatory advice and support to the review of digital health technology.[8] Of note, DHCoE is not responsible for making marketing authorization decisions. The DHCoE provides a range of services for different stakeholders including patients, developers, providers, industry, payers and other government agencies. DHCoE aims to "[empower] stakeholders through fostering responsible and high-quality innovation, connecting stakeholders by facilitating partnership, sharing knowledge to increase awareness and understanding, and innovating regulatory approaches."[8]

Digital Health Centers of Excellence's key functional areas

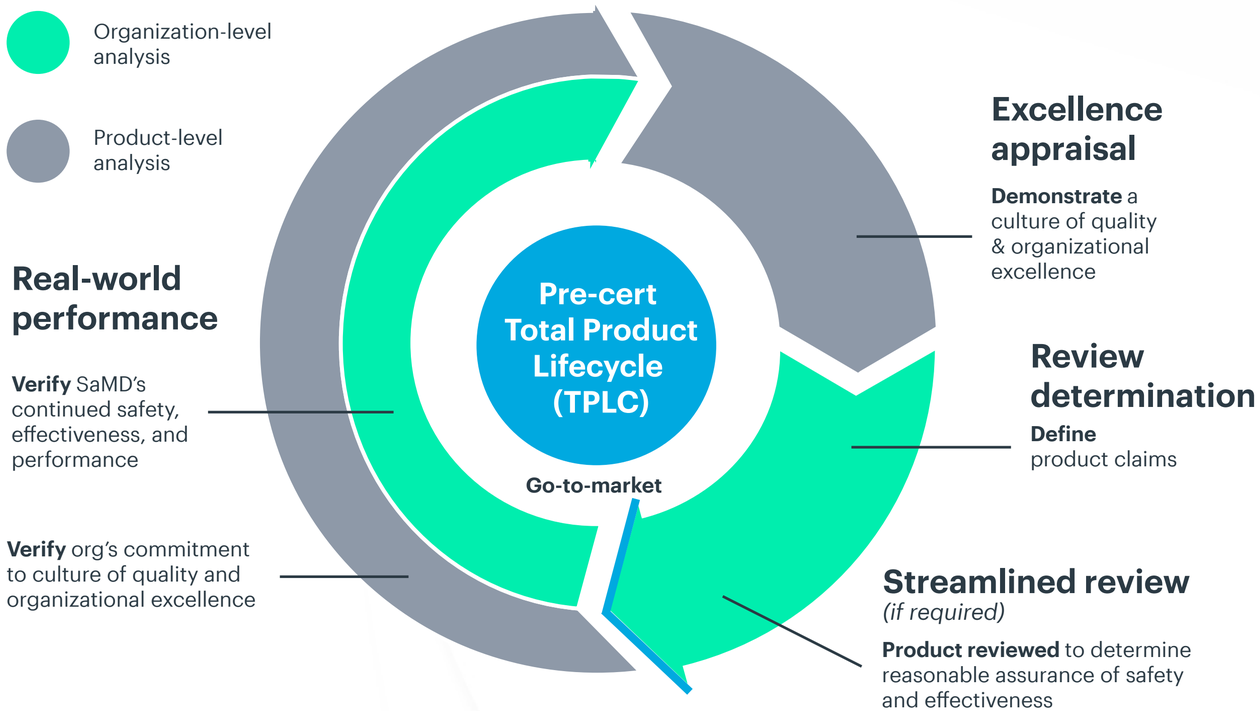
- Empowering stakeholders
- Connecting stakeholders
- Sharing knowledge
- Innovating regulatory approaches

The Digital Health Innovation Action Plan also provided a framework for the Pre-cert pilot program that aims to shift the FDA approval process for digital therapies to the developer rather than the product itself. The program is meant to "inform the development of a future regulatory model that will provide more streamlined and efficient regulatory oversight of software-based medical devices."[9] Key components of the Pre-cert process include an excellence appraisal, streamlined review, review determination and real-world performance (Figure 1). Software developers that receive precertification from the FDA are intended to "continue to meet the same safety and effectiveness standard that the agency expects for products that have followed the traditional path to market."[9]

Companies chosen by the FDA to undergo the Pre-cert program in 2017 were selected based on size, record of quality and clinical focus. Nine out of 100 candidates are participating in the pilot program: Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Tidepool, Verily and Samsung.[9] A 2020 update provided progress in goals of the program and outlined next steps.

