



Pear Prescription Digital Therapeutics (PDT) Digest



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Message From Pear Leadership



Message From Pear Therapeutics' CEO, Corey McCann, MD, PhD



We are living in a transformational moment for healthcare. Multiple trends have converged to create a need for software to treat human disease. Chronic disease continues to drive healthcare spending and burden for millions of people. We are in the midst of a provider shortage, where trained clinicians are unavailable to treat many prevalent conditions like addiction and other behavioral health disorders. Due to COVID-19, expectations for care have shifted toward telemedicine settings, and mobile devices are easily accessible. Technology is ubiquitous in our lives.

Pear believes that software can directly treat most diseases. These products, called prescription digital therapeutics (PDTs), are the next therapeutic modality, with hundreds of disease treatment applications alone and in combination with drugs. Like wellness apps, PDTs engage patients via a software interface. Like pharmaceuticals, these products undergo regulatory review to assess safety and effectiveness. Unlike both, PDTs integrate with provider workflows to transfer real-world data back to payers and providers to inform clinical care.

We think that providers, payers, and patients are all looking for a better way to deliver healthcare. PDTs align incentives across major healthcare stakeholders and are designed to enhance access and convenience for patients, to improve reach and efficiency for clinicians, and to reduce cost for payers by replacing and augmenting human intervention as well as reducing costly clinical outcomes.

Broad access to FDA-authorized PDTs is consistent with the necessary sea change in provision of treatment and care. Pear believes that PDTs are the next frontier of medicine.

Message From Editorial Advisors



Message From the Chief Editorial Advisor of the PDT Digest



John Fox, MD, MHA

President, Foxworthy Healthcare Consulting, LLC

Sometimes, quotes stick with you, and you're not sure why. The explosion of digital therapeutics reminds me of a quote from Cindy Bryce from the University of Pittsburgh. Back in 1998, she wrote, "Technological advances have the potential for enormous medical, social, and economic benefits. However, the diffusion of these technologies has outpaced our ability to evaluate their appropriate use and to fully maximize their value."¹

Evaluation of the appropriate use of digital therapeutics and quantification of their health impacts has been simplified by the advent of prescription digital therapeutic regulations. In December 2017, the FDA issued guidance to manufacturers regarding the clinical evaluation of software as a medical device (SaMD). This guidance outlined the specific analytic and clinical validation studies required to obtain FDA authorization, and thus distinguish PDTs from other digital therapeutics.²

PDTs are poised to provide transformative care to patients and expand access to treatment. Leveraging technological advancements to address gaps in care using software can provide safer and potentially more effective methods to prevent, manage, and treat diseases across multiple therapeutic areas. In addition, PDTs permit access to more convenient and flexible modes of care.

However, PDTs face challenges in coverage and reimbursement. Overcoming these challenges using evidence generated in FDA-required randomized controlled trials will enable broader access and utilization. At the time of this writing, 6 PDTs have been authorized and dozens more are in the pipeline, signaling a growing investment in this space. Increased awareness and knowledge of PDTs among patients, providers, payers, and other key stakeholders—including the FDA evidentiary requirements—will help drive uptake and ensure that opportunities for access are optimized for this new treatment modality.

We are pleased to participate with Pear Therapeutics and Avalere Health in the publication of the inaugural PDT Digest. The PDT Digest is the first in a series of publications highlighting key findings from payers and employer group survey respondents around level of awareness, issues, and opportunities with PDTs. On behalf of the Editorial Panel who contributed to developing this Digest, we thank the survey respondents who participated in the PDT Survey. We welcome your future insights and participation in the PDT Digest and thank you for your interest.

1. Bryce CL and Cline KE, 17 Health Affairs 213-24, The Supply and Use Of Selected Medical Technologies (January/February 1998). Available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.17.1.213>.

2. FDA, Guidance for Industry, Software as a Medical Device (SaMD): Clinical Evaluation (December 8, 2017). Available at <https://www.healthaffairs.org/doi/full/10.1377/hlthaff.17.1.213>.

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Executive Summary



Executive Summary

Pear Therapeutics, in collaboration with Avalere Health, conducted a survey of payers and employers to develop and publish the first annual Pear Prescription Digital Therapeutics Digest (Pear PDT Digest), outlining current challenges and opportunities with PDTs, identifying barriers to coverage, and proposing solutions and recommendations to inform coverage decisions, and ultimately improving patient access.

This project supports efforts from key industry leaders such as the Academy of Managed Care Pharmacy (AMCP) and the Digital Therapeutics Alliance (DTx Alliance) to define the coverage landscape and provide guidance to payers. AMCP has recently identified the following as key considerations³ to improve support for appropriate and evidence-based coverage decisions for digital therapeutics, including the:

- Vital role that Pharmacy and Therapeutics Committees, or equivalent bodies, have in the evaluation of digital therapeutic products;
- Expectation that clinical evidence of a digital therapeutic product will be reviewed in comparison to standards of care;
- Importance of approval or market authorization by a regulatory body to payers;
- Expectation that digital therapeutic innovators generate and publish evidence that demonstrates that their product improves quality of care;
- Necessity that coverage decisions for digital therapeutics are based on scientific data that demonstrate that a product is appropriate and safe. As with traditional drug therapies and biologics, evidence of cost-effectiveness—to the extent that it is available—is also important to support payers' coverage decisions;
- Understanding that digital therapeutic innovators collect, store, and process users' data in a safe, fair, and lawful way; and
- Need for communicating impactful product updates to payers, healthcare decision-makers, and patients.

The Pear PDT Digest incorporates findings from a survey of 40 major US payers and employers on their perspectives of the PDT market landscape. All respondents reported a high level of familiarity with PDTs as a requirement for participating in the survey. **Variation in stakeholder responses regarding coverage and reimbursement pathways for PDTs confirms fundamental misconceptions about PDTs among key players in this space.**

The survey results address the following key questions, as they relate to market access for PDTs, including:

- What are the evidentiary requirements for review?
- What is the value proposition for PDTs?
- How are payers covering or thinking about covering PDTs?
- What is the consensus approach to contracting?
- What are the critical items from an operational perspective?
- To what extent will this category evolve over the next 12 months?

This Digest is the first in a series of publications in which we will provide key insights, as they relate to PDTs, and track payers' level of familiarity with—and management of—PDTs. The goal of this Digest series is to provide a road map for payers and employer groups to use as a starting point as they review, cover, and manage PDTs.

3. AMCP, AMCP Partnership Forum Develops Steps to Strengthen Evaluation of Digital Therapeutics (September 9, 2021). Available at <https://www.prnewswire.com/news-releases/amcp-partnership-forum-develops-steps-to-strengthen-evaluation-of-digital-therapeutics-301371733.html>.

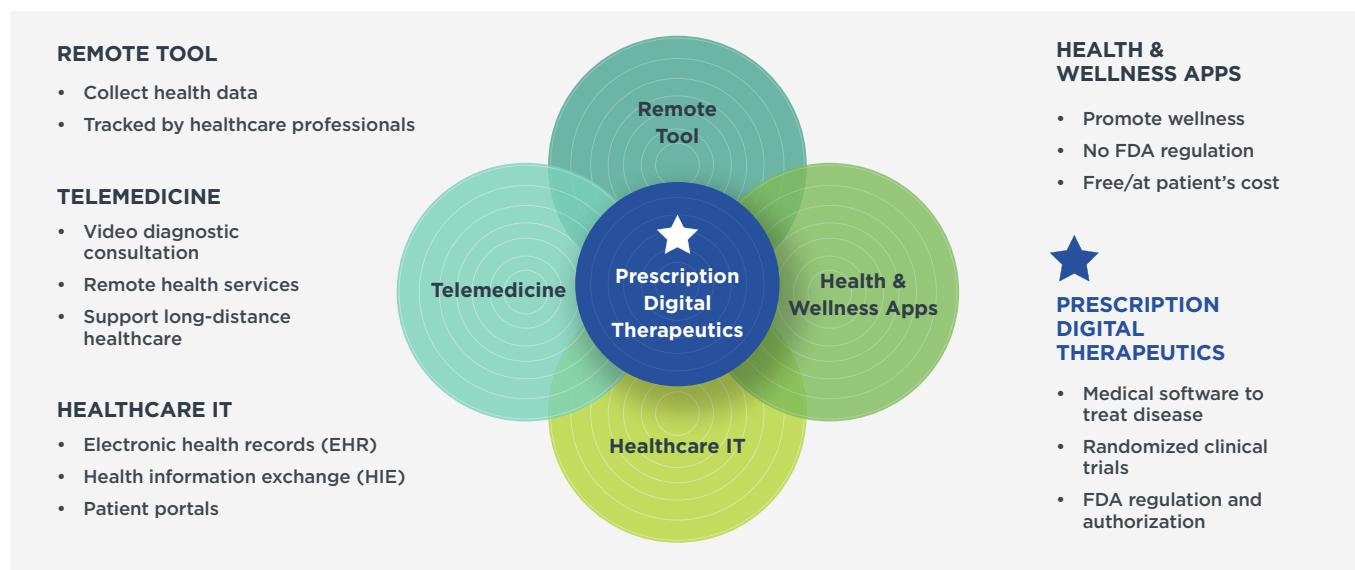
PDT Value Proposition



Prescription Digital Therapeutics Have Emerged as the New Frontier of Digital Health Technologies and Are Differentiated From Other Digital Health Modalities

Digital therapeutics are “evidence-based therapeutic interventions that are driven by high quality software programs to prevent, manage or treat a medical disorder or disease.”⁴ While digital therapeutics are available through a direct-to-consumer approach, prescription digital therapeutics (PDTs) are only available via consultation with a healthcare professional (HCP) and a prescription. Unlike other digital health interventions or wellness devices and applications, PDTs are required to demonstrate evidence of clinical effectiveness and patient safety through a well-controlled clinical trial. This is reviewed by a regulatory body in order to be authorized for sale in interstate commerce—in the United States that is the Food and Drug Administration (FDA), which regulates PDTs as medical devices.⁵ The regulatory rigor governing this review process is the same as any other medical device.

Figure 1. Prescription digital therapeutics (PDTs) are a category within digital health defined by clinical efficacy and FDA market authorization



4. Digital Therapeutics Alliance, Digital Therapeutics Definition and Core Principles Fact Sheet (November 2019). Available at https://dtxalliance.org/wp-content/uploads/2021/01/DTA_DTx-Definition-and-Core-Principles.pdf.

5. See, e.g., 21 U.S.C. § 321(h)(1), defining “device” (2021).

At the time of this publication, there are 6 PDTs that have been authorized by the FDA. These PDTs and their indications are summarized in Table 1 below.

Table 1. Current FDA-Authorized PDTs

PDT Product	Therapeutic Area
reSET ⁶	Substance Use Disorder
Nightware ⁷	PTSD Driven Traumatic Nightmares
reSET-O ⁸	Opioid Use Disorder
Somryst ⁹	Chronic Insomnia
EndeavorRx ¹⁰	Attention Deficit Hyperactivity Disorder (ADHD)
Mahana for IBS ¹¹	Irritable Bowel Syndrome (IBS)

Additionally, there are currently 8 putative PDTs with FDA breakthrough designation and dozens more in pipeline development.

