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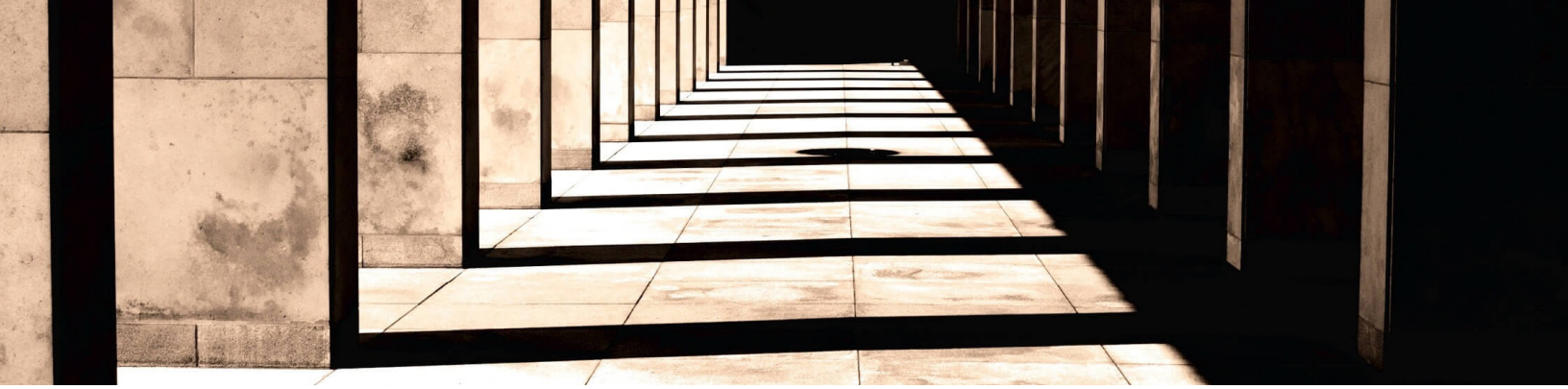
Katie Hayes
Rachel Rothschild MPH
Voytech Sudol MBA

Policy Initiatives Can Improve Access to Prescription Digital Therapeutics



Current policies lack PDT coverage guidance

Mental health is a growing public health issue, with more than 20% of adults experiencing a mental illness, equivalent to more than 50 million Americans.[1] The prevalence of mental illness in the United States has increased over the last decade, particularly in young adult age groups.[2] At the same time, 55% of adults with a mental illness go untreated because of significant barriers in mental health care, including patients' inability to afford care and worsening provider shortages.[3] Though there has been some movement at the Congressional level to enhance mental health coverage, action to address regulatory barriers has been marginal.

Prescription digital therapeutics (PDTs), clinically validated, FDA-authorized, software-based interventions intended to prevent, manage, or treat mental or physical conditions, are designed to help address some of these barriers in mental health care. With the rapid growth of the PDT market, this new therapeutic offering could alleviate the burden of mental illness and address the demand for new or alternative treatment options. However, there is a need for legislative initiatives and modifications to current medical policies to ensure that these digital therapeutics are more accessible to those in need.

In 2022 alone, 2 legislative initiatives were introduced in each house of Congress that addressed reimbursement and coverage for PDTs. The first bill, the Access to Prescription Digital Therapeutics Act of 2022, introduced in both the House of Representatives and the Senate in March of that year, defined Medicare and Medicaid coverage and reimbursement categories for PDTs and expanded access to these products.[4,5]

In December 2022, the Medicaid Children's Health Insurance Program (CHIP) Access to Prescription Digital Therapeutics Act was introduced in the Senate. This bill provided a framework for coverage of PDTs under Medicaid and CHIP and gave states clarity regarding coverage and reimbursement of these products.[6] Although neither of these bills was included in the FY2022 Omnibus Appropriations Bill passed in December 2022, the introduction of the bills shows that the federal government is recognizing the momentum of PDTs and the need for legislation that clarifies reimbursement and codifies the definition of PDTs. In fact, the Access to Prescription Digital Therapeutics Act of 2022 was reintroduced on March 8, 2023, in both the House of Representatives and Senate.[7,8]

As the PDT market continues to grow, recognition from legislators and payers will be necessary to ensure more access to these products. Although the 2 PDT access bills introduced in 2022 were not incorporated in the FY2022 Omnibus Appropriations Bill, the appropriations bill did include legislation that was previously introduced as the Pre-Approval Information Exchange (PIE) Act of 2022.[9] This is important for PDT manufacturers, especially as this market continues to grow, because the inclusion of what was formerly known as the PIE Act of 2022 within the FY2022 Omnibus Appropriation Bill codifies the FDA's final guidance from 2018, making it law. The guidance stated that the communications addressing health care economic information (HCEI) that are mentioned in Section 502(a) of the Food and Drug Administration Modernization Act of 1997 apply to both drug and device manufacturers.[10] However, up until this point, this was only guidance and not law. With the inclusion of the PIE Act of 2022 within the Omnibus bill, the language has been updated to refer to both drugs and devices, allowing manufacturers to communicate earlier with payers, potentially leading to coverage and formulary inclusion.[11]

Both private and public payers are also experiencing the impact of the increasing number of PDTs entering the market and the need to clearly define them. Plans such as Premera Blue Cross have created thorough medical policies outlining all of the necessary criteria for a PDT to be considered medically necessary, such as the need for credible scientific evidence and information that the product is proven to improve health outcomes. Though none of the PDTs on the market today meet these criteria, Premera does provide a complete list of products that it considers investigational at this time, which includes guidance to other manufacturers as to the plan's expectations.[12] Other plans, for example Highmark's, have also outlined the necessary criteria for PDTs to be considered medically necessary, but unlike Premera, they do not require that PDTs demonstrate scientific evidence beyond FDA authorization. As a result, Highmark currently covers 9 PDTs, including products such as Somryst, NightWare, and EaseVRx, which are clearly listed in its medical policy.[13]

With rates of mental illness increasing, and a multitude of existing barriers to access care, PDTs are a natural answer to the growing public health problem. Lumanity's research indicates that payers expect PDTs to deliver tremendous value both for them and their plan members. More importantly, having a clearly defined evaluation process and reimbursement pathway will enable payers to offer additional coverage to members, while potentially satisfying a multitude of quality measures. As such, it is imperative for payers to closely watch the development of policy as it relates to PDTs.

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