Figure 1. FDA Pre-cert pathway key components[9]

Proposed key components of a future Pre-cert program



In response to the COVID-19 pandemic and the increased prevalence of psychiatric/behavioral health diagnoses, the FDA issued a guidance in April 2020 regarding the review process of digital health products that treat psychiatric disorders, specifically those that administer computerized behavioral therapy and low-risk general wellness and digital health products for psychiatric conditions. The premarket notification (510(k)) requirement was waived to provide a simpler pathway for submission.[10] As a result, more products have been brought to market and more companies have become engaged in the creation, production and advancement of digital therapeutics. Happify Health's Ensemble is an investigational computerized behavioral therapy product for major depressive disorder (MDD) and generalized anxiety disorder (GAD) that was created under this guidance.

Navigating the complexities of DTx reimbursement

With the increasing provider and patient acceptance of digital therapeutics, reimbursement for these therapies has become a necessary but complicated topic for payers. Payer adoption has lagged considerably compared to the rapid development of DTx. The lack of coverage is fueled in part by uncertainty of clinical efficacy due to less rigorous FDA approval criteria than traditional drugs.[10] National medical associations and international health agencies, including the American Medical Association (AMA) and the World Health Organization (WHO), are attempting to develop a basis for evaluating PDTs.

Currently, there is no consensus on payment strategy and/or evaluation of PDTs among insurers and medical authorities.[11]

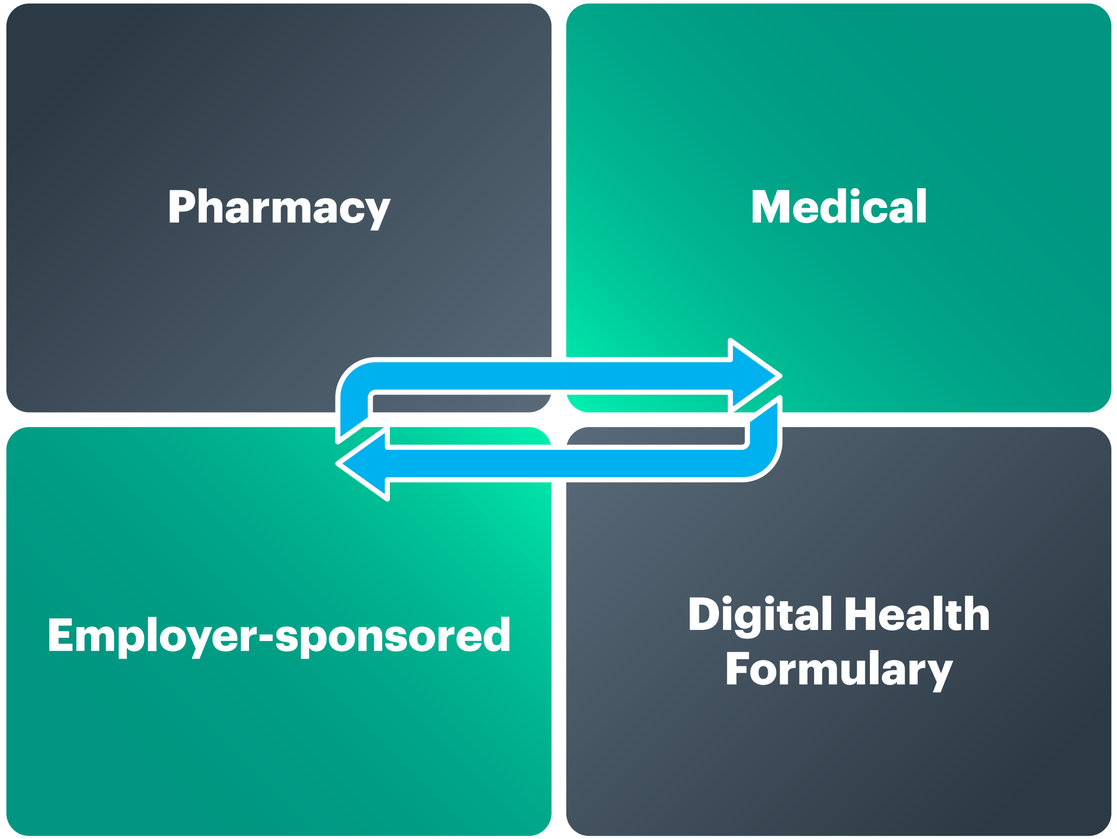
Payers have addressed the growth of DTx in varying methods of coverage and levels of internal review. The extremes range from the creation of a distinct DTx formulary with preferred and non-preferred agents to non-coverage of all DTx. Examples of current DTx coverage pathways and health plan billing practices have been compiled and listed in Figure 2 and Table 4, respectively.