PDTs can help improve health outcomes by offering patients additional avenues to overcome treatment access barriers associated with pharmaceutical or in-person therapy, including perceived stigma and logistical and pharmacological hurdles.¹² In addition, PDTs enable clinicians to enhance treatment impact through a larger variety of treatment options and provide the ability to conduct remote monitoring. Research has shown that conditions treated by PDTs, including substance abuse disorders, depression, and diabetes, tend to impact patients of lower socio-economic status as well as racial and ethnic minorities, indicating that PDTs could potentially help close disparity gaps in healthcare.¹³

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6. Pear Therapeutics, PEAR Obtains FDA Clearance of the First Prescription Digital Therapeutic to Treat Disease (August 25, 2018). Available at <https://peartherapeutics.com/fda-obtains-fda-clearance-firstprescription-digital-therapeutic-treat-disease/>.
 7. Truong K, MedCity News, Nightware receives breakthrough designation for its PTSD nightmare therapy technology (May 21, 2019). Available at <https://medcitynews.com/2019/05/nightware-receives-breakthrough-designation-for-its-ptsd-nightmare-therapy-technology/>.
 8. Pear Therapeutics, Pear Therapeutics Receives Expedited Access Pathway Designation from FDA for reSET-OTM Prescription Digital Therapeutic to Treat Opioid Use Disorder (August 25, 2018). Available at <https://peartherapeutics.com/pear-therapeutics-receives-expedited-access-pathway-designation-fda-reset-o-prescription-digital-therapeutic-treat-opioid-use-disorder/>.
 9. Pear Therapeutics, Pear Therapeutics Launches Somryst™ for Chronic Insomnia via an End-to-End Virtual Care Experience (November 17, 2020). Available at <https://peartherapeutics.com/pear-therapeuticslaunches-somryst-for-chronic-insomnia-via-an-end-to-end-virtual-care-experience/>.
 10. Akili Interactive, Akili Announces FDA Clearance of EndeavorRx™ for Children with ADHD, the First Prescription Treatment Delivered Through a Video Game (October 2, 2020). Available at <https://www.akiliinteractive.com/news-collection/akili-announces-endeavortm-attention-treatment-is-now-available-for-children-with-attention-deficit-hyperactivity-disorder-adhdal3pw>.
 11. Mahana, Mahana Therapeutics Obtains FDA Marketing Authorization for the First Prescription Digital Therapeutic to Treat Irritable Bowel Syndrome (December 8, 2020). Available at <https://www.mahanatx.com/press/parallel-fda-authorization>.
 12. See, e.g., Digital Therapeutics Alliance, Value of DTx (Accessed 4 October 2021). available at <https://dtxalliance.org/value-of-dtx/>.
 13. See, e.g., McKnight-Eily LR, et al., 70 MMWR Morb. Mortal. Wkly. 162-66, Racial and Ethnic Disparities in the Prevalence of Stress and Worry, Mental Health Conditions, and Increased Substance Use Among Adults During the COVID-19 Pandemic – United States, April and May 2020 (February 5, 2021). Available at <https://www.cdc.gov/mmwr/volumes/70/wr/mm7005a3.htm>; see also Dang A, Arora D, Rane P. 9 J. Family Med. Prim. Care 2207-13, Role of digital therapeutics and the changing future of healthcare (May 31, 2020). Available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7380804/pdf/JFMPG-9-2207.pdf>.

PDTs are medical devices. By virtue of being regulated as medical devices, they are more like drugs and biologics as a regulatory and legal matter compared to other digital health technologies. PDTs incorporate the innovative functions of each category since they:

- Like drugs, biologics, and certain other medical devices, require a prescription from a healthcare professional as compared to other digital health technologies;
- May allow providers, including the entire care team, to gain insight from their patients throughout the care continuum through the ability to receive data from the PDT about their patient and customize treatment sessions according to patient-reported feelings, behaviors, and activities;
- May be designed to collect real-world data (RWD) for use by sponsors and prescribing clinicians in the development of real-world evidence (RWE), and by payers and health systems for population health management;
- May offer a less invasive method to treat and manage disease, including fewer side effects or adverse events, improve adherence, and offer potential expansion for patient access;
- Can help payers and public health organizations understand the potential reduction in healthcare costs to enable more informed decision-making about the effectiveness of treatment approaches or when determining treatment value; and
- Unlike nonphysician-directed digital therapeutics, PDTs complement, rather than replace or potentially contradict, a treatment plan.

Some of these distinguishing features are summarized in Table 2 below.

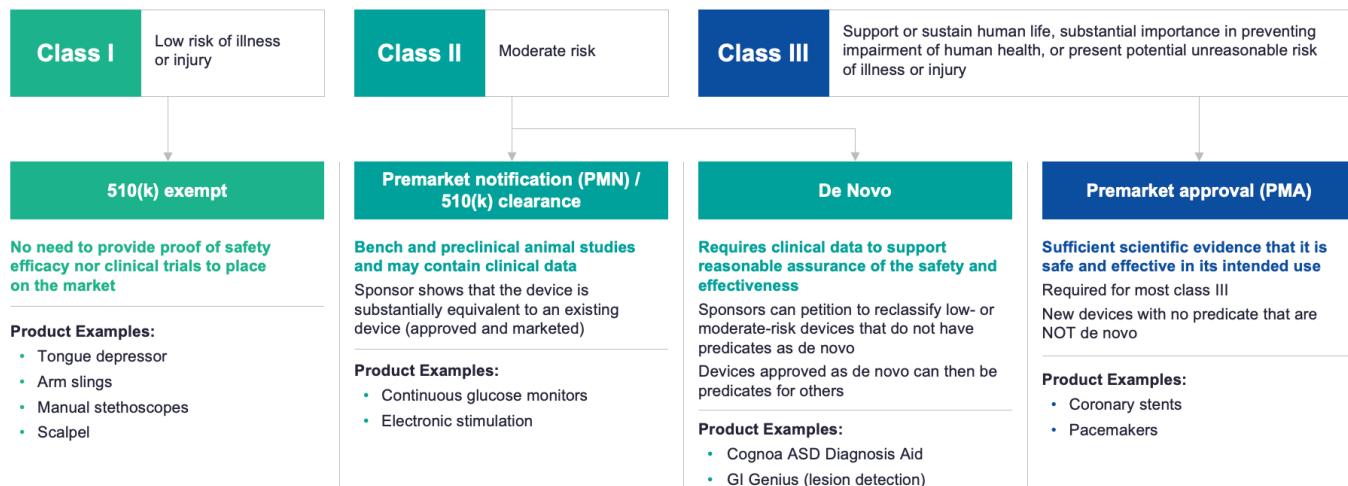
Table 2. Contrasting PDTs With Other Care Modalities

	HEALTH AND WELLNESS APPS	PHARMACEUTICALS	PRESCRIPTION DIGITAL THERAPEUTICS
Utilizes digital technology to improve human health	✓		✓
Require randomized controlled trials		✓	✓
Authorized or approved as safe and effective		✓	✓
Reimbursement pathways via specific product code		✓	✓
Capability for real-time feedback for clinicians			✓

PDTs Are US Food and Drug Administration (FDA) Authorized Through the De Novo Classification or 510(k) Premarket Notification Processes

Like other medical devices, PDTs are regulated by the FDA through the Center for Devices and Radiological Health (CDRH).¹⁴ This enables the manufacturer not only to sell their device in interstate commerce but to have an FDA-approved label for their device of which the manufacturer can then make health and promotional claims about the effectiveness of the device. FDA classifies devices as Class I-III, depending on the intended use of the device and the indications for use; Class I devices present the lowest risk of use for the patient, and Class III devices present the highest risk.¹⁵ PDTs sold in interstate commerce are regulated by the FDA in that they must be made using good manufacturing practices (GMPs) and manufacturer-established quality systems.¹⁶ PDTs currently on the market are categorized by the FDA as Class II computerized behavioral therapy devices. A PDT will thus be authorized by the FDA for sale in interstate commerce either by De Novo Classification¹⁷ or 510(k) Premarket Notification.¹⁸ The device pathways are summarized in Figure 2 below.¹⁹

Figure 2. Comparing Device Classes and FDA Pathways



14. FDA, Center for Devices and Radiological Health (Current as of April 28, 2020). Available at <https://www.fda.gov/about-fda/fda-organization/center-devices-and-radiological-health>.

15. See 21 U.S.C. § 360c(a)(1) (2021).

16. See 21 U.S.C. § 360j(f) (2021); see also 21 C.F.R. Parts 807, 814, 820 (2021); see also FDA, Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan, at 3-4,7 (regarding Good Machine Learning Practices, or GMLP) (January 2021). Available at <https://www.fda.gov/media/145022/download>.

17. See 21 U.S.C. § 360c (2021); see generally FDA, De Novo Classification Request (Current as of November 20, 2019). Available at <https://www.fda.gov/medical-devices/premarket-submissions/de-novoclassification-request>.

18. See 21 U.S.C. § 360(k) (2021); see generally FDA, 510(k) Clearances (Current as of August 31, 2021). Available at <https://www.fda.gov/medical-devices/device-approvals-denials-and-clearances/510kclearances>.

19. See FDA, Step 3: Pathway to Approval (Current as of February 9, 2018). Available at <https://www.fda.gov/patients/device-development-process/step-3-pathway-approval>; see also FDA, Classify your medical device (Current as of February 7, 2020). Available at <https://www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device>; see also Sutton WM, FDA CDRH, FDA Small Business Regulatory Education for Industry (September 29, 2015). Available at <https://www.fda.gov/files/drugs/published/Device-Classification-Overview.pdf>; see also FDA, Premarket Notification 510(k) (Current as of March 13, 2020). Available at <https://www.fda.gov/medical-devices/premarket-submissions/premarket-notification-510k>; see also FDA, De Novo Classification Request (Current as of October 4, 2020). Available at <https://www.fda.gov/medical-devices/premarket-submissions/denovo-classification-request>; see also FDA, Medical Device Exemptions 510(k) and GMP Requirements (Last updated October 4, 2021). Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpdc/315.cfm>; see also FDA, Device Classification Under Section 513(f)(2)(De Novo) (Last updated October 4, 2021). Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm>.

Some new PDT entrants will be authorized by the FDA through the De Novo Classification process. This pathway is for new categories of medical devices that lack substantial equivalence to a predicate device already on the market. The manufacturer requests that the FDA classify the new device based on, among other things, a device description, intended use(s), classification information, and supporting data (including clinical data) that support safety and efficacy.

More common among medical device regulation is the 510(k) Premarket Notification and review. PDTs may be cleared through the 510(k) pathway if there is a predicate PDT to which the manufacturer can demonstrate substantial equivalence to: either by showing that the new PDT has the same technological characteristics as the predicate PDT or, if not identical, that the new PDT is as safe and effective as the predicate PDT through novel clinical and scientific data, including a randomized controlled trial (RCT). As more PDTs enter the market through the De Novo Classification, more and more new devices will likely be cleared through the 510(k) pathway.

