Medical Coverage Policy | Digital Health Technologies for Attention Deficit/Hyperactivity Disorder

EFFECTIVE DATE: 02|01|2026
POLICY LAST REVIEWED: 09|02|2026

OVERVIEW

Digital health technologies is a broad term that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device, and include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). The scope of this review includes only those digital technologies that are intended to be used for therapeutic application and meet the following 3 criteria: 1) Must meet the definition of "Software as a medical device" which states that software is intended to be used for a medical purpose, without being part of a hardware medical device or software that stores or transmits medical information. 2) Must have received marketing clearance or approval by the U.S. Food and Drug Administration (FDA) either through the de novo premarket process or 510(k) process or pre-market approval and 3) Must be prescribed by a healthcare provider. This review will assess whether a digital therapy in the form of a computer game can improve attention in children with ADHD.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

The use of EndeavorRx for all indications including attention-deficit/hyperactivity disorder is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

The use of EndeavorRx for all indications including attention-deficit/hyperactivity disorder is not covered and is considered a contract exclusion.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not covered benefits/coverage.

BACKGROUND

Attention-deficit/hyperactivity disorder (ADHD) is a chronic condition characterized by core symptoms of hyperactivity, impulsivity, and inattention, which are considered excessive for the person's age. Both the International Classification of Mental and Behavioral Disorders 10th edition (ICD-10) and the Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-5) require that the symptoms are reported or observed in several settings and that the symptoms of ADHD affect psychological, social, and/or educational/occupational functioning. Prevalence estimates for ADHD vary from 7.2% to 15.5% of children.

For children younger than 17 years of age, the DSM-5 requires at least 6 symptoms of hyperactivity-impulsivity or at least 6symptoms of inattention. The combined type requires a minimum of 6 symptoms of hyperactivity-impulsivity plus at least 6symptoms of inattention. The symptoms must 1) occur often, 2) be present in more than 1 setting, 3) persist for at least 6months, 4) be present before 12 years of age, 5) impair function in academic, social, or occupational activities, and 6) be excessive for the developmental level of the child.

Treatment may include environmental adjustments, behavioral and psychological interventions, and medications. In some children, these treatments do not sufficiently address symptoms. In others, there may be resistance by the parents to treat children with medications, or there may be other barriers to obtaining established therapies. EndeavorRx is proposed to address these barriers with improved access to care and minimal side effects. The therapy is based on research showing that impairments in attention and cognitive control are associated with lower activation of frontal, frontoparietal, and ventral attention networks. Previously, a game-like intervention was shown to improve cognitive performance and alter the electroencephalogramin the prefrontal cortex in older adults. The similarity between cognitive control in older adults and attention deficits in ADHD led to the development of EndeavorRx for the treatment of ADHD in children.

In April 2020, EndeavorRx (Akili Interactive Labs) received marketing clearance by the U.S. Food and Drug Administration (FDA) through the De Novo premarket review process (DEN200026). EndeavorRx is a prescription device that is indicated to "improve attention function as measured by computer-based testing in children ages 8-12 years old with primarily inattentive or combined type ADHD, who have a demonstrated attention issue. Patients who engage with EndeavorRx demonstrate improvements in a digitally assessed measure Test of Variables of Attention (TOVA) of sustained and selective attention and may not display benefits in typical behavioral symptoms, such as hyperactivity." EndeavorRx is intended to be used as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs.

For individuals who are children ages 8-12 years with ADHD who receive EndeavorRx, the evidence includes a pivotal randomized controlled trial (RCT) and an open label study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal STARS-ADHD RCT compared outcomes of EndeavorRx with a word game that targeted different cognitive abilities (digital control intervention). The experimental treatment group had significantly greater improvement on a computerized test of attention but the experimental and control groups improved to a similar extent on parent and clinician assessments. STARS-ADHD was well-designed and well conducted. However, several limitations affect its relevance to clinical practice. First, the study population was not representative of intended use. The trial eligibility criteria only allowed inclusion of children not taking ADHD medication, while EndeavorRx is intended to be used as part of a therapeutic program that may include clinician-directed therapy, medication, and/or educational programs. Additionally, the 4-week study duration was insufficient to evaluate long-term effects on ADHD-related impairment and functioning, which is critical given the chronic nature of the condition. Lastly, the clinical significance of an improvement in a computerized test of attention without a detectable improvement in behavior by parents and clinicians is uncertain. A second open label study STARS-Adjunct compared EndeavorRx plus stimulant medication with EndeavorRx alone. This study design does not permit conclusions about the adjunctive treatment effect of EndeavorRx as both study arms received EndeavorRx. An appropriate study design would be comparing EndeavorRx plus stimulant medication versus stimulant medication alone. A number of questions remain concerning the efficacy of this treatment, and additional studies to assess the effect of the digital therapy in adolescents and in children on stimulant medication have recently been completed but not yet published. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans

