Digital Health 2023 Reimbursement Trends & Policy Updates

The evolving US digital health reimbursement landscape signals long-term potential for the opening of coverage pathways, but critical adoption issues persist

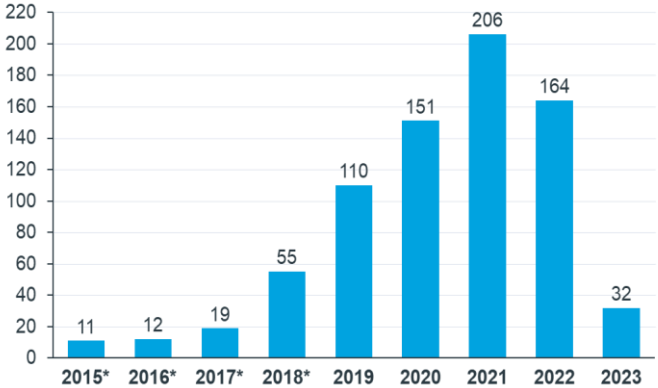
Amid the rising adoption of digital health solutions in the United States, the reimbursement landscape remains complex and varied. While some commercial payers like Highmark have made coverage decisions to fund FDA-cleared digital therapeutics (DTx), Medicare and Medicaid options remain limited. However, bi-partisan bills both previously and recently introduced in the US Senate aim to broaden digital health coverage, potentially increasing reimbursement and revenue opportunities. In this fact sheet, IQVIA explores key recent developments (and some still pending decisions) in digital health reimbursement legislation, policy, and implications for digital health manufacturers within the United States.

Ensuring Patient Access to Critical Breakthrough Products Act

What is it?

The 'Ensuring Patient Access to Critical Breakthrough Products Act of 2023' is one bi-partisan bill recently introduced to expand coverage standards for digital therapeutics. If passed, the bill would require Medicare to provide temporary coverage for FDA-designated breakthrough medical devices (including combination products, i.e., drug/device) for a period of four years, aiming to remove barriers that prevent beneficiaries from

Graph 1: Number of Granted Breakthrough Device Designations by Fiscal Year [3]



*Data includes devices that were designated under the precursor Expedited Access Pathway (EAP). Since the vision and designation criteria between the precursor EAP Program and the Breakthrough Devices Program are consistent, the FDA considers devices granted designation under the EAP to be a part of the Breakthrough Devices Program.

accessing the most innovative treatments.[1,2] This includes temporary coverage for some breakthrough devices that were not considered when Medicare was first created, such as digital therapeutics. During this time, CMS must make permanent coverage decision for some digital therapeutics with breakthrough designation and provide payment codes within three months of FDA designation. This bill or one of similar intent has circulated through at least two prior editions of Congress, but one differentiating factor is that this legislation may carry additional funding for CMS's information technology infrastructure. Along with same-day Medicare coverage, the Ensuring Patient Access Act carries a requirement of additional payment, when necessary, via a modern technology add-on mechanism for hospital in-patient use and the new technology pass-through mechanism for outpatient use. A device covered in this manner would enjoy four years of coverage, while requiring CMS to identify any additional evidence it may want to see for coverage extended post-four years. CMS would have an additional year to propose a formal coverage policy for any devices that are not captured in an existing coverage policy, after which the device would be covered per the product label approved or cleared by the FDA.

KEY IMPLICATIONS	
Access	Guarantees coverage and improves access for innovative care for specific patient groups, like seniors. For example, expedited Medicare coverage for ReCor Medical's high blood pressure treatment could extend seniors' lifespan and decrease cardiovascular crises.[3]
Adoption	Enables immediate use of cleared medical technologies but HCP and patient adoption challenges for digital health solutions, including DTx, will remain.
Enactment Probability	CMS previously reversed a similar act in 2021, the Medicare Coverage of Innovative Technology and Definition of "Reasonable and Necessary" final rule, due to concerns over the types of clinical studies used to obtain FDA-cleared designation.[4] Although the Ensuring Patient Access Act may be differentiated by additional funding for CMS's information technology infrastructure, it is unclear whether this change will be sufficient to garner a different legislative outcome.
Impact Timeline	Even if approved, the act's benefits for biopharma may take years to materialize, though it could spur investment in innovative medical technologies, including DTx.