Survey Results



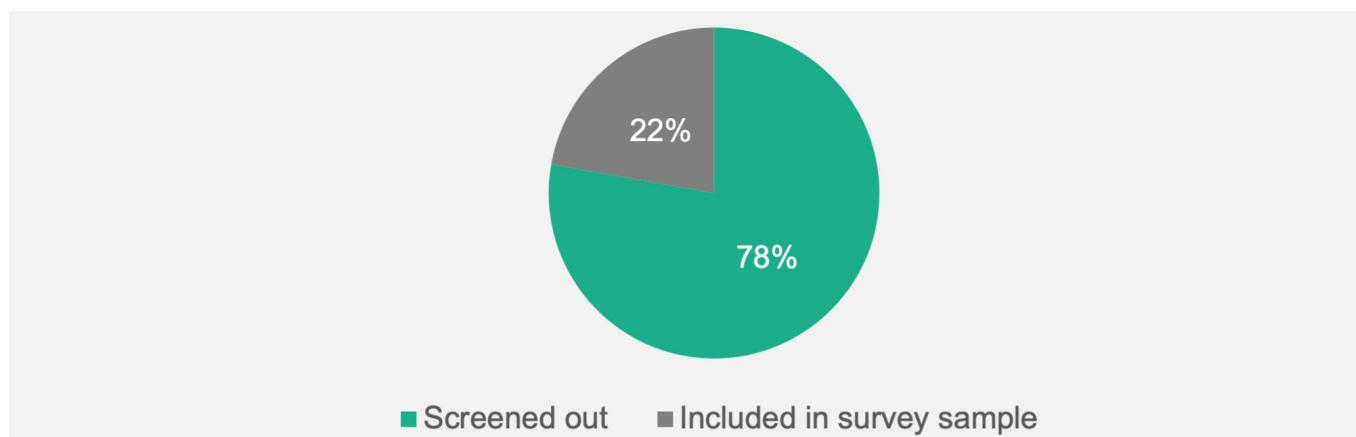
Respondent Profile

Pear PDT Survey Overview

The basis for this publication stems from engagement with key industry leaders through the distribution of a survey intended to measure employer and payer stakeholder knowledge of PDTs and current considerations and perceptions that comprise the coverage landscape. Currently, there is limited guidance to assist payers in determining the optimal approach to review, cover, and operationalize PDTs.

By conducting this research, Pear and Avalere were able to identify gaps in knowledge, expected evidentiary review requirements, drivers of coverage decisions, anticipated coverage over the next 12 months, optimal approaches to contracting, and potential issues and barriers for the category.

180 respondents were originally included in the survey sample; however, 140 were screened out due to unfamiliarity with PDTs, leaving 40 total participants

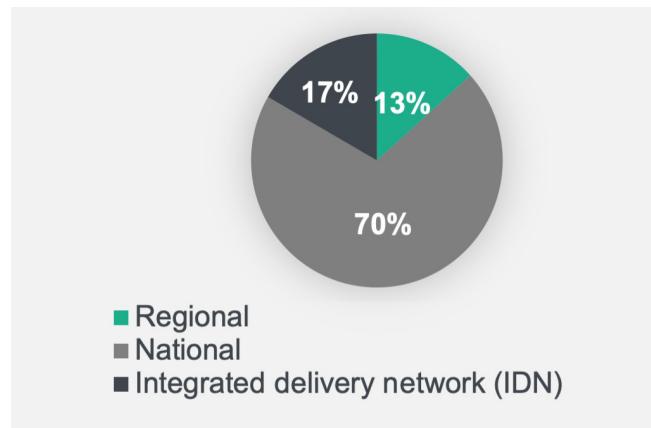


- Respondents served in a variety of roles including payers (n=30) and employers (n=10).

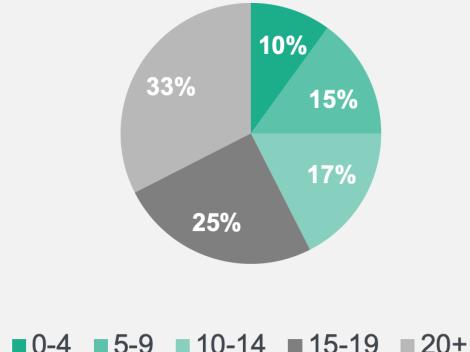
Respondent Types



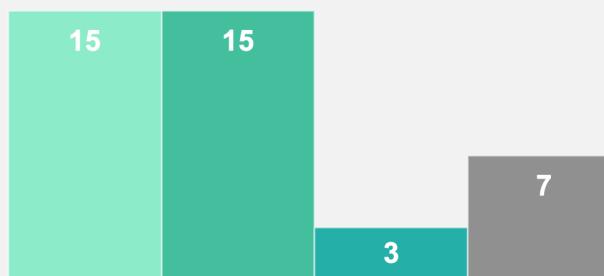
Health Plan's Affiliation/Jurisdiction



Employer Groups

Years of Experience in Role


Decision-Making for Coverage, Management, Adoption, or Utilization of PDTs



- Payer - Directly involved and primary decision-maker
- Payer - Directly involved and decision influencer
- Employer - Directly involved and primary decision-maker
- Employer - Directly involved and decision influencer

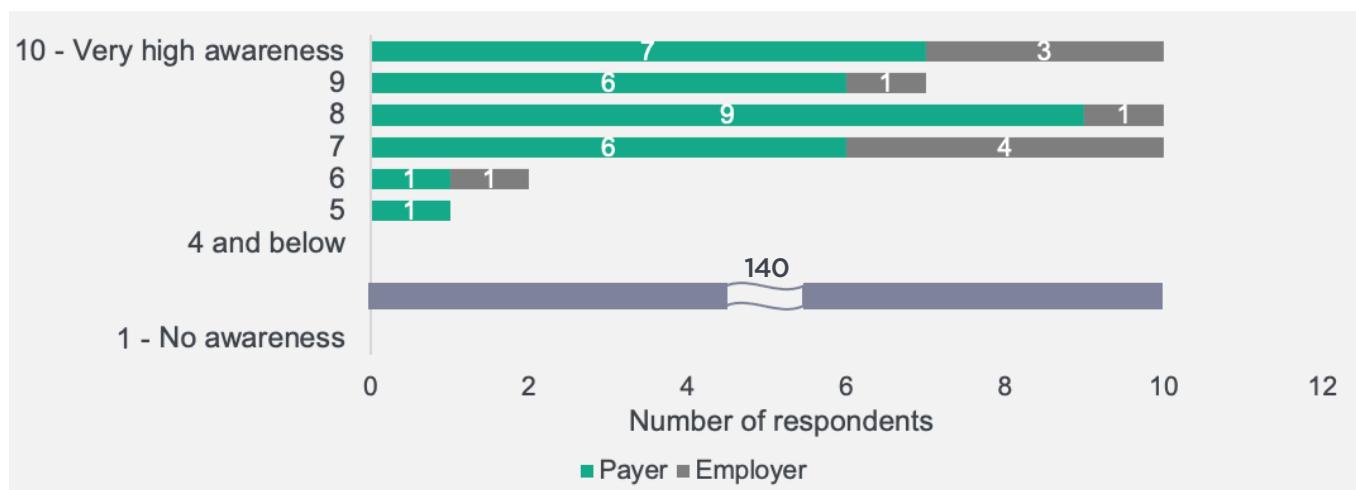
- A total of 192 million lives were covered by payers participating in the survey. Out of these lives, we saw the following breakdown in terms of books of business:
 - Commercial - 55%
 - Managed Medicaid - 25%
 - Medicare Advantage - 17%
 - Uninsured - 3%

Level of Awareness

Stakeholders Demonstrated Familiarity With PDTs, However Payers Expect Manufacturers to Educate Providers

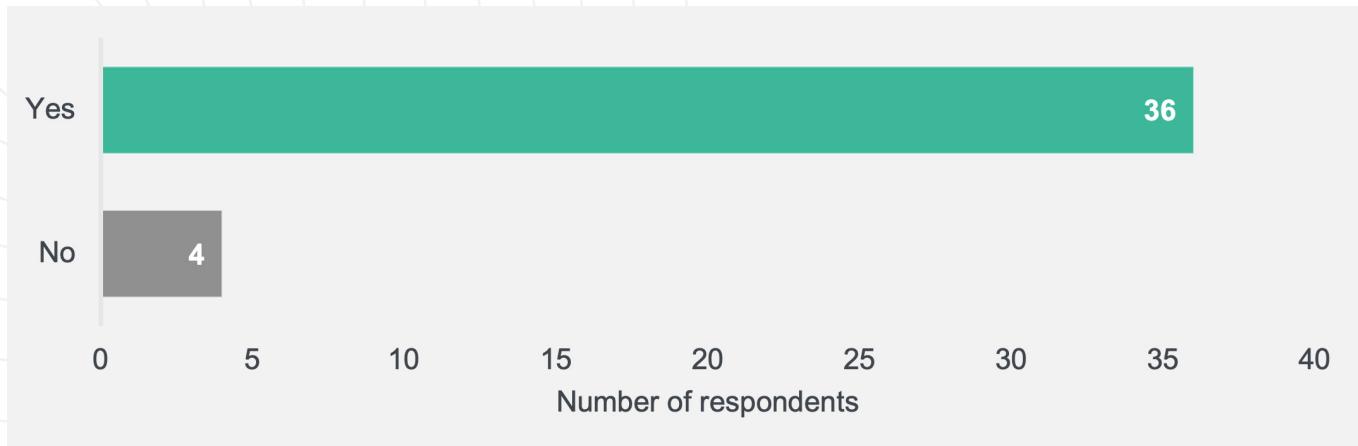
90% or more of payer and employer respondents ranked their awareness of PDTs 7 and above out of 10.

On a scale of 1-10, with 1 being the lowest, what is your level of awareness of what a PDT is?



Although respondents demonstrated familiarity with PDTs, other parts of the survey indicate that there are existing gaps in their perceived knowledge of PDTs and their actual level of understanding.

Do you expect manufacturers to educate you and your staff on the value of PDTs?



90% of respondents identified that they expect manufacturers to educate their organization on the value of PDTs. Respondents identified that manufacturers could provide this education through providing multimedia materials, training programs, and continuous support.

Respondents also identified the following topics as important for manufacturers to provide education on:

- “In-services on the clinical benefits and cost effectiveness of the PDT.”
- “Potential CE [continuing education] programs on the quality and effectiveness of the PDT, and which disease states will benefit most from these programs.”
- “Complete overview including costs, implementation, and reporting.”