With the increasing provider and patient acceptance of digital therapeutics, reimbursement for these therapies has become a necessary but complicated topic for payers.

Figure 2. DTx Benefit Types for Reimbursement[11]

Retail prescription product utilizing NDC, UPC and/or HCPCS numbers

Receive benefit directly from a wellness package offered as an employer-sponsored benefit



Fee-for-service as a procedure or physician-administered drug (PAD)

Separate digital health insurance benefit directly accessed by members

Table 4. Examples of current coverage types for PDTs*[10]

Company	Coverage Type	Details
Humana [1] (employer)	Employer-based benefit	• Humana recently partnered with Virta Health, a DTx for diabetes management, to benefit Humana's self-funded employer group members
EverNorth (a subsidiary of Express Scripts) [2] (PBM)	Digital health formulary	• Digital health formulary with preferred/non-preferred status • More than 15 digital solutions available on formulary clinically reviewed and evaluated by pharmacists, physician, user experience experts and health research doctorates
Premera Blue Cross Blue Shield [3] (PBM)	Not covered	• Medical necessity policy for PDTs • Separate criteria for PDTs that are considered investigational
Aetna [4] (PBM)	Not covered	• Policy statement listing PDTs as investigational due to insufficient evidence that supports their effectiveness

Company	Coverage Type	Details
Anthem [5] (PBM)	Not covered	• Medical necessity policy for PDTs
CVS Caremark/CVS Point Solutions Management [6] (vendor management)	NA	• Service provided to payers to enhance their benefits program with wellness solutions "focused on specific conditions including weight management, mental well-being, musculoskeletal health and infertility"
OptumRx [7] (PBM)	Pharmacy benefit	• Pear Therapeutics products (reSET, reSET-O and Somryst) are covered under pharmacy benefit for members who chose to add these products to their formularies

*This list is not meant to be exhaustive. Some insurer policies on DTx may be excluded.

1. "Humana and Virta Health Team Up to Bring Type 2 Diabetes Reversal Treatment to Humana Employer Group Members." News Release. November 8, 2021. Accessed May 2022. https://humananews.com/news-details/2021/Humana-and-Virta-Health-Team-Up-to-Bring-Type-2-Diabetes-Reversal-Treatment-to-Humana-Employer-Group-Members/default.aspx#gsc.tab=0
2. Evernorth Digital Health Formulary. Express Scripts 2020. Accessed May 22, 2022. https://my.express-scripts.com/digital-health-formulary.html
3. Prescription Digital Therapeutics: Medical Policy-13.01.500. Premera. May 1, 2022. Accessed May 22,2022. https://www.premera.com/medicalpolicies/13.01.500.pdf
4. Prescription Digital Therapeutics-Policy. Aetna. January 1, 2022. Accessed May 22, 2022. https://www.aetna.com/cpb/medical/data/900_999/0999.html#dummyLink3
5. Mobile Device-Based Health Management Applications-Clinical UM Guideline. Anthem. April 1, 2022. Accessed May 22, 2022. https://www.anthem.com/dam/medpolicies/abcbs/active/guidelines/gl_pw_e000367.html
6. Point Solutions Management. CVS Health. 2021. Accessed May 22, 2022. https://payorsolutions.cvshealth.com/point-solutions-management
7. Pear Therapeutics Announces Formulary Availability for its Three FDA Authorized Prescription Digital Therapeutics at OptumRX. Businesswire. August 10, 2021. Accessed May 22, 2022. https://www.neuro-central.com/pear-therapeutics-announces-formulary-availability-for-its-three-fda-authorized-prescription-digital-therapeutics-at-optumrx/

