

# ACTION for PDTs (Prescription Digital Therapeutics)

## *A Prospectus for Stakeholder Organizations*

### **Mission**

ACTION for PDTs is a multi-disciplinary partnership that works to expand the adoption of, coverage of, and access to prescription digital therapeutics (PDTs) for individuals with chronic diseases. By accelerating the use of this novel technology, we aim to improve therapeutic outcomes for people with chronic diseases, including those in underserved communities, meeting people where they are, whoever they are. As such, ACTION stands for Adoption, Coverage and Access, Therapeutic Outcomes, Inclusion, Options, and Novel Technology.

### **Introduction**

Chronic conditions affect 60 percent of the U.S. population,<sup>1</sup> and it is estimated that treating chronic conditions accounts for more than 85 percent of the nation's health care costs. Additionally, one of the most dramatic demographic shifts in history is underway as [more than 10,000 U.S. adults turn age 65 every day](#) through 2030, putting added pressure on the health system. Therefore, it is critical to accelerate the adoption of new therapeutic interventions that have significant potential to reduce the burden of chronic diseases and to overcome the barriers that result in suboptimal care. This includes addressing the numerous behavioral, social, economic, medical, and policy-related issues affecting adherence to treatment regimens. [Lack of adherence, in particular](#), causes nearly 125,000 deaths a year, 10 percent of hospitalizations, and costs the already strained healthcare system between \$100-\$289 billion a year.

Additionally, the COVID-19 pandemic has highlighted growing health disparities in the U.S. and the need to address these inequities in underserved communities. For example, [studies](#) have shown that communities of color and low-income individuals who face elevated risks for many health conditions are also more likely to experience transportation barriers that prevent them from accessing care. As such, patients require access to care wherever and whoever they are.

Against this backdrop, the emergence of prescription digital therapeutics (PDTs) is especially significant. Considered a new category of therapeutics, PDTs are evidence-based medical interventions using software that can be accessed on a tablet or smartphone to prevent, manage, or treat a range of diseases and disorders. As such, PDTs deliver high-quality diagnostic care and treatments without requiring patients to travel to a healthcare facility.

PDTs are similar to traditional therapeutics in several ways. For example, they are regulated by the FDA. As such, they are tested for safety and efficacy, developed using strict quality standards, and labeled according to FDA requirements. Additionally, PDTs are only available to patients when prescribed by a licensed healthcare provider and must be used under clinician supervision. They are also eligible to be priced and reimbursed similar to traditional medication via federal, state, and commercial insurers.

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<sup>1</sup> Centers for Disease Control and Prevention. Chronic Diseases in America. Accessible at: <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>

Today, PDTs approved or cleared by FDA and those undergoing clinical trials aim to treat a variety of diseases and disorders, including cancer and Type 2 diabetes, chronic stroke, multiple sclerosis, Parkinson's disease, autism, chronic insomnia, ADHD, and many mental health conditions. Yet, access to these innovative therapeutics is not a certainty. For example, because PDTs are relatively new, they do not fall under an existing Medicare benefit category, meaning they are now excluded from Medicare coverage. Creating a new Medicare benefit category specifically for PDTs that could also pave the way for Medicaid and private payers to offer similar coverage. Additionally, patients and providers must be educated on the benefits and availability of PDTs for patients with chronic and complex conditions.

ACTION for PDTs is a new multi-disciplinary collaborative working to overcome these challenges through Adoption, Coverage and Access, Therapeutic Outcomes, Inclusion, Options, and Novel Technology (ACTION). ACTION for PDTs will be the catalyst for increased awareness of PDTs and will drive policy changes that will ensure prescription digital therapeutics become a vital part of patients' treatment options.

## **Purpose**

ACTION for PDTs is committed to six areas of purpose:

### ***1. Adoption***

The "A" in ACTION stands for "Adoption." With the goal of encouraging adoption of PDTs as evidence-based, FDA-regulated medical interventions, the collaborative will serve as a resource for patients, health care providers, payers, lawmakers and policymakers. Specifically, ACTION for PDTs will provide stakeholders with the latest information on the capabilities of PDTs in preventing, managing, and treating diseases and disorders as well as the clinical improvements associated with PDTs and their cost-savings to the health system.

