



BRIEF

Operational Readiness for Covering Prescription Digital Therapeutics

EXECUTIVE SUMMARY

The Academy of Managed Care Pharmacy (AMCP) convened a focus group in March 2024 to discuss operationalizing the coverage of prescription digital therapeutics (PDTs) by health payers. The focus group was comprised of seven health payer experts from commercial health plans, pharmacy benefit managers, and state Medicaid programs.

The focus group discussed the following issues:

- Evidentiary standards that justify coverage.
- Coding practices required to facilitate coverage.
- Considerations for benefit design.
- Unique supply chain and reimbursement requirements.
- Federal legislation that would authorize Medicare coverage of PDTs.

PDTs offer significant promise in treating certain conditions and improving access to care, but participants agreed that a new modality requires new approaches to coverage.

This brief, which summarizes the focus group's findings, is intended to help prepare the American health care system to begin covering PDTs.

- **Health payer** readers will learn about the unique considerations for evaluating PDTs for coverage and incorporating them into their benefit design.
- **PDT developer** readers will learn more about the needs of health payers to better inform the development of their products and informational materials.

Using Comparisons and Evidence to Guide Utilization

Overall, focus group participants believed that PDT manufacturers need to provide payers with evidence above and beyond the standard required by the Food & Drug Administration (FDA) for medical devices to achieve formulary coverage.

Pharmacy and Therapeutics (P&T) Committees will typically review products that have gone through one of the drug approval pathways established by the FDA. Though the evidentiary standards vary, drug approval pathways generally require product sponsors to conduct pre-market randomized controlled trials (RCTs) to demonstrate the product's safety and efficacy. The P&T Committee relies on RCT results to evaluate the relative clinical and economic benefits of each product and design programs to monitor potential safety concerns.

Many P&T Committees are unfamiliar with the FDA's medical device pathways and are hesitant to include PDTs on formulary. Most PDTs are classified as Class II medical devices and receive pre-market clearance by the FDA under either the De Novo or 510(k) pathways as Software as a Medical Device. Focus group participants found that formulary decision-makers are most concerned with the 510(k) pathway, which generally does not require clinical trials but relies on other clinical data to determine whether a device is substantially equivalent to another device that is already on the market.

PDTs' classification as medical devices also creates confusion about whether the P&T Committee is the appropriate body to review these products. This may result in some products falling through the cracks as neither the P&T Committee nor the medical benefit team review the PDT and make a coverage determination. The focus group participants agreed that AMCP should provide education to formulary decision-makers about the FDA's approval pathways for Software as a Medical Device, including the 510(k) pathway, which could improve the capacity of P&T Committees to review PDTs.

The participants recommended several options for PDT manufacturers to meet the evidentiary standards required by P&T Committees to have a product placed on a payer's formulary. The first option is to conduct RCTs that provide greater causal validity than other forms of evaluations.

Participants also agreed that PDT manufacturers should publish comparative studies that demonstrate where PDTs fit within existing standards of care, particularly in combination with other treatments. Another option is to supplement clinical data with real-world evidence (RWE). Although RWE cannot substitute for RCTs, this information can provide evidence that guides real world utilization as well as effectiveness for groups that tend to be underrepresented in clinical trials. The focus group participants agreed that it is the PDT manufacturer's responsibility to develop this evidence.

Striving for Consensus on PDT Classification and Coding Practices

Existing coding and reimbursement systems are not optimized for PDTs, particularly if these products are going to be covered under the pharmacy benefit. For example, participants noted existing PDT billing codes cannot be easily adapted to pharmacy reimbursement. Coding systems and national compendia deal with PDTs differently (or don't recognize them at all). This complicates pharmacy claims processes that rely on a disparate chain of verifications. Participants likened the current coding situation to trying to maintain a beehive without a beekeeper.

In 2022, the Centers for Medicare and Medicaid Services (CMS) established two HCPCS Level II A-codes for PDTs, which apply to cognitive behavioral therapy or visual therapy. These codes are used to reimburse physicians and are not generally used to process pharmacy claims. They also lack specificity, meaning that products with very different characteristics will be recognized as the same when filling out a claim.