The following HCPCS code(s) is not covered for Medicare Advantage Plans:

A9291 Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment

Commercial Products

The following code(s) are non-covered and are considered a contract exclusion for Commercial Products:

A9291 Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment

RELATED POLICIES

Digital Health Therapies for Substance Abuse Disorders

PUBLISHED

Provider Update, November 2026
Provider Update, December 2025
Provider Update, November 2024
Provider Update, October 2023
Provider Update, October 2022

REFERENCES

1. International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Key Definitions. 2013. https://www.imdrf.org/working-groups/software-medical-device-samd. Accessed May 26, 2026.
2. National Institute for Health and Care Excellence (NICE). Evidence standards framework for digital health technologies. Updated August 2022. https://www.nice.org.uk/corporate/ecd7. Accessed May 26, 2026.
3. Wolraich ML, Hagan JF, Allan C, et al. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. Pediatrics. Oct 2019; 144(4). PMID 31570648
4. Anguera JA, Boccanfuso J, Rintoul JL, et al. Video game training enhances cognitive control in older adults. Nature. Sep 05 2013; 501(7465): 97-101. PMID 24005416
5. DuPaul GJ. Parent and teacher ratings of ADHD symptoms: Psychometric properties in a community based sample. J Clin Child Psychol 1991; 20:242.
6. Guy W, editor. ECDEU Assessment Manual for Psychopharmacology. Rockville, MD: US Department of Heath, Education, and Welfare Public Health Service Alcohol, Drug Abuse, and Mental Health Administration; 1976.
7. Conners CK. Conners 3rd Edition. Toronto, Multi-Health Systems, Inc., 2008.
8. Wolraich ML, Feurer ID, Hannah JN, et al. Obtaining systematic teacher reports of disruptive behavior disorders utilizing DSM-IV. J Abnorm Child Psychol. Apr 1998; 26(2): 141-52. PMID 9634136
9. Wolraich ML, Lambert W, Doffing MA, et al. Psychometric properties of the Vanderbilt ADHD diagnostic parent rating scale in a referred population. J Pediatr Psychol. Dec 2003; 28(8): 559-67. PMID 14602846
10. Forbes GB. Clinical utility of the Test of Variables of Attention (TOVA) in the diagnosis of attention-deficit/hyperactivity disorder. J Clin Psychol. Jun 1998; 54(4): 461-76. PMID 9623751
11. Kollins SH, DeLoss DJ, Cañadas E, et al. A novel digital intervention for actively reducing severity of paediatric ADHD (STARS-ADHD): a randomised controlled trial. Lancet Digit Health. Apr 2020; 2(4): e168-e178. PMID 33334505
12. Kollins SH, Childress A, Heusser AC, et al. Effectiveness of a digital therapeutic as adjunct to treatment with medication in pediatric ADHD. NPJ Digit Med. Mar 26 2021; 4(1): 58. PMID 33772095
13. Mikami K, Miyajima T, Nishino R, et al. Efficacy and safety of SDT-001, a dual-task digital device, in managing attention-deficit/hyperactivity disorder symptoms in children and adolescents: a phase 3, randomized, standard treatment-controlled study. Psychiatry Clin Neurosci. Aug 2025; 79(8): 447-457. PMID 40317565
14. Kollins, S.H., Childress, A., Heusser, A.C. et al. Effectiveness of a digital therapeutic as adjunct to treatment with medication in pediatric ADHD. npj Digit. Med. 4, 58 (2021). https://doi.org/10.1038/s41746-021-00429-0

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