In February 2022, Centers for Medicare and Medicaid Services (CMS) published a new level of HCPCS codes for PDTs that address behavioral health. The new code, A9291, became effective April 2, 2022, with the following descriptor: "prescription digital behavioral therapy, FDA cleared, per course of treatment."[12] This coding decision by CMS allows for the billing of some PDTs under the medical benefit and provides further validation of the existence of digital therapeutics and their integration into patient treatment.

Current Medicare and Medicaid coverage of PDTs is offered through a claim-by-claim review and under local or national coverage determinations.[13] In addition to the new HCPCS code, some DTx products have been assigned national drug codes (NDC) or universal product codes (UPC), which could be utilized for pharmacy benefit reimbursement. However, the FDA recently released a guidance for the industry stating the use of NDC numbers on device labels and packages is prohibited, and therefore, the use of NDCs in pharmacy reimbursement will no longer be an option starting in 2023.[10]

With the increasing provider and patient acceptance of digital therapeutics, reimbursement for these therapies has become a necessary but complicated topic for payers.

Value-based purchasing (VBP) agreements have been a hot topic in formulary management for pharmacy benefit managers (PBMs) for the past several years. VBP agreements between drug manufacturers and purchasers seek to contain upfront costs and control waste by requiring various positive outcomes.[14] Digital therapeutics have not been immune to this shift in contracting agreements. Pear Therapeutics has entered several such agreements, including one recently with the Oklahoma Health Care Authority (OHCA) to provide access to its reSET and reSET-O products. The VBP agreement provides Oklahoma Medicaid patients access to these DTx products.[15]

Ultimately, DTx developers will need to actively engage with payers to optimize coverage, which will likely require demonstrated efficacy through robust comparative clinical trials and innovative reimbursement and contracting strategies.

Additional DTx considerations for payers

- **Replacement for existing pharmaceuticals.** Various PDTs, such as EndeavorRX (ADHD) and Somryst (insomnia), have the potential to replace medications for their respective treated disease states as they technically "treat" the disease. In the future, these PDTs may be evaluated in either non-inferiority or superiority comparative studies to standard medication therapy.
- **Use in conjunction with pharmaceutical therapy.** Several DTx are indicated for use in combination with drug therapy to treat their respective disease states. Currently, drugs and medical devices have separate approval pathways. Drug/digital combination products could potentially be approved under either pathway.[10]
- **Cost considerations.** Cost-effectiveness studies of digital therapeutics have been completed in opioid use disorders and insomnia:
  - In opioid use disorder, Fulton F. Velez and Daniel C. Malone found that over 12 weeks, the addition of Pear Therapeutics' reSET-O to treatment as usual (TAU) was economically dominant (less costly, more effective) than TAU alone.[16]
  - In insomnia, Michael Darden et al found that digital CBT (Sleepio®) was the most cost-effective insomnia treatment due to its smallest incremental cost-effectiveness ratio (-$3,124.73) followed by group CBT, pharmacotherapy and individual CBT.[17]
- **Accessibility and patient ease of use and acceptance.** Most digital therapeutics require access to a mobile smartphone and reliable internet. Additionally, some DTx (including reSET and reSET-O) require at least a 7th-grade reading level and fluency in the English language, which may limit their use.
- **Surveillance, tracking and monitoring.** Product labeling updates and ongoing surveillance and tracking of patient safety and product performance remain concerns for payers.