### ***2. Coverage and Access***

The "C" in ACTION stands for "Coverage and Access." To allow for adequate adoption of PDTs, health plans must provide comprehensive coverage of and access to PDTs. Yet, despite the medical benefits of PDTs, there is currently no statutory benefit category that allows for Medicare coverage. The impact extends far beyond seniors because Medicare policy serves as a model for state Medicaid programs and commercial insurance plans. Thus, without an established benefit category, coverage decisions will remain largely ad-hoc, impeding many patients from benefitting from this innovative technology. To remove this roadblock, legislative and regulatory actions are needed to create a pathway for comprehensive coverage and access to PDTs for qualifying patients. As such, the collaborative will educate Congress on the need to create a new benefit category for PDTs similar to the pathway Congress created for Medicare reimbursement of mammography screening. Until Congress took this legislative action, the Centers for Medicare and Medicaid Services did not have authority to cover the costs of mammograms for Medicare beneficiaries. The same is now the case for PDTs.

Additionally, the collaborative will advocate for new laws, regulations, and policies so that both public and private payers cover and provide meaningful access to PDTs.

### ***3. Therapeutic Outcomes***

The “T” in ACTION stands for “therapeutic outcomes.” PDTs are used independently or in concert with medications, devices, or other therapies [to optimize patient care and improve patient outcomes](#). Accordingly, the collaborative will raise awareness of the evidence showing that PDTs can improve patient outcomes in a wide range of chronic conditions, including cancer, ADHD, depression, substance use disorder, asthma, schizophrenia, and insomnia, with additional therapeutic areas on the horizon.

### ***4. Inclusion***

The “I” in ACTION stands for “Inclusion.” PDTs can play a vital role in addressing health inequities, disparities, and social determinants of health (SDOHs). [SDOHs](#) are conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. SDOHs include transportation and access to health care. Because SDOHs prevent underserved communities from accessing quality care, leading to health inequities and disparities, ACTION for PDTs will encourage greater adoption of PDTs as a strategy to improve health equity by providing accessible treatment to all patients in real-time and from any location.

### ***5. Options***

The “O” in ACTION stands for “Options.” For many chronic conditions, there is no one-size-fits-all approach that works. Practitioners and individuals with chronic diseases need all available FDA-regulated treatment options at their disposal for the treatment of these conditions. Therefore, the collaborative will advocate for policies that ensure patients, in consultation with their providers, have access to all effective PDTs for their condition so they can choose the one best suited for them without unnecessary interference or barriers from policymakers and third-party payers.

### ***6. Novel Technology***

The “N” in ACTION stands for “Novel Technology.” Novel technology is critical to the evolution of medicine. In encouraging the adoption of PDTs, it is important to understand that these therapeutics are regulated by the FDA, similar to traditional medicine. They must go through rigorous clinical trials establishing positive patient outcomes in order to receive FDA approval or clearance. For this reason, the partnership will educate stakeholders, so they fully comprehend the significance of clinical rigor and testing to ensure safety and efficacy of PDTs.

## Join Us

ACTION for PDTs' members include a diverse group of like-minded organizations and individuals working toward the common goal of improving adoption and coverage of and access to PDTs. These include:

- Patient and caregiver advocacy groups
- Health policy organizations
- Professional associations
- Research, innovation, and technology organizations
- Individual patients, caregivers, and loved ones
- Individual health care providers and academics
- Commercial supporters

If you are interested in joining ACTION for PDTs, please click [here](#).

## Contact Us

If you have questions, please visit us at [www.aimedalliance.org/ACTIONforPDTs](http://www.aimedalliance.org/ACTIONforPDTs) or contact us at [ACTIONforPDTs@gmail.com](mailto:ACTIONforPDTs@gmail.com).

## Funding and Independence

Spearheaded by Aimed Alliance, ACTION for PDTs shall, at all times, retain full independence and control over its activities and content. Should the collaborative obtain funders, the entity shall not be directed or otherwise influenced by the commercial interests of a funder or potential funder. While the collaborative may advocate for improved access to prescription digital therapeutics, it will not advocate for specific products.

## About Aimed Alliance

Aimed Alliance is a 501(c)(3) non-profit health policy organization that works to protect and enhance the rights of health care consumers and providers. The organization achieves this mission by conducting legal research and analysis; developing sound, patient-centered policy recommendations; and disseminating its findings to inform policymakers and increase public awareness.

Aimed Alliance's list of funders can be found here: <https://aimedalliance.org/supporters/>.