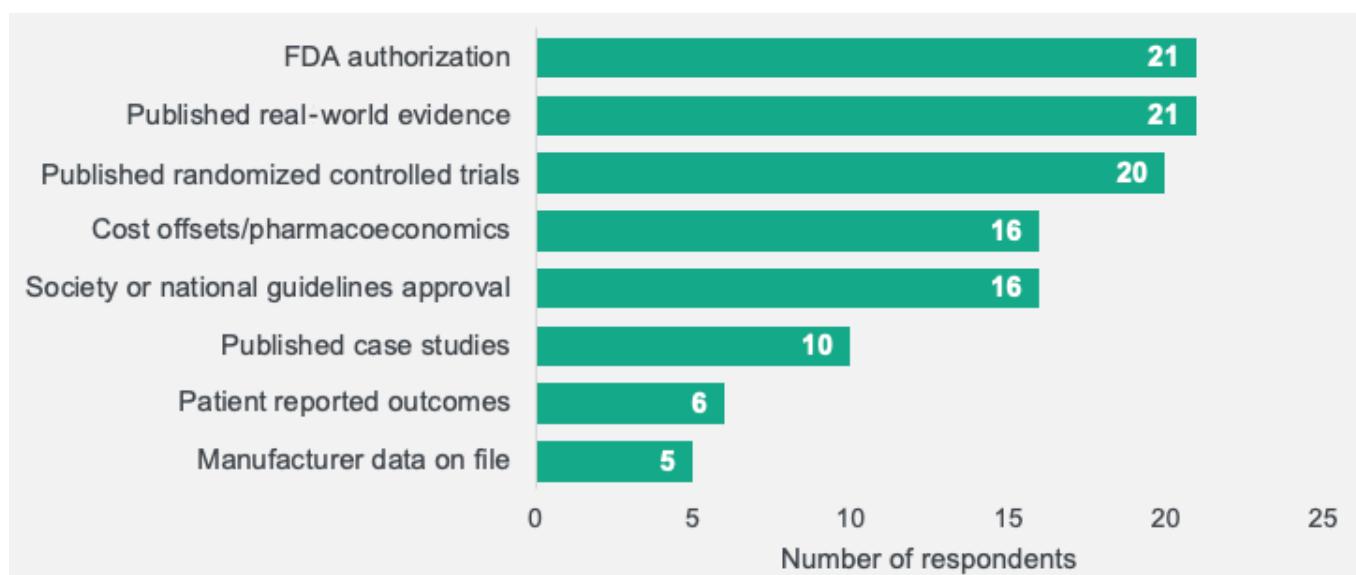
Even though respondents had a high level of awareness around PDTs generally, this underscores the need for durable and iterative payer education as new PDTs enter the market. In addition, payers likely will need education to support provider and patient adoption.

Evidentiary Requirements and Drivers of Coverage

Evidentiary Requirements Are Top of Mind for Decision-Making Stakeholders as They Consider PDT Adoption

As employer and payer organizations consider PDT coverage, it is important to understand the evidentiary requirements that stakeholders identified as most important when making a coverage determination for PDTs.

What outcomes or evidence of efficacy are most crucial to making a coverage determination?

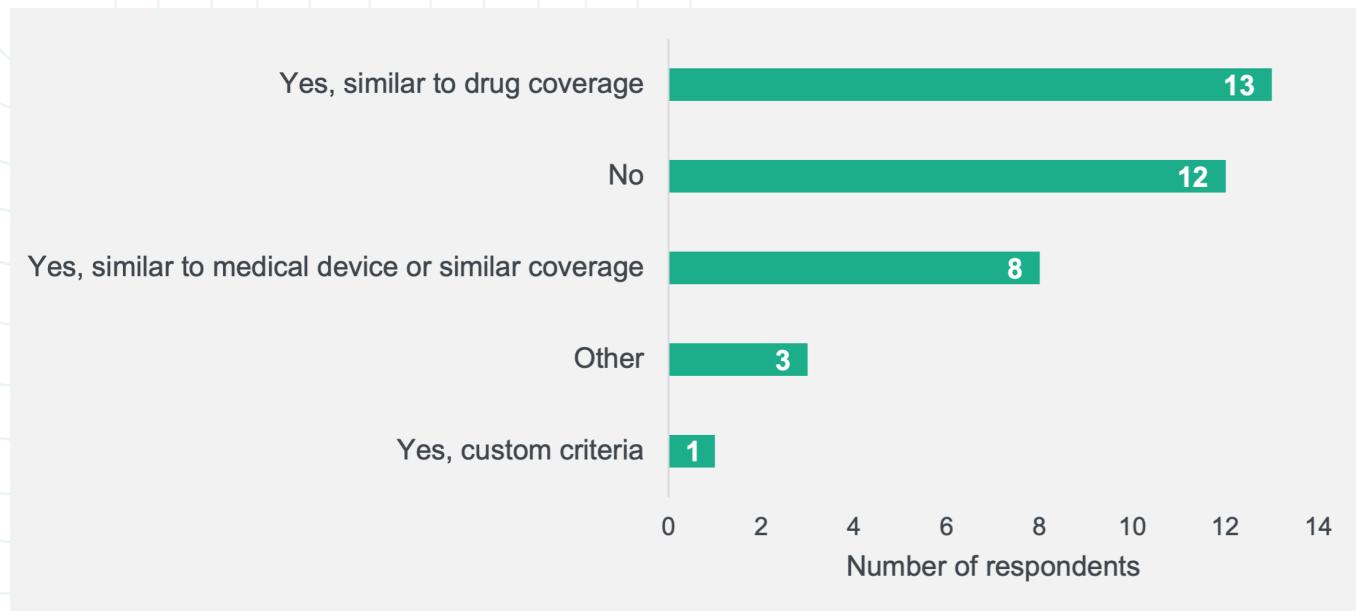


How important is FDA authorization for PDT coverage consideration?



RCTs, FDA authorization, and RWE are thought to be the biggest drivers of coverage followed closely by cost offsets. FDA authorization is the core differentiator between PDTs and other digital health modalities. As payers consider what coverage would look like within their organization, it is critical for payers to understand the FDA authorization process for PDTs (as previously noted).

Has your organization established specific coverage criteria for PDTs, including evidentiary requirements?



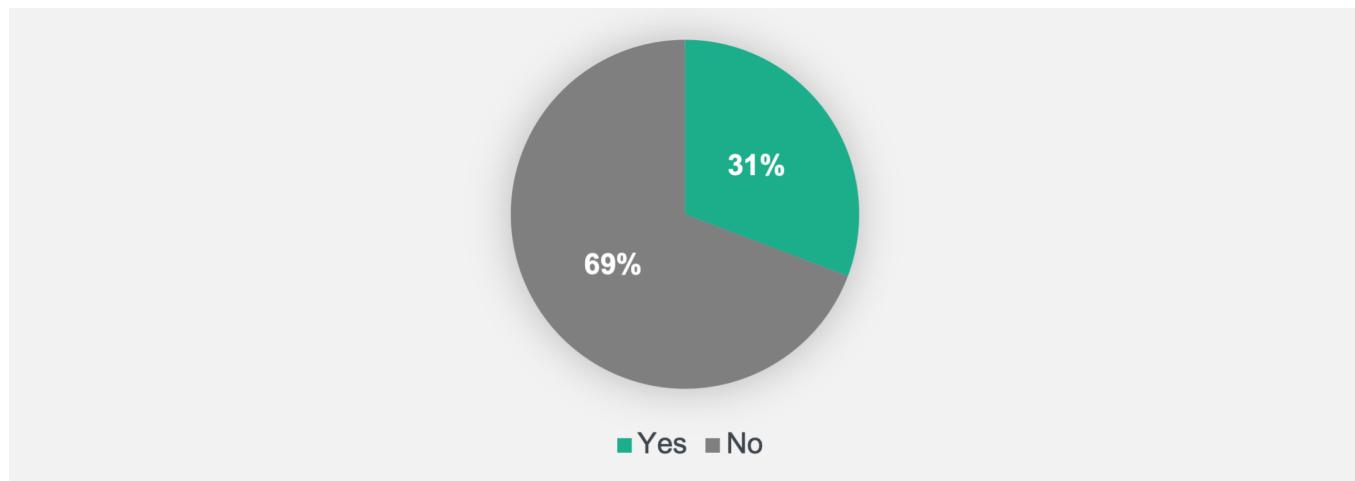
Almost one-third of respondents have not developed specific coverage criteria for PDTs. Among the payers that have, the majority have evidentiary requirements similar to drug coverage.

Respondent rationale included:

- “Because of the direct interventional component, it makes sense to align with the [drug] coverage criteria.”
- “Today there is no standardization for how PDTs are “prescribed,” so we add them to our coverage based on plan provider preference.”
- “Actively assessing with support from health plans and PBMs [pharmacy benefit managers].”

Data Management and Patient Privacy Were Not a Concern for the Majority of Respondents

Do you have concerns regarding compliance with data privacy or data sharing requirements?



69% of respondents indicated that they did not have concern regarding data management and privacy related to the use of PDTs. Respondents attributed this lack of concern to the following:

- “There is a precedence for safety.”
- “None because the anticipation is that quality control and validation are a required mission-critical component.”
- “Confidence in vendors.”
- “Most are high-tech health certified.”
- “The technology has advanced to the point where this isn’t a big concern.”
- “Assume software will be HIPAA compliant and data encrypted.”

However, among those who do have concerns, some respondents noted:

- “We are concerned with the security and sharing of PHI [personal health information].”
- “Need to have secure transmission.”
- “Data privacy and sharing must be solidly managed.”

AMCP has indicated there is an “understanding that digital therapeutic innovators collect and process users’ data in a safe, fair, and lawful way.” This understanding is a key factor in demonstrating to payers and employers that PDTs are responsible stewards of patient data, and addressing lingering doubts can help facilitate coverage of PDTs.

PDT Value Proposition

Respondents Identified a Few Key Characteristics of PDTs That Would Be Most Meaningful in Decision-Making

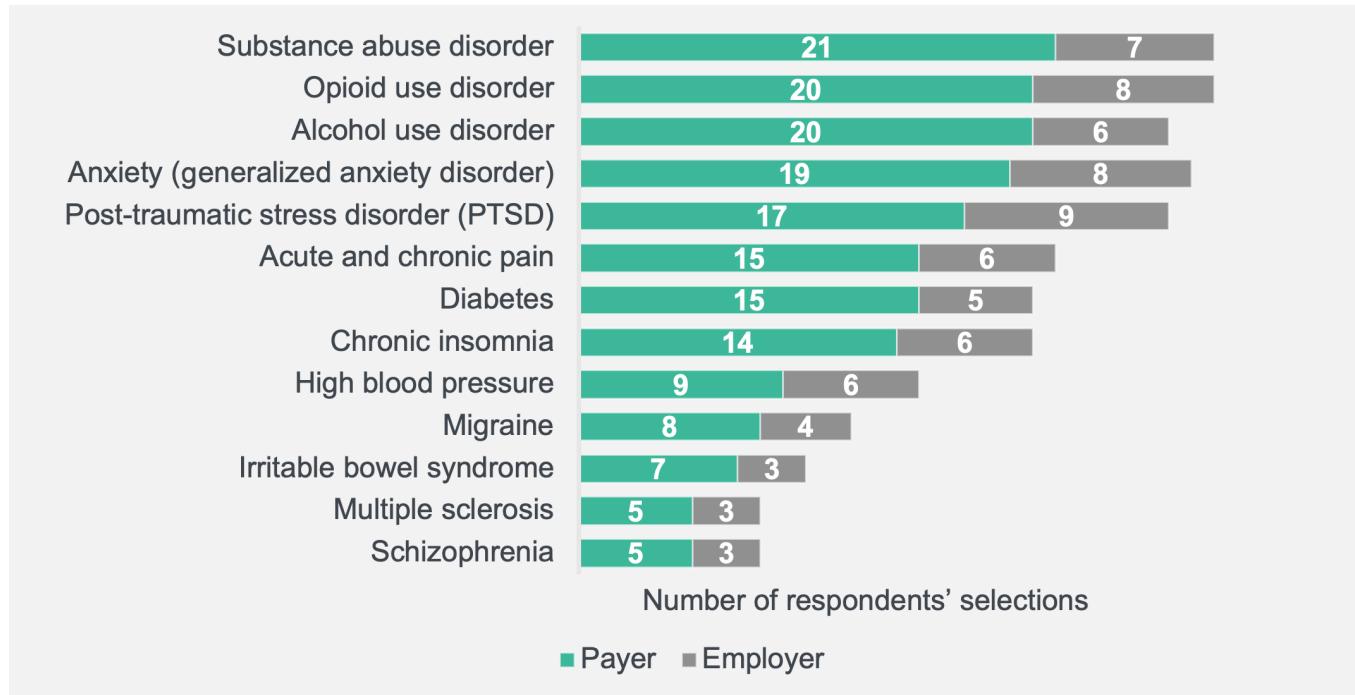
Which of the following attributes do you view as the most meaningful differentiators for PDTs?