Expanding access to DTx coverage: legislative actions

Congress has made several legislative efforts to allow coverage of DTx through Medicare and Medicaid. In 2020, the Prescription Digital Therapeutics to Support Recovery Act was introduced to Congress but did not receive a vote. This legislation would allow for the coverage of all FDA-cleared or approved PDTs intended to prevent, manage or treat mental health and substance use disorders.

In 2021, CMS released the Medicare Coverage for Innovative Technology (MCIT) rule that provided coverage of medical devices designated as breakthrough technologies up to four years after the FDA approval date. DTx can and have been classified as breakthrough devices, including MedRhythms, a software designed to improve impairments associated with strokes.[18] However, DTx currently do not have a benefit category recognized by CMS, which is required for coverage.[19] In a November 2021 press release, CMS repealed the MCIT rule due to concerns that "the provisions in the final rule may not have been sufficient to protect Medicare patients."[13] CMS plans to hold at least two stakeholder public meetings in CY 2022 to discuss future policies for DTx.[13]

In March 2022, a group of bipartisan lawmakers introduced the Access to Prescription Digital Therapeutics Act to expand Medicare and Medicaid coverage to include DTx benefit categories, outline coverage and reimbursement framework, produce product-specific HCPCS codes and establish a DTx manufacturer reporting process. It is uncertain if this bill will be voted into law during the current legislative session.

At the time of this publication, DTx coverage under Medicare and Medicaid is not clearly defined and will likely require alternative billing strategies including indirect billing and/or bundling into other medical services.[20]

New opportunities and responsibilities for PBMs

Digital therapeutics are a fast-growing class of therapies that treat a variety of disease states and have the potential for widespread adoption by providers and patients. The FDA regulatory review pathways for DTx have not been fully established; however, the FDA has put forth a concerted effort to better define these pathways. Payers have been reluctant to cover DTx due to insufficient clinical efficacy data for use and wide variability in the quality of studies among products. Additionally, a comprehensive guidance on payment strategies for DTx has not been published, which leaves coverage pathways variable and inconsistent.

PBMs have the unique opportunity to be market leaders for reimbursement of DTx due to their focus on cost-effective therapeutics and evidence-based medicine. Some large-payer PBMs have published policies regarding DTx, including criteria for medical necessity and adoption of a digital health formulary to streamline coverage. CMS has attempted to address the issue of covering DTx; however, guidance on best practices from the organization has been elusive. Developers of digital therapeutics will need to continually engage with key stakeholders, including providers, patients, government agencies (i.e., FDA and CMS) and commercial payers to ensure their products are reimbursed and widely accepted.

Gainwell Technologies is committed to serving our clients by offering PBM as a service. Our end-to-end pharmacy solutions cover all aspects of pharmacy benefit management, with measurable results. Building on our decades of experience, we are well prepared to continue guiding agencies in the delivery of quality pharmacy care in the future.

Key takeaways

- Digital therapeutics (DTx) are a fast-growing novel treatment option for a variety of chronic conditions including behavioral health, IBS, substance use disorders and musculoskeletal pain.
- FDA authorization of Prescription Digital Therapeutics (PDTs) is through either De Novo or 510(k) pathways via traditional medical device approval and requires potentially less rigorous clinical efficacy data than pharmaceutical products.
- The FDA has piloted a Pre-cert program with nine digital health companies to reimagine the approval process for digital therapeutics.
- Payer adoption of digital therapeutics has lagged largely due to wide variability of clinical evidence reported among products.
- Reimbursement of PDTs differs widely among payers. Some PBM servicers have digital therapeutic policies that outline medical necessity and/or exclusions of coverage.
- Digital health formularies have been developed by some PBMs to streamline DTx coverage for payers.
- Medicare and Medicaid coverage for DTx remains undefined. Bipartisan legislation introduced in 2022 (Access to Prescription Digital Therapeutics Act) seeks to allow coverage of DTx through Medicare and Medicaid.
- DTx developers and stakeholders will need to actively engage with payers to move reimbursement of products forward.