Access to Prescription Digital Therapeutics Act of 2023

What is it?

Specifically, regarding prescription digital therapeutics (PDTs), two bi-partisan bills have been proposed to standardize coverage for FDA-cleared PDTs under Medicare, Medicaid and state Children's Health Insurance Programs (CHIPs). The 'Access to Prescription Digital Therapeutics Act (APDTA) of 2023' seeks to add PDTs to the list of covered services and products under Medicare and Medicaid and direct the CMS to establish payment methods and product-specific codes.[5] Similarly, the 'Medicaid and CHIP Access to Prescription Digital Therapeutics Act' introduced in mid-December 2022, would create standardized coverage in Medicaid and CHIP plans for approved digital health tools and platforms.[6] This bill would make it easier for clinicians to prescribe innovative new technologies, such as digital health devices and mHealth apps in Medicaid and CHIPs. Both acts could enable patients with a diverse range of conditions, such as substance and opioid-use disorders, mental and behavioral health issues, diabetes, and Parkinson's disease to efficiently access the necessary care and support.

KEY IMPLICATIONS	
Access	One of the biggest hurdles today is the lack of a standardized reimbursement pathway for digital health solutions through Medicare due to the regulatory gap, and the APDTA should help eliminate this major barrier. However, there doesn't seem to be any evidence that the Medicaid and CHIP Access to Prescription Digital Therapeutics Act will increase access to care, let alone access to high-quality care. There are also concerns about technology deserts, where patients lack access to a computer or reliable internet.
Adoption	Even with PDT coverage, HCP willingness to prescribe and patient willingness to adopt/remain on treatment is still a challenge, as evidenced by Pear Therapeutics' recent bankruptcy, where they cited difficulties in scaling the business.[7,8]
Enactment Probability	The Biden administration has prioritized improving access to mental health services, but additional Congressional support is needed. Therefore, the likelihood of passing the APDTA, introduced in 2022 and again this year, is low without significant lobbying/support.
Impact Timeline	Even if the act passes, biopharma may not realize its benefits for years given both Medicare and commercial payers and providers would need to account for the operational considerations related to adoption (e.g., integrating solutions in clinical workflows, training staff on processes, etc.).

Advancing Telehealth Beyond Covid-19 Act

What is it?

With the end of the public health emergency in May 2023, changes to the reimbursement landscape for telehealth services have occurred, as exemplified by 'The Advancing Telehealth Beyond COVID-19 Act'. This act was passed in 2022 and extends Medicare telehealth flexibilities until December of 2024, specifically allowing for beneficiaries to receive telehealth services at any site, certain practitioners to provide telehealth services (occupational therapists, physical therapists, speech-language pathologists, and audiologists), and audio-only technology for evaluation and behavioral health services.[9,10] In-person evaluation requirements for mental health telehealth services will also be delayed until January 1, 2025.

KEY IMPLICATIONS	
Access	The act guarantees extended and broader access for specific patient segements like rural residents and seniors, but this shouldn't be misconstrued with increased usage or adoption, despite the preservation of ongoing access through 2024.
Adoption	Despite expanded coverage and telehealth adaptability, the demand for telehealth services has declined since its Apex in April 2022, with telehealth visits accounting for only 5% of total visits in 2022 compared to 26% during the pandemic.[11,12] This suggests a fading reliance on such services, though telehealth visits are still higher than they were pre-pandemic (<1%). The pandemic may have generated a fundamental shift in healthcare delivery, where telehealth offers a viable channel for DTx prescribing.[11]
Enactment Probability	The act was originally passed in July 2022 and provides that certain flexibilities continue to be granted until December 31, 2024, if the emergency period ends before that. However, a new audit from the Office of the Inspector General (OIG) found that Medicare had an estimated $580 million in improper payments for psychotherapy services during the Covid-19 PHE, most of which were payments for telehealth services.[13] This will likely create a major barrier to broader adoption despite the act already having passed.
Impact Timeline	The bill also delays implementation of certain in-person evaluation requirements for mental health telehealth services until January 1, 2025, or the first day after the end of the emergency period, whichever is later.