Many respondents noted that demonstration of clinical effectiveness is most meaningful to them. This is similar to what is expected of a drug, in that efficacy and safety are most often the components most highly valued.

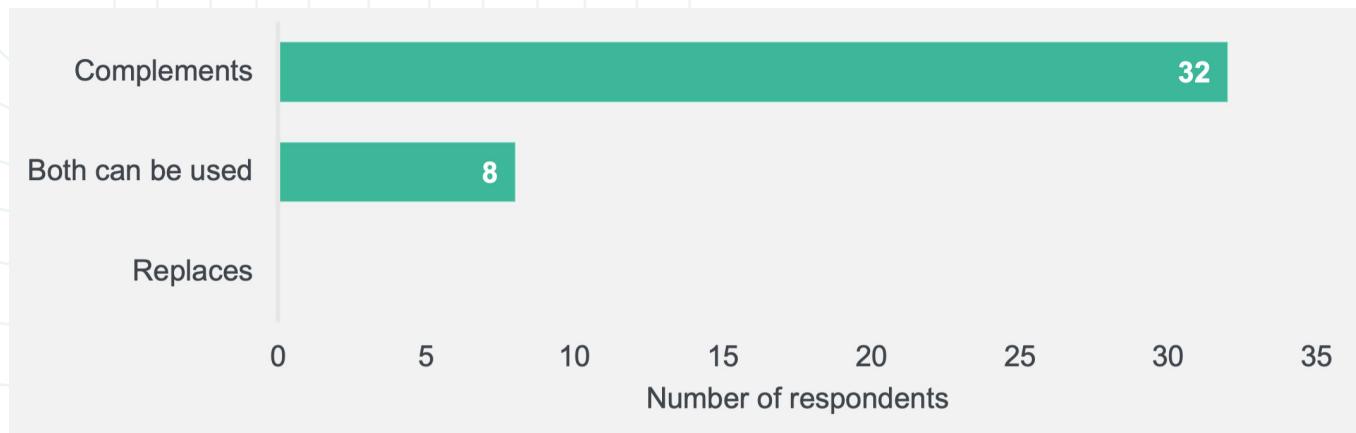
20. AMCP, AMCP Partnership Forum Develops Steps to Strengthen Evaluation of Digital Therapeutics (8 September 2021). Available at <https://www.prnewswire.com/news-releases/amcp-partnership-forum-develops-steps-to-strengthen-evaluation-of-digital-therapeutics-301371733.html>.

**Do you view PDTs as an effective tool for treating unmet needs in the disease areas below?
Please select all that apply.**



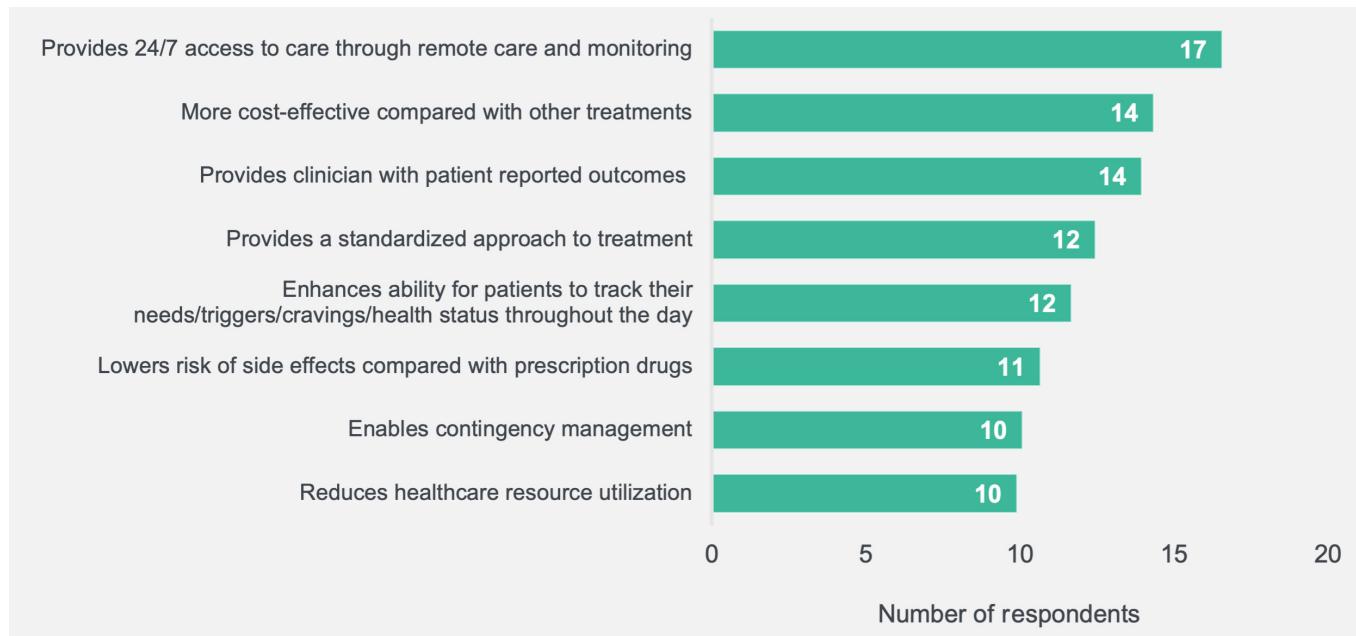
After identifying the importance of clinical efficacy, the survey also sought to understand which therapeutic areas may be best suited for PDTs. Substance use disorders, opioid use disorder, and generalized anxiety disorder were the 3 disease areas respondents identified PDTs as being most effective to treat. Mental health disorders composed the top 5 disease areas included in the survey.

Do you view PDT treatment as complementary to an existing treatment plan vs a replacement to another form of treatment?



All participants indicated that PDTs are not a sufficient replacement to another form of existing treatment, but 80% identified that they would be an effective complementary treatment. Meanwhile, the remaining 20% indicated that both PDTs and existing treatments should be used. This may indicate that it will be important to highlight where PDTs fit into the current standard of care.

In your opinion, what is the unique value proposition of PDTs?

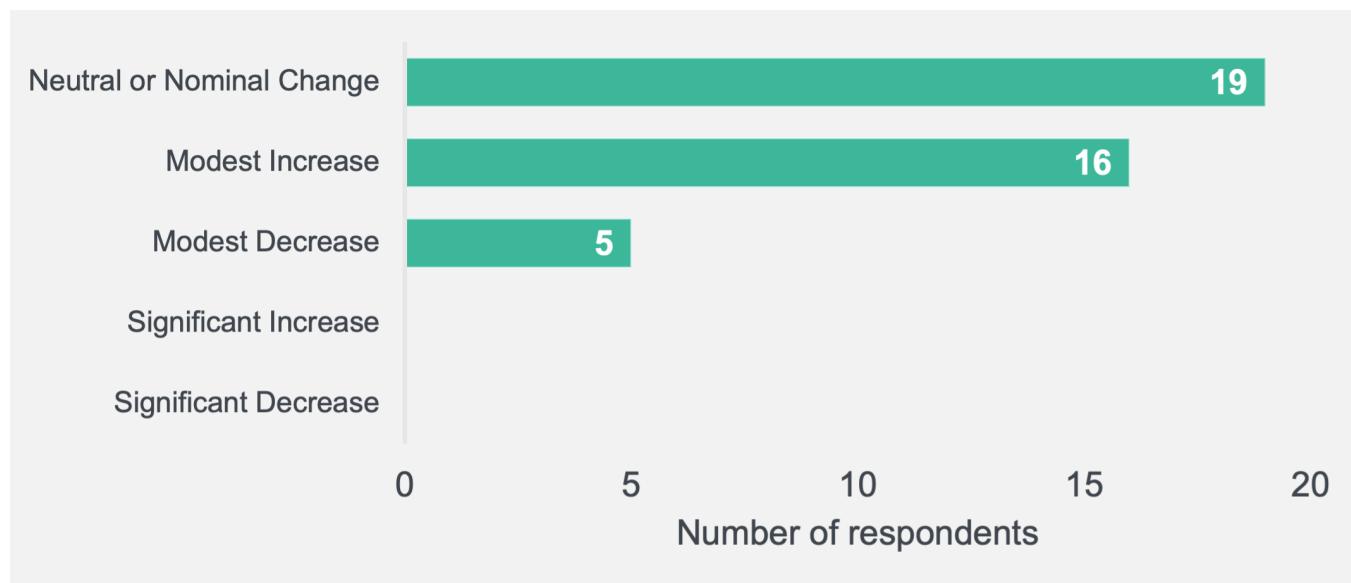


The top 3 value propositions identified in the survey were 24/7 access to care, cost-effectiveness, and providing clinicians with patient outcomes. This aligns with the need to provide better access to care, reduce the total cost of care, and utilize data to improve population health.