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Sources

1 What Is Digital Health? US Food & Drug Administration. September 22, 2020. Accessed May 22, 2022. https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health

2 Digital Therapeutics Alliance. Digital Therapeutics Definition and Core Principles Fact Sheet. November 2019. Accessed May 20, 2022. https://dtxalliance.org/wp-content/uploads/2019/11/DTA_DTx-Definition-and-Core-Principles.pdf#:~:text=Digital%20therapeutics%20definition%3A%20Digital%20therapeutics%20%28DTx%29%20deliver%20evidence-based,manage%2C%20or%20treat%20a%20medical%20disorder%20or%20disease.

3 Weir, K. The Ascent of Digital Therapies. American Psychological Association. November 2018, 49 (10). Accessed May 22, 2022. https://www.apa.org/monitor/2018/11/cover-digital-therapies#:~:text=In%202017%2C%20Pear%E2%80%99s%20reSET%20therapy%20for%20the%20treatment,cleared%20by%20the%20Food%20and%20Drug%20Administration%20%28FDA%29.

4 Galvin G. COVID-19 Accelerated Use of Digital Therapeutics, but Coverage Issues and Regulatory Questions Could Slow Their Momentum. Morning Consult. June 15, 2021. Accessed May 24, 2022. https://morningconsult.com/2021/06/15/digital-therapeutics-use-coverage-polling/

5 Digital Therapeutics Market Size, Share & Trends Analysis Report By Application (Diabetes, Obesity, CVD), By End User (Patients, Providers, Payers, Employers), By Region, And Segment Forecasts, 2022 - 2030. Grand View Research July 2020. Accessed May 22, 2022. https://www.grandviewresearch.com/industry-analysis/digital-therapeutics-market

6 IPD Analytics. Digital Therapeutics. Payer & Provider Insights. May 2022. Accessed May 21, 2022. https://www.ipdanalytics.com/payer-provider-insights

7 The Device Development Process-Step 3: Pathway to Approval. US Food & Drug Administration. February 9, 2018. Accessed May 24, 2022. https://www.fda.gov/patients/device-development-process/step-3-pathway-approval

8 Digital Health Center of Excellence. US Food & Drug Administration. February 4, 2022. Accessed May 22, 2022. https://www.fda.gov/medical-devices/digital-health-center-excellence/about-digital-health-center-excellence

9 Digital Health Software Precertification (Pre-cert) Program. US Food & Drug Administration. May 6, 2021. Accessed May 22, 2022. https://www.fda.gov/medical-devices/digital-health-center-excellence/digital-health-software-precertification-pre-cert-program

10 IPD Analytics. The Current Landscape and Complexities of Digital Therapeutics. August 2021. Accessed May 22, 2022. https://www.ipdanalytics.com

[11] Access and Reimbursement: Access to Digital Therapeutics in a Post-COVID-19 World. Trinity Blog. July 14, 2020. Accessed May 22, 2022. https://trinitylifesciences.com/access-to-digital-therapeutics-in-a-post-covid-19-world/

[12] The Digital Therapeutics Alliance Welcomes Decision by CMS to Establish a HCPCS Code for Prescription Digital Behavioral Therapy. DTA Release & Statements. February 25, 2022. Accessed May 22, 2022. https://dtxalliance.org/2022/02/25/the-digital-therapeutics-alliance-welcomes-decision-by-cms-to-establish-a-hcpcs-code-for-prescription-digital-behavioral-therapy/

[13] CMS Repeals MCIT/R&N Rule; Will Consider Other Coverage Pathways to Enhance Access to Innovative Medical Devices. Centers for Medicare & Medicaid Services Press Release. November 12, 2021. Accessed May 22, 2022. https://www.cms.gov/newsroom/press-releases/cms-repeals-mcitrn-rule-will-consider-other-coverage-pathways-enhance-access-innovative-medical

[14] Armstrong J, Becker C. “Value-based Pricing to Address Drug Costs.” National Conference of State Legislatures. Vol. 27 (15) April 2019. Accessed May 22, 2022. https://www.ncsl.org/research/health/value-based-pricing-to-address-drug-costs.aspx#:~:text=Valuebased%20purchasing%20agreements%20are%20created%20when%20drug%20manufacturers,new%20drugs%20if%20the%20manufacturer%20guarantees%20their%20effectiveness.