Other coding systems and compendia that influence pharmacy billing systems do not recognize PDTs at all. For instance, these products often do not have national drug codes and are not always included in drug databases managed by First Databank or the US Pharmacopeia. Until a comprehensive coding scheme is developed, PDT developers should ensure that their products are listed in the appropriate compendia and apply for national drug codes if they believe their product is appropriate for the pharmacy benefit. Pharmacy billing systems require information such as a product's national drug code and classification in nationally recognized compendia to perform near instantaneous verifications at the point-of-service. The absence of a national drug code render PDTs ineligible for rebates under the Medicaid Drug Rebate Program, which may make PDTs less appealing for state Medicaid programs.

The focus group participants agreed that the FDA, CMS, and other stakeholders must find consensus on a unified approach to PDT classification that will facilitate claims processing. Pharmacy claims adjudication could be optimized if PDTs were made to "look like a drug." Under this approach, the FDA would establish unique 11-digit "national prescription digital codes" (NPDCs) for each PDT that would mimic a national drug code. National compendia would provide summaries of FDA-cleared PDTs that would include criteria used to match products to their appropriate code, like the product's therapeutic category, standard days' supply, and unit of billing.

The focus group agreed that AMCP should play a leading role in the development of a comprehensive coding and reimbursement system for PDTs. AMCP can shape the conversation around PDT coding by convening key stakeholders and advocating for novel approaches like NPDCs.

The Evolving Conversation Around Benefit Design & Differentiation

PDTs create unique challenges to benefit design when compared to traditional pharmaceuticals and biologics. Due to the at-home nature of many PDTs, it will often be appropriate to cover them under the pharmacy benefit. Other PDTs are used in the presence of a physician or therapist and may belong under the medical benefit.

The following cascade of criteria are used in determining whether a product belongs in the medical or pharmacy benefit:

- Site of care — where the patient will actually use the therapy.
- Reimbursement — whether through the pharmacy or physician's office.
- Fulfillment process — where the prescription is filled.

Site of care is a top consideration for designing PDT coverage. PDTs that can be used in settings other than a provider's office, like a patient's home, are more appropriate for the pharmacy benefit than the medical benefit. This is comparable to the patient experience for prescription drugs.

Covering PDTs under the pharmacy benefit would also reduce patient complications in accessing and paying for their treatment. Pharmacy claims are adjudicated instantly at the point of sale, and the patient knows their out-of-pocket costs at that time. Medical claims can take weeks to process and may surprise patients when the bill arrives. This may require a delay in dispensing access codes or related equipment needed to use the PDT, unlike the instant processing of a pharmacy claim. However, dispensing the PDT at the prescriber's office will likely improve patient uptake and adherence, due in part to the greater access to patient educational resources, including the prescribers themselves.

Because PDTs will be a new treatment modality for most patients, patient education is another key concern for benefit design. Whatever system is in place must be prepared to provide additional information to patients. Physician practices may be resistant to hiring new staff or devoting limited staff time to conduct hands-on training. The focus group recommended that manufacturers develop robust, detailed training materials that are accessible in multiple languages. This training should largely be available within the PDT program itself. The advantages of using the "cleaner" pharmacy claims process must be weighed against the availability of and need for patient education and training.

The mere fact that some payers commonly cover devices under the medical benefit complicates the issue across our health care system. While practices will vary across payers, there is ample precedent for covering medical devices under the pharmacy benefit, especially when the device is closely associated with drug

therapy. As an example, Medicare Part D plans cover certain insulin pumps and other devices used to inject insulin, which are commonly dispensed at pharmacies.

Participants acknowledged that benefit design will likely evolve over time as payers develop a more comprehensive perspective on PDT technology. Interestingly, they may default to the medical side initially because it is easier to switch a product from medical to pharmacy rather than vice versa. Payers should consider the impact of their benefit designs on providers both in terms of amount of payment to the provider and administrative costs.