Respondents Indicated That PDTs Will Have a Positive Budget Impact

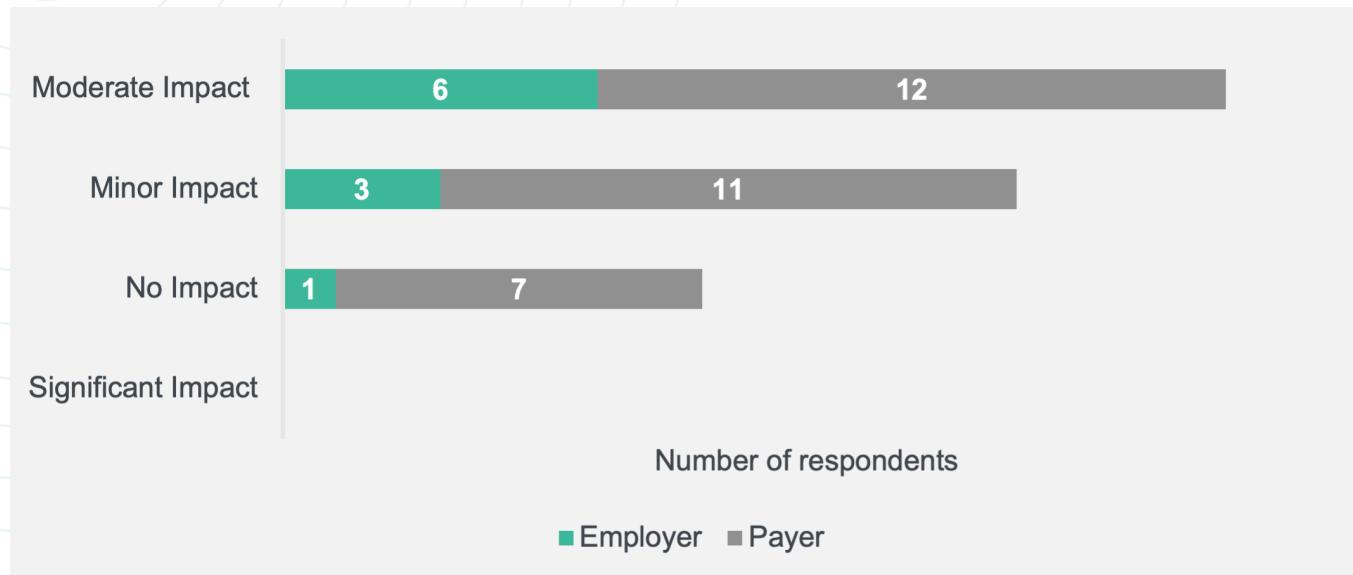
Cost-effectiveness is a major consideration for payers and employers when determining organizational coverage of any product. Although many organizations have yet to cover PDTs, 40% of respondents indicated that PDTs could incur only moderate costs to their organization as they initially move forward with covering the category.

Do you anticipate that PDTs will incur high costs for your organization?



However, over time, a majority identified that there would still be a positive budget impact in that PDTs will be cost-effective.

To what extent do you expect PDTs to have a positive budget impact? (ie, are they cost-effective?)

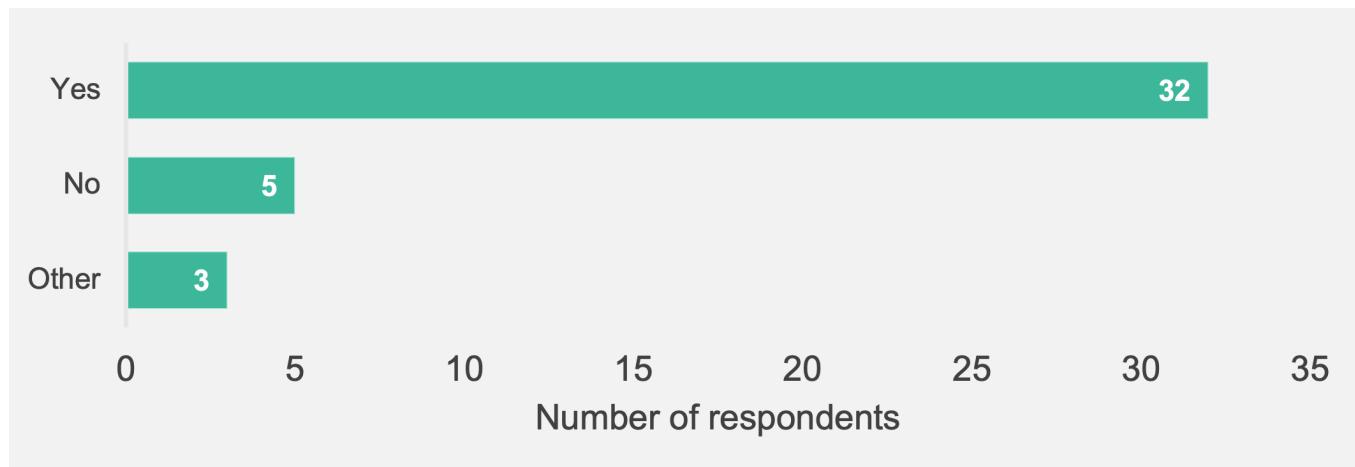


Although some research has shown that PDTs may be a valuable way to reduce costs for employers and payers, it is important to note that this insight might be somewhat speculative among respondents since many organizations have not yet adopted coverage for PDTs.

P&T Processes

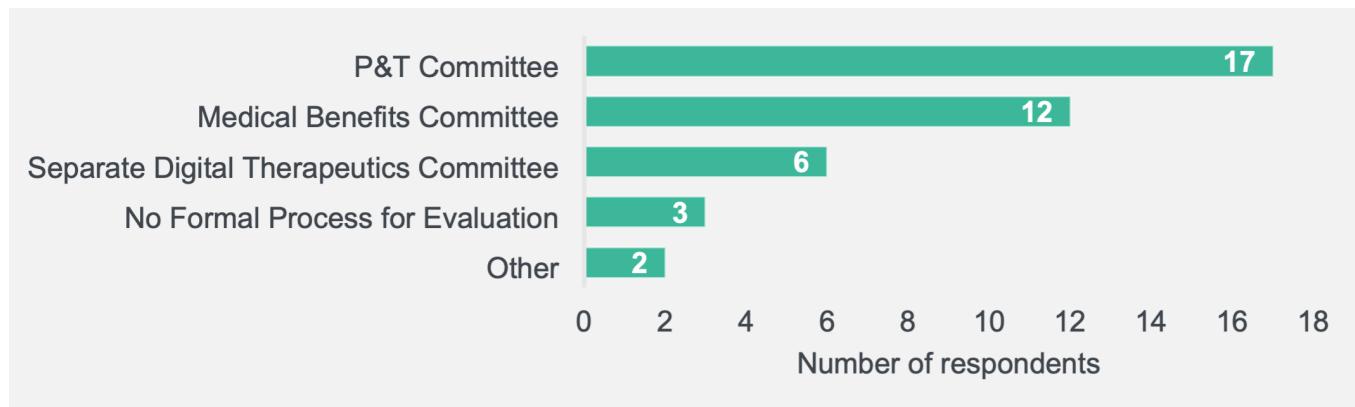
Survey Responses Highlighted a Lack of Consistency on How to Review PDTs

Are PBMs responsible for evaluating PDTs?



80% of participants indicated that PBMs are primarily responsible for evaluating PDTs. This may indicate that many expect their PBMs to determine PDT coverage, after which they may choose to opt in or opt out of coverage.

How are PDTs reviewed?



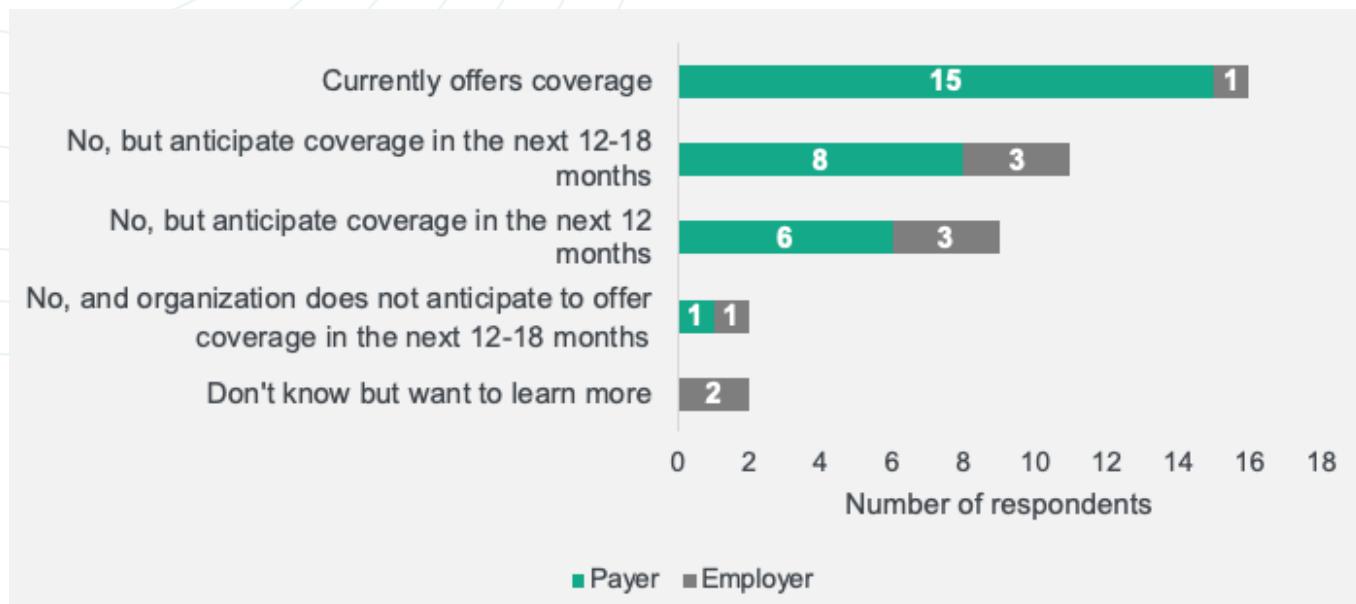
Almost half of organizations are reviewing PDTs via a Pharmacy and Therapeutics (P&T) Committee, which indicates that most respondents are thinking of this as a pharmacy benefit-covered category. However, 30% are reviewing through a medical benefit committee.

Expected Coverage of PDTs

The Coverage Landscape of PDTs Is Expected to Grow in the Near Term

While PDT coverage is still a nascent and growing part of organizations' coverage offerings, responses indicate that more organizations expect to cover PDTs in the next 12 months.

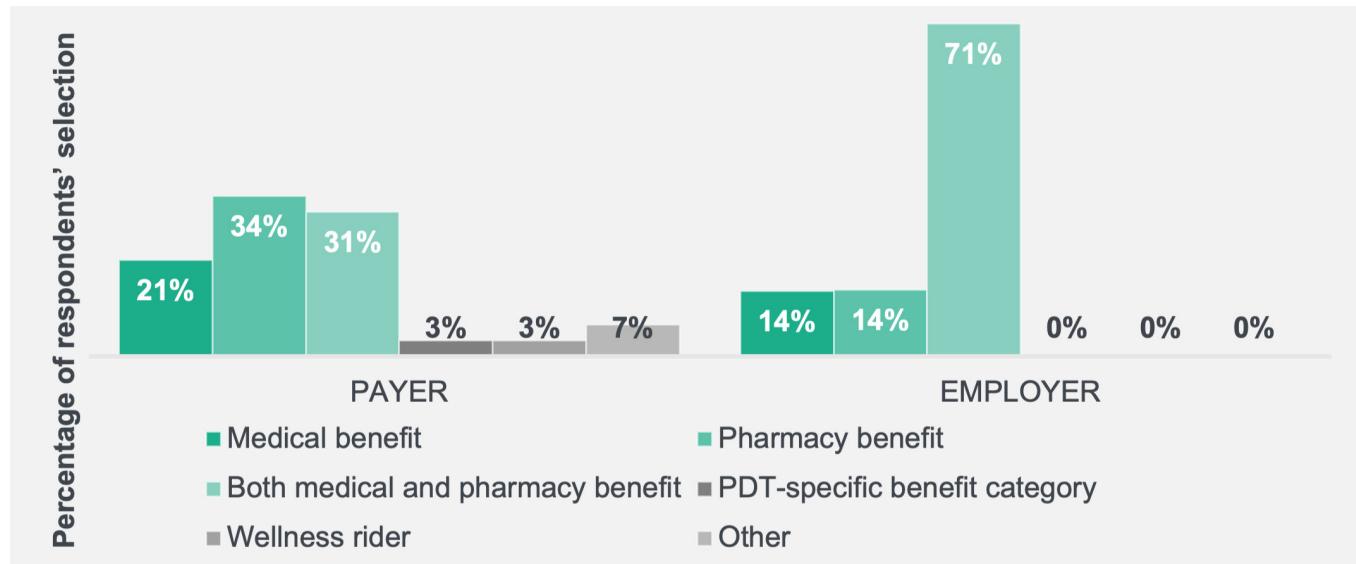
Does your organization currently offer coverage or anticipate offering coverage for PDTs?