2008 Ryan Haight Act

What is it?

Some pandemic-era telehealth flexibilities, however, may come to an end in May of 2023. Prior to the pandemic, the 2008 Ryan Haight Act amended the Controlled Substances Act to prohibit clinicians from prescribing controlled substances via online forms and required an in-person office visit prior to prescription. During the pandemic, the Drug Enforcement Agency (DEA) waived this requirement, but the new post-pandemic proposed rule (Exception #7 to the Ryan Haight Act) will be more complex and restrictive.[14] Clinicians will no longer be allowed to prescribe controlled substances via telemedicine if a patient has never had an in-person exam (with exception of an initial prescription period of no more than 30 days' supply), and an initial in-person exam will be required for patients needing certain medications (Schedule II, Schedule III-V narcotics).[14] Additionally, the Special Registration for Telemedicine, which would outline the registration process for certain clinicians to waive the in-person requirement, has been caught up in regulatory review since March of 2022 and was not included in the new proposed rules. Organizations such as the American Telemedicine Association have cited concerns over the potential impact on patient access to appropriate prescriptions for a variety of medical conditions, calling out mental health and substance use disorders in particular.

For those with a substance use disorder, the Modernizing Opiod Treatment Access Act introduced in March 2023 may offer a solution. This legisltation would help patients access medication treatment for Opiod Use Disorder (OUD) by updating outdated rules, allowing board-certified physicians to prescribe methadone, and granting U.S. pharmacies permission to dispense methadone. It would also require the Substance Abuse and Mental Health Services Administration (SAMHSA) and the DEA to submit an annual report that provides the names of patients who were prescribed methadone, as well as those of the providers and state physicians who are registered to prescribe methadone. It will be intruiging to see how these acts counter-balance each other, and whether digital health solutions / digital therapeutics for mental health and opiod-use disorders become more popular than traditional medications, given the potential logistical and travel challenges of attending in-person consultations.

KEY IMPLICATIONS

Access	The DEA's new rule aims to balance telemedicine access and flexibility, altering the original Ryan Haight Act, yet it tightens pandemic-era leniencies by mandating in-person visits for controlled substance prescriptions tied to mental health and substance use disorders[14,15]

 **Adoption**	As certain telehealth flexibilities end, patients may begin searching for alternative channels like telehealth for digital health and DTx prescriptions, especially for care in therapy areas most affected by post-pandemic amendments, such as mental health and opioid-use disorders.
 **Enactment Probability**	Despite the DEA's inaction since 2008 to create a special registration process for remote prescribing, providers, anticipating significant challenges like extensive patient travel for in-person visits, are preparing accordingly
 **Impact Timeline**	Currently, industry stakeholders, including the American Telehealth Association (ATA), have criticized the rule's restrictive nature and are concerned about potential disruptions to care continuity and the barriers posed to the forementioned patient populations above

Conclusion

The key policy and legislation updates discussed within this factsheet clearly aim to preserve and increase access to innovative digital medicine and services for diverse sets of patient populations. However, a consistent theme within digital health and digital therapeutics, especially in the US, is the complex and heretergenous commercial pathways that exist, as well as challenges HCP and patient adoption. We look forward to monitoring these digital health policies as they have the potential to impact the development, approval, and reimbursement of innovative medical technologies, including DTx. While some legislation may provide clear regulatory pathways and encourage continued adoption for digital solutions beyond the Covid-19 pandemic, other changes could lead to greater restrictions and challenges for clinicians and patients alike. Therefore, it willl be important to track these legislative changes and their implications for the healthcare industry throughout 2023 and beyond. Please contact us if we can help support your DTx commercial / Go to Market plans and navigate these potential scenarios.

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Anwen Tobalske, Associate, U.S. (anwen.tobalske@iqvia.com)

Brian Lovinguth, Associate Principal, U.S. (brian.lovinguth@iqvia.com)

Nick Mageras, Principal, U.S. (nicholas.mageras@iqvia.com)