[15] Oklahoma Health Care Authority and Pear Therapeutics Enter Into a Value-Based Agreement for reSET and reSET-O. Pear Therapeutics News Release via Business Wire. January 26, 2022. Accessed May 22, 2022. https://markets.financialcontent.com/stocks/article/bizwire-2022-1-26-oklahoma-health-care-authority-and-pear-therapeutics-enter-into-value-based-agreement-for-reset-and-reset-o#:~:text=Pear%20Therapeutics%2C%20Inc.%20%28Nasdaq%3A%20PEAR%29%2C%20the%20parent%20company,fight%20the%20growing%20substance%20and%20opioid%20addiction%20crisis.

[16] Velez F, Malone D. Cost-Effectiveness Analysis of a Prescription Digital Therapeutic for the Treatment of Opioid Use Disorder. J Mark Access Health Policy. 2021; 9(1): 1966187. Accessed May 22, 2022. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8381930/

[17] Darden M, Espie CA, Carl JR, et al. Cost-effectiveness of digital cognitive behavioral therapy (Sleepio) for insomnia: A Markov simulation model in the United States. Sleep. zsaa223. doi: 10.1093/sleep/zsaa223. Accessed May 22, 2022. https://pubmed.ncbi.nlm.nih.gov/33151330/

[18] MedRhythms Receives FDA Breakthrough Device Designation for Chronic Stroke Digital Therapeutic. MedRhythms News Release. June 15, 2020. Accessed May 22, 2022. https://www.prnewswire.com/news-releases/medrhythms-receives-fda-breakthrough-device-designation-for-chronic-stroke-digital-therapeutic-301076597.html

[19] Ostrovsky, A. Medicare Should Break an Old Rule To Let Breakthrough Digital Therapeutics Save Lives. STAT-First Opinion. October 19, 2020. Accessed May 22, 2022. https://www.statnews.com/2020/10/19/medicare-proposed-rule-breakthrough-digital-therapeutics/#:~:text=Medicare%20reimbursement%20for%20digital%20therapeutics%20could%20happen%20either,therapy%2C%20and%20treatment%20services%20for%20opioid%20use%20disorder.

[20] IPD Analytics. Prescription Digital Therapeutics: Software-Based Treatments. June 2020. Accessed May 22, 2022. https://www.ipdanalytics.com

Appendix I

Key features of digital therapeutics identified by 2020 AMCP Forum participants

In an effort to evaluate the emerging digital therapeutics market and implications, the Academy of Managed Care Pharmacy (AMCP) convened a forum in 2020 to discuss the impact of DTx on healthcare delivery. Key takeaways from those discussions include insight into descriptions, evidence and reimbursement of digital therapeutics (Table 5).

Table 5. Key features of digital therapeutics identified by 2020 AMCP forum participants*

Feature	Description
Definition	• Interventions that are driven by software programs to prevent, diagnosis, manage or treat a medical disorder or disease
Approval/Regulatory Process	• Impartial third party provides premarket validation of efficacy, clinical effectiveness, safety, data security, privacy and quality by regulatory or equivalent national body • Level of regulation should be dependent on the risk-benefit analysis of the therapeutic claim and potential for harm • In the United States, the FDA is responsible for products making therapeutic claims, guided by the software as a medical device (SaMD) framework and developed by the International Medical Device Regulators Forum • DTx may fall under the De Novo, 510(k) regulatory pathway for DTx and NDAs, including 505(b)(2) for combination products • Other regulatory bodies may also be involved
Evidence	• Clinical trials and ongoing evidence generation required for safety and efficacy • Standard tiered levels of evidence required based on claims • Pragmatic trials in real-world settings • User experience testing

* AMCP Partnership Forum: Digital Therapeutics—What Are They and Where Do They Fit in Pharmacy and Medical Benefits? Volume 26 Issue (5)J Manag Care Spec Pharm, 2020 May;26(5):674-681. Accessed May 22, 2022. https://doi.org/10.18553/jmcp.2020.19418

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