



August 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-2025-P Proposed Rule - Inclusion of Digital Therapeutic Codes in the 2025 Physician Fee Schedule

Dear Administrator Brooks-LaSure:

Aimed Alliance is a 501(c)(3) not for profit health policy organization that seeks to protect and enhance the rights of healthcare consumers and providers. We appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) 2025 Physician Fee Schedule. We are writing to express our support for the proposal to include digital mental health treatment (DMHT) codes in the 2025 fee schedule and respond to CMS' inquiry for feedback regarding certain aspects of the proposal related to implementation of DMHT codes.

I. Support for Payment Flexibility Regarding FDA-Cleared DMHT Devices for “Off-Label” Use

Aimed Alliance supports CMS's efforts to expand access to DMHT devices and encourages CMS to allow payment for all DMHT devices that have been approved by the FDA, and are furnished incident, or integral to, professional behavioral health services.

Health care providers should have the discretion to determine the appropriate therapeutic interventions for their patients, including the use of DMHT devices where evidence supports their safety and efficacy. This approach would respect the clinical judgment of providers and enable innovative care solutions in the mental health space where patient needs are diverse and dynamic. Moreover, this would align the digital health space with conduct that is already occurring within the prescription drug space, as health care providers currently prescribe off-label treatments when certain conditions have no FDA-approved treatments available.

Importantly, mental health conditions are highly individualized, and an effective treatment often requires experimentation with various therapies and interventions to find the best approach for each patient's individual needs. By allowing payment for FDA-approved DMHT devices, CMS could implement a patient-centered approach that empowers providers to utilize available resources to address the growing mental health crisis. Limiting payment to only those devices specifically cleared by the FDA for a specific mental health condition, could unnecessarily restrict access to these therapeutics. As such, we support allowing payment for all DMHT devices that have received FDA approval.



II. Expanding Payment Beyond 21 CFR 882.5801 to Include Other FDA-Cleared Devices

We also urge CMS to expand payment eligibility to include DMHT devices cleared under regulatory pathways beyond 21 CFR 882.5801, provided that sufficient evidence exists demonstrating the device's safety and effectiveness for mental health applications. Limiting payment to devices under this single regulatory code may overlook valuable therapies that have demonstrated clinical effectiveness in mental health settings. CMS should explore additional types of computerized behavioral therapies for treating mental health disorders, such as digital therapy devices to reduce sleep disturbance for psychiatric conditions approved under § 882.5705 or digital therapy device for Attention Deficit Hyperactivity Disorder approved under § 882.5803. By broadening the criteria, CMS will facilitate greater access to innovative therapies that can address mental health conditions. Patients and providers benefit when they have access to a wider range of evidence-based digital tools that can be tailored to individual treatment needs.

III. Cautious Approach to Payment Limitation for Discontinuation of Digital Therapeutics

Treatment compliance is essential to ensure a prescribed medication or device is used appropriately and effectively. Digital therapeutics are a relatively new treatment for many consumers; therefore, some consumers may experience challenges in maintaining their treatment as they adjust to the new digital tool. These challenges may be exacerbated due to technologic difficulties, age, or location. With this in mind, Aired Alliance urges CMS to allow flexibility in billing for digital therapeutics. For example, we urge CMS against revoking coverage if a patient misses one month out of a six-month treatment plan, as this does not allow the health care provider to attempt any intervention to address treatment compliance challenges. Instead, CMS should approve coverage for the proposed treatment's duration and then reassess as appropriate after the initial treatment period. Billing in this manner would align the digital therapeutic space with the prescription drug space, as a health plan would never deny coverage for a prescription drug because a patient missed several doses within a one-month period.

Moreover, strict compliance requirements that result in abrupt payment cutoffs could inadvertently penalize patients who are already struggling with the very conditions these digital therapeutics aim to address. Mental health conditions can be unpredictable, leading to temporary lapses in engagement or motivation. Penalizing patients for short-term non-compliance may undermine overall treatment progress and could discourage continued participation in care. Thus, we urge CMS to adopt a billing structure that prioritizes maintaining care continuity while still encouraging treatment adherence.

IV. Concerns About Setting Caps on the Number of Digital Therapeutics Per Patient

Lastly, we urge CMS not to impose a cap on the number of DMHT devices that a patient can access within a calendar month. A rigid cap could limit comprehensive care, particularly for patients with complex medical needs or multiple mental health conditions who might benefit from several complementary digital interventions. Instead, we recommend that CMS collaborate with professional societies to establish guidelines on the feasible number of DMHT devices a



patient can reasonably engage with while maintaining flexibility to accommodate individual needs. Adopting a flexible, case-by-case approach—guided by clinical judgment and evidence-based best practices—would allow providers to develop personalized treatment plans that incorporate multiple DMHT devices as necessary. This would ensure that patients have access to the full range of treatment tools needed to improve health outcomes.

V. Conclusion

In conclusion, we support CMS’s inclusion of DMHT codes in the 2025 Physician Fee Schedule. We believe this is a significant step forward in expanding access to innovative care in the mental health space and encourage CMS to maintain a flexible, patient-centered approach as it finalizes this rule.

Thank you for providing Aired Alliance the opportunity to comment on CMS-2025-P. Please contact us at policy@aimedalliance.org if you have any questions regarding this comment.

Sincerely,

Olivia Backhaus
Staff Attorney
Aimed Alliance