Only 40% of respondents' organizations currently cover PDTs, but an additional 50% indicated their organizations' intention to cover PDTs in the near future, demonstrating that this may be a top priority for many stakeholders. Among those who do not yet offer coverage but will offer coverage, respondents indicated the following:

- “Actively assessing clinical and economic data.”
- “Building this formulary now.”
- “We do see this as the wave of the future.”
- “Waiting for ROI to justify price.”
- “Want to see more results and peer actions.”

Under which benefit do you or your organization cover or plan to cover PDTs?



These results show that there is currently a lack of consensus among payers and employers regarding which benefit type PDTs should be covered under. Establishing industry guidance, key considerations, and best practices for payers will be important, as they decide whether—and how—to cover PDTs.

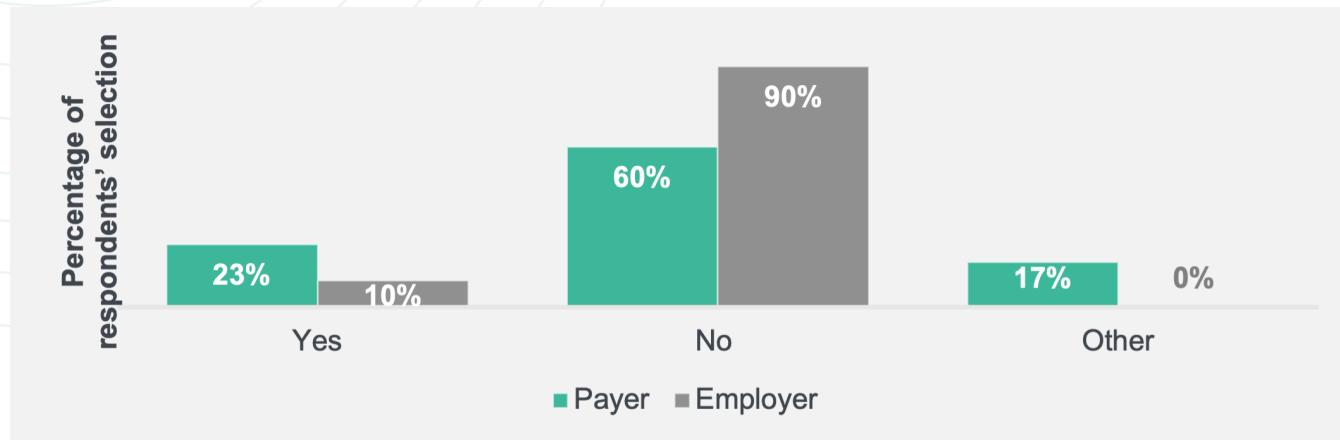
Respondent answers varied regarding benefit type for PDTs:

- Medical benefit: “Currently offer some on medical benefit because they have no drug component or [National Drug Code] ndc #.”
- Pharmacy benefit: “If a prescription is required, PDTs should be adjudicated as part of formulary coverage and pricing.”

Stakeholders Are Considering the Various Options Available to Manage PDTs

Digital health and PDT formularies are a potential strategy for managing PDT coverage. Questions remain as to what the optimal formulary looks like and where PDTs are included. Payers will need to identify if PDTs will be part of a stand-alone PDT formulary, part of an existing digital health formulary, or another formulary.

Does your organization currently have a PDT formulary?



Additional insight from this question identified that many respondents indicated that they are developing a formulary, but it does not exist yet. Some indicated that they are unsure where a PDT would fit in a formulary. Among those who do not have a PDT formulary, rationale included:

- “We do not because the area is not fully developed enough yet to have a stand-alone PDT formulary.”
- “Still in evaluation phase.”
- “Budget constraints.”
- “Still developing strategy.”

Utilization management strategies are another area of interest for both employers and payers, and impact the coverage structure of PDTs. When asked what type of utilization management strategies might be most effective, there was a broad range of answers.

- Many highlighted the use of prior authorization as a primary tool.
- Quality and outcomes tracking as well as adherence tracking were also highlighted as ways to ensure that PDTs are being used appropriately.

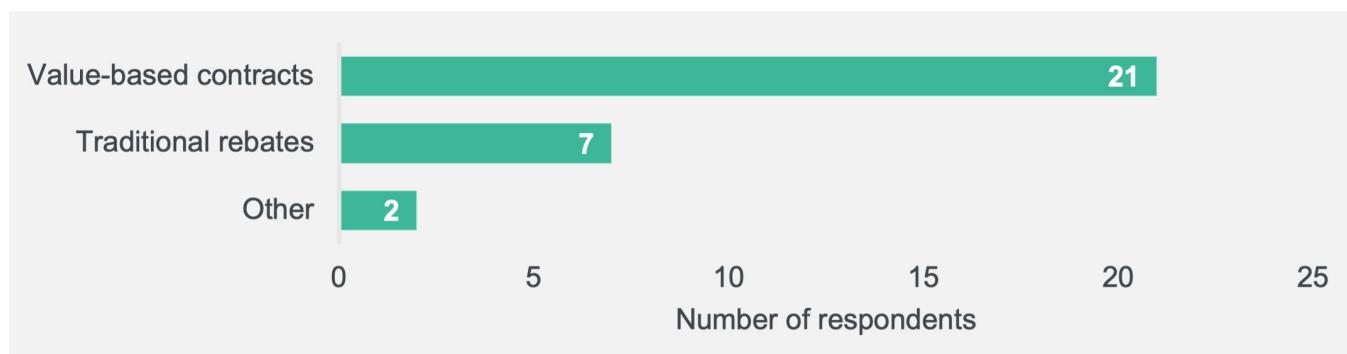
Survey data indicate that there will need to be back-end work to leverage data to identify which patients may most benefit from PDT use, highlighting potential opportunity for the use of data analytics to optimize PDT utilization.

Anticipated Approaches to Contracting

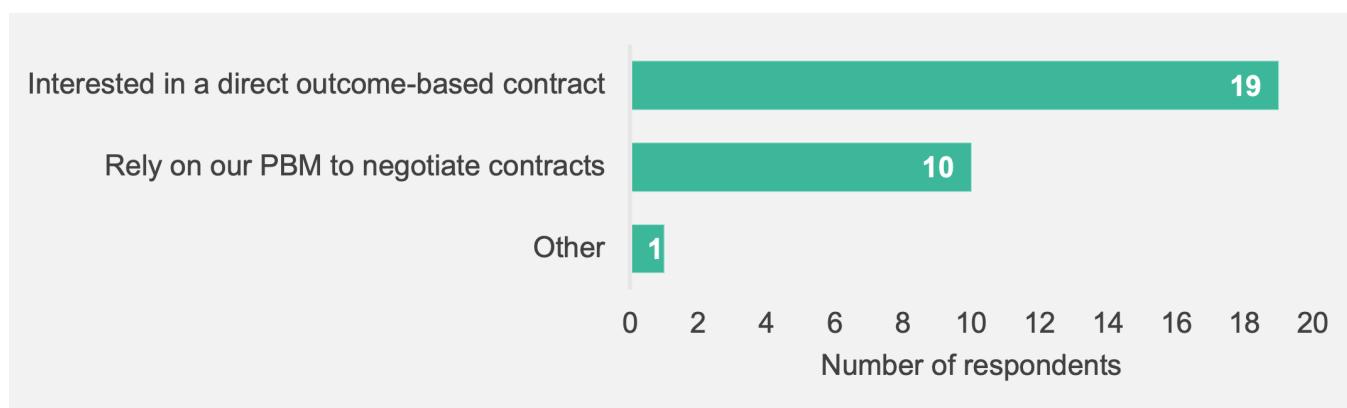
Respondents Indicate that Value-Based Contracting Would Be Most Appropriate

Payers are addressing the need to establish appropriate strategies for payment mechanisms and contract structures. Respondent answers varied but highlighted value-based contracting for PDTs as a key area of consideration.

What type of contract structure would be most appropriate for PDTs?



What are the considerations for designing a value-based arrangement with PDT manufacturers?



Most respondents indicated that value-based contracting would be the most appropriate structure for PDTs compared to traditional rebates.

When considering who would be responsible for negotiating outcomes-based contracts with PDT manufacturers, over half indicated they would be interested in a direct outcome-based contract with manufacturers, while a third of respondents handle negotiations through their PBM.

Respondents considered the following metrics as key considerations for a value-based arrangement:

- Cost savings
- Patient adherence
- Reduction in hospitalizations and physician office visit utilization
- Patient satisfaction
- Clinical outcomes
- Reduced patient fall-off

Additional insight from payers on key considerations for a value-based arrangement highlighted considerations such as:

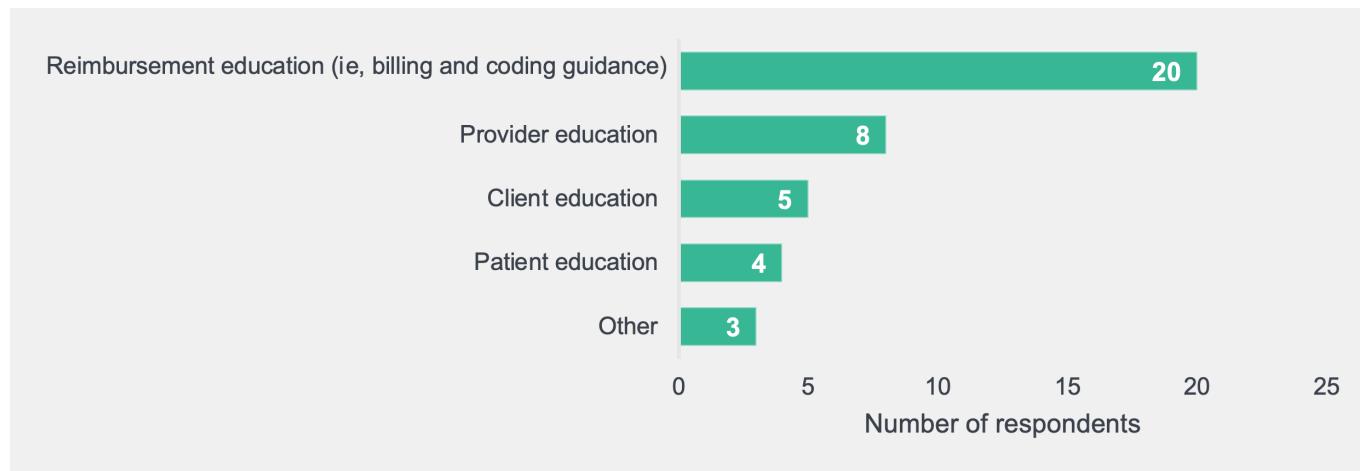
- “Overall reduction in hospitalizations and additional diagnostic testing.”
- “Adherence, number and percentage of complications, patient quality of life, treatment outcomes and ease of use.”
- “Actual outcomes including improved condition management, reduction in future admittance, decreased longer term costs, [increased] patient satisfaction, greater mobility, better adherence, reduced patient fall-off.”