Finding Equilibrium Across PDT Funding, Supply Chain, and Reimbursement

Lack of a standard reimbursement structure

The lack of a statutorily defined Medicare and Medicaid benefit category for PDTs has given way to a nationwide patchwork of reimbursement strategies and coding practices for these products. While some private payers may elect to cover PDTs, others have hesitated, given the significant uncertainty around how PDTs may be reimbursed.

Although a statutorily defined coverage category for PDTs would help regulate reimbursement and coding procedures among public and private payers, supply chain considerations also play a major role in determining the best avenue for reimbursement. Focus group participants agree that reimbursement strategies ultimately depend on whether the PDT is prescribed as a standalone product, or if it is used in conjunction with drug therapy or related health care service. They believe that reimbursement would be streamlined for PDTs that are paired with drugs already covered under a plan's formulary. For PDTs considered under the pharmacy benefit, manufacturers may also need to offer rebates to secure placement on a prescription drug formulary.

Value- and outcomes-based solutions

It remains unclear whether PDTs can demonstrate a causal relationship between the administration of treatment and clinical changes in a patient. Nonetheless, focus group participants agree that value- or outcomes-based arrangements (VBAs) and bundled payments are pathways to increase the uptake of PDTs. To better understand the health outcomes associated with the use of PDTs, manufacturers and payers must agree on more comprehensive indicators beyond the patient's use of a PDT.

Many PDTs can collect real-time health information, including demographic data and biometrics, from their users. When used in combination with other drug therapies, these PDTs may augment the collection of RWE related to the course of treatment. To supplement the collection of outcomes data, focus group participants

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found that payers could require PDT manufacturers to administer validated testing instruments, or collect patient-reported outcomes through the application or device itself. Understandably, payers will seek data that demonstrates the PDT's ability to measure a clinical change in the patient's health, as well as a measurable reduction of health care utilization. Bundled payments also increase the incentive for health care providers and patients to use PDTs, when clinical evidence demonstrates the product's ability to lower the total cost of care. It is important to note that a PDT must have the ability to demonstrate safety and efficacy, before bundled payments can be considered.

Research & development funding concerns

Unlike traditional pharmaceutical manufacturers, focus group participants note that many PDT manufacturers rely on investments from venture capital firms. Participants agree that the unique funding structure for PDT manufacturers, which prioritizes quick returns on the venture capital investments, inhibits manufacturers' ability to develop RCT data. PDT manufacturers, many of whom lack the sustained funding necessary to conduct long-term drug development trials, are unable to share RCT data with payers, which exacerbates payers' unwillingness to cover PDTs. This, in turn, leads to a vicious cycle where venture capital firms pull funding due to a lack of product uptake.

Focus group participants believe that the investment structure used by many PDT manufacturers must significantly shift to prioritize the long-term, data-driven development of these therapies. Although they are fundamentally different than traditional drug therapies, PDTs must be treated as such when it comes to funding research and development.

Advancing Federal Legislation to Expand Patient Access to Affordable, Novel Therapies

The Access to Prescription Digital Therapeutics Act of 2023 (S. 723/H.R. 1458) is a federal bill that would create a Medicare benefit category for prescription digital therapeutics. The bill also directs CMS to develop product-specific HCPCS codes for PDTs and to create a reimbursement framework.

The absence of language addressing NDCs or an NDC-like code in the legislation was identified as a potential problem for implementation. Many PDTs are most appropriate under the pharmacy benefit and using only HCPCS codes could unintentionally push coverage entirely into the medical benefit. While it is possible to translate a HCPCS code into pharmacy claims adjudication, participants agreed that the obstacles associated with doing so would strongly discourage coverage. Participants recommended updating the language to include a coding approach appropriate for the pharmacy benefit.

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Overall, focus group participants felt that the passage of the Access to PDTs Act would be a major milestone for expanding coverage of PDTs. Several participants noted that commercial payers do not currently cover PDTs because “they don’t have to.” Creating a federal scheme for public programs to cover and reimburse for PDTs would put additional pressure on commercial payers to also cover them.

PDTs have the ability to help millions of Americans receive the care they need to treat a growing range of conditions and illnesses. It is imperative that health payers and PDT developers work together to ensure that patients have cost-effective access to these novel therapies.

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