Challenges and Opportunities

Organizations Are Focused on Understanding How to Educate Providers

Not only are payers and employers considering what a PDT coverage structure may look like, they are also considering how to support providers and patients.

Where do you anticipate the greatest need in promoting adoption of PDTs?



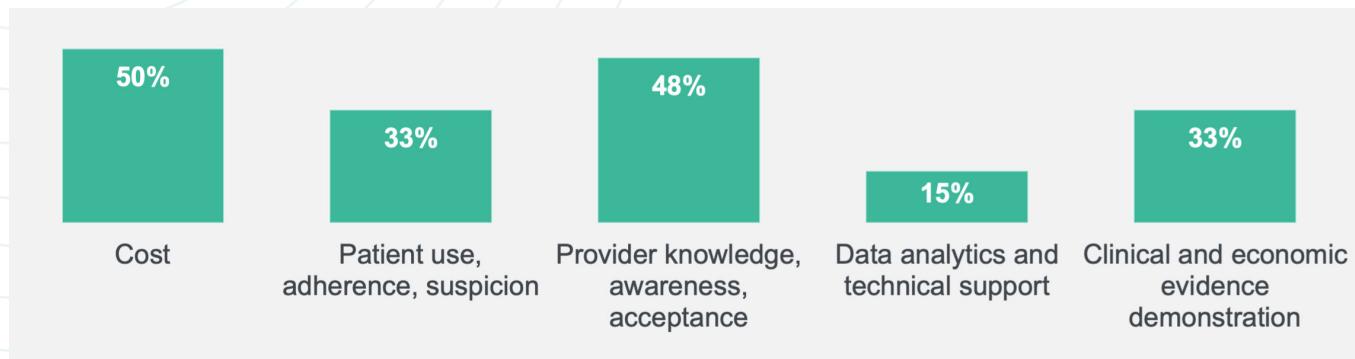
Half of respondents identified that coding and reimbursement education will be vital for promoting PDT adoption.

Looking Forward, Stakeholders Have Identified Key Areas of Opportunity and Growth as Well as Challenges Related to PDTs

Although the results of the Digest indicate that PDTs are an area where leaders are dedicating great thought to what coverage may look like, key challenges were also identified.

Respondents were asked to identify the top 3 barriers and opportunities to PDT adoption. The following figures capture these key barriers and opportunities.

What are the top 3 barriers to PDT adoption in your view?



What are the top 3 opportunities for PDTs in your view?



Cost continues to be an area of uncertainty, where stakeholders are unsure about the true cost impact of PDT adoption and long-term use. To alleviate this concern, manufacturers can:

- Show cost offsets
- Engage in value-based contracting to mitigate risk
- Clearly identify the population appropriate for treatment

To support providers, manufacturers can:

- Provide materials for payers to give to their network of providers
- Engage providers in webinars led by thought leaders
- Work with provider offices to better understand their needs

While stakeholders identified that there are still barriers to adoption, they also recognized that there is a valuable opportunity to bring care to patients through this modality. Respondents noted that showing improved patient adherence and cost-effectiveness are opportunities for PDT manufacturers.

Recommendations



Establishment of Recommendations for PDT Coverage Will Help Guide Employers and Payers as They Navigate the PDT Landscape

The results of this survey highlighted that there are areas where best practices related to PDTs and their coverage are limited, and that stakeholders may need more education on what truly differentiates PDTs from other tools across the digital health landscape. Recommendations for PDT adoption highlight the need for the development of operationalizable steps that payers and employers can take, and main ideas that they should consider.

The results of this survey elucidated that the stakeholders highly value FDA authorization, but may need more education on the process. In addition, the survey found that the current approach and process to covering PDTs is inconsistent. However, we did see consistent responses in terms of what payers will value when reviewing PDTs, when they expect to cover the category, and how they may approach contracting using value-based contracts. As we mentioned upfront, we attempted to take the results of this survey and develop that into a working road map that could be considered when covering PDTs.

As such, organizations could consider the following as they approach coverage for the PDT category:

1. Determine a process and timeline for covering PDTs that include answering:
 - a. What entity in the organization may review the product?
 - b. How many days after FDA authorization will the product be reviewed?
 - c. Will PDTs fall under the pharmacy or medical benefit?
2. Understand the FDA authorization process required for PDTs to reach the market;
3. Establish evidentiary requirements to review PDTs, which may include development of a harmonized way to review the category;
4. Define contracting incentives tied to outcomes (eg, value-based contracting);
5. Confirm (with the PDT manufacturer) that the proper steps have been taken to ensure the privacy of patient-level data;
6. Establish and communicate best practices as it relates to the management of PDTs; and
7. Support providers and patients, who will prescribe and utilize this technology, respectively.

Editorial Advisor Biographies



Editorial Advisors



Katie Archer, BBA

Director, Director, Health and Welfare Benefits Design, Planning and Analysis,
The Hartford Financial Services Group

Katie is a director at The Hartford Financial Services Group, Inc., and focuses on designing meaningful health and welfare insurance plans for employees. Prior to working at The Hartford, she managed domestic and international benefit and well-being programs at Alexion Pharmaceuticals, International SOS, and Goldman Sachs. Katie is a graduate of Susquehanna University and lives in Connecticut with her husband and 2 children.



Pat Gleason, PharmD, FCCP, FAMCP, BCPS

Assistant Vice President, Health Outcomes, Prime Therapeutics

As assistant vice president, Health Outcomes, at Prime Therapeutics (Prime), Dr. Pat Gleason leads Prime's clinical health outcomes assessment team in developing and improving pharmacy benefit management programs. Through integrated medical and pharmacy claims data analysis, he assesses clinical program opportunities and post-implementation outcomes. In addition, he negotiates and fulfills pharmaceutical manufacturer value-based purchasing agreements.

Dr. Gleason has more than 40 peer-reviewed publications in medical and health policy journals, including the *Journal of Managed Care & Specialty Pharmacy* (JMCP), *Value in Health*, *American Journal of Managed Care*, *Medical Care*, *Health Affairs*, and *JAMA: The Journal of the American Medical Association*.

Dr. Gleason is on the board of directors for the Academy of Managed Care Pharmacy (AMCP), is a past chair of the JMCP Editorial Advisory Board, and currently serves as an Adjunct Professor at the University of Minnesota, College of Pharmacy. He is a board-certified pharmacotherapy specialist (BCPS), an elected Fellow of the American College of Clinical Pharmacy (FCCP) and an elected Fellow of the Academy of Managed Care Pharmacy (FAMCP).

Dr. Gleason earned his bachelor of science and pharmacy doctorate degrees at the University of Minnesota. He completed an ambulatory care pharmacy practice residency at the University of Pittsburgh Medical Center and a fellowship in outcomes research through the University of Pittsburgh, School of Pharmacy.

**Kelly McGrail Pokuta, PharmD**

Chief Trade Relations Officer and Vice President of Trade Relations and Strategy, Prime Therapeutics

Dr. Kelly McGrail Pokuta is currently chief trade relations officer and vice president of Trade Relations and Strategy at Prime Therapeutics. Her team is responsible for pharmacy and medical rebates, manufacturer contracting, value-based care initiatives, and trade client strategy services.

Most recently, Kelly served as principal/owner of Specialty Strategy Solutions, a healthcare consulting company established in 2017 and located in the Chicagoland area. Clients included pharmaceutical manufacturers, specialty pharmacy providers, payors/PBMs, and other life sciences organizations.

With more than 30 years of healthcare experience, Kelly brings a wealth of industry knowledge. Before joining Prime Therapeutics, she served as senior vice president, Industry Relations where she led Diplomat Pharmacy, Inc., the largest independent specialty pharmacy in the United States, in developing and managing relationships with pharmaceutical manufacturers and PBMs/payors. She was also responsible for overall specialty strategy and channel management, contract management and implementation, and specialty pipeline and generic strategies. Prior to Diplomat, she was vice president, Specialty Pharmacy and Industry Relations at OptumRx, a United Healthgroup Company.

Kelly has also held roles at CVS Health, Takeda Pharmaceuticals North America, Premier Inc., and the University of Illinois College of Pharmacy. Her expertise includes managed care, new product development, brand strategy and marketing, physician practice management, drug intelligence and pipeline management, payor access, and manufacturer contracting. She has extensive clinical experience including hematology/oncology, neurology, infectious diseases, and immunology.

Kelly earned her doctor of pharmacy at the University of Illinois College of Pharmacy. She completed her postgraduate pharmacy practice residency at the University of Illinois Hospital and Clinics. Kelly also obtained credentialing as a board-certified pharmacotherapy specialist.



Michael Rothrock, BS, MBA, MHA
President, Allegheny Strategic Partners LLC

Michael brings over 20 years of experience within both the managed care as well as the pharmacy benefit manager (PBM) industry, working in both national and regional health plans as well as a large national PBM. He has an excellent reputation for negotiating skills, leadership, delivering financial results, resolving problems, building relationships, and overall healthcare industry and PBM drug formulary tactics.

As a former pharmacy senior leader across multiple lines of business, Michael provides a high-level approach to payer strategy by leveraging a variety of perspectives, including clinical, financial, trade relations, trend/utilization management, contracting, and formulary tactics. Michael has a vast amount of experience within pharmacy benefit management, contracting GPOs, pharmacy and medical benefits as well as a variety of reimbursement options and decision-making methodologies.

Before creating Allegheny Strategic Partners LLC, Michael was the VP of Pharma Strategy and Contracting at Express Scripts, where he was responsible for leading commercial and Medicare formulary contracting and strategy, as well as leading a team of contracting directors who consistently delivered results for their downstream clients. Prior to his time at Express Scripts, Michael worked at Aetna and Coventry Health Care, Inc. in a variety of areas, including commercial and Medicare formulary management, manufacturer contracting, specialty drug management, retail networks, MAC pricing, medical benefit contracting, and J-code pricing.

Michael received his MBA/MHA degree from the University of Pittsburgh as well as his bachelor of science from the University of Pittsburgh and currently resides in Pittsburgh, PA.