Prescription Digital Therapeutics for Attention Deficit Hyperactivity Disorder

Clinical Policy ID: CCP.1470

Recent review date: 9/2026

Next review date: 1/2028

Policy contains: Attention deficit and hyperactivity disorder; digital therapeutics; EndeavorRx, Prismira.

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Coverage policy

The following prescription digital therapeutics for attention deficit hyperactivity disorder are investigational/not clinically proven and, therefore, not medically necessary:

- EndeavorRx (Akili Interactive Labs, Inc., Boston, Massachusetts)
- Prismira, now marketed as LuminosityRx (Lumos Labs, Inc., San Francisco, California)

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

Medication (stimulants and non-stimulants); behavior management.

Background

Attention deficit hyperactivity disorder is a psychiatric and neurodevelopmental condition that affects a child's ability to function. Symptoms generally include developmentally inappropriate loss of concentration and focus, inattentiveness, hyperactivity, and impulsivity. The disorder is usually first suspected in childhood during elementary school with children demonstrating difficulty completing tasks, becoming disorganized and forgetful, and losing things. A diagnosis is made based on these symptoms usually before age 12. Symptoms interfere with daily living activities and last six months or longer. Although the condition begins in childhood, it frequently extends into adulthood. The three main subtypes are predominantly inattentive, predominantly hyperactive-impulsive, and a combination of the two (Magnus, 2023).

An estimated seven million (11.4%) of U.S. children have been diagnosed with attention deficit hyperactivity disorder, typically between ages three and 17 years. The condition's prevalence is higher in boys than in girls (15% compared to 8%), and 78% of children with the condition have at least one other co-occurring condition (Centers for Disease Control and Prevention, 2024).

Causes have remained elusive, but several risk factors have been implicated. Studies of twins have identified a genetic link in some cases. Other suspected risk factors include brain injury; exposure to environmental toxins (e.g., lead) during pregnancy or at a young age; prenatal alcohol and tobacco exposure; and parental mental health and family environment (Centers for Disease Control and Prevention, 2024).

Available treatments address symptoms and function but are usually not curative. As a chronic condition, treatment is age-specific and can include medication with or without behavioral therapy, usually following principles of the chronic care model and the medical home (Wolraich, 2019).

The goal of treatment is to reduce the impact of ADHD symptoms on daily functioning and build coping strategies. Current therapies do not help all children with attention deficit hyperactivity disorder, and alternative treatments may be sought. Digital therapeutics (software applications for clinical use) have been proposed to improve attention problems.

The U.S. Food and Drug Administration has issued 510(k) clearance to three digital therapeutic devices to improve attention function in individuals with primarily inattentive or combined type attention deficit hyperactivity disorder. These devices are used as part of a therapeutic program that may include clinician directed therapy, medication, and/or educational programs, which further address symptoms of the disorder. Of note, patients who engage with these devices may demonstrate improvements in attention functioning but may not display benefits in other behavioral symptoms such as hyperactivity:

- EndeavorRx, the predicate device, is a video game indicated for children ages eight to 17 years and available by prescription only (U.S. Food and Drug Administration, 2023)
- EndeavorOTC is indicated for patients ages 18 and older and available over-the-counter (U.S. Food and Drug Administration, 2024)
- Prismira (now LuminosityRx) is a game app indicated for patients ages 22 to 55 years and available by prescription only (U.S. Food and Drug Administration, 2025)

Findings

Guidelines

Current guidelines for treatment of pediatric attention deficit hyperactivity disorder do not include the use of digital therapeutics, including the EndeavorRx video game or Prismira game app (American Academy of Family Physicians, 2026; Barbaresi, 2020; Wolraich, 2019).

Evidence review

Prescription digital therapeutics are attractive as non-pharmacological therapeutic options for improving attentional function in individuals with attention deficit hyperactivity disorder. Digital interventions such as video games and apps show potential improvements in inattention and executive function, but low evidence quality limits conclusions about their effectiveness (Gabarron, 2025). Future research should address safety assessments, standardize reporting, and determine long-term effectiveness.

EndeavorRx is the first and only digital therapeutic indicated for pediatric populations. The newly approved Prismira is marketed for adult populations as substantially equivalent to EndeavorRx in terms of safety and efficacy but, to date, has no independently published studies supporting its clinical use.

The evidence for EndeavorRx consists of two reported studies performed in children under controlled conditions. EndeavorRx appears safe and well-tolerated and offers short-term improvement in inattention and hyperactivity, but its effectiveness in real world settings and over the long term is unclear.

Before developing EndeavorRx, Akili Interactive tested prototype digital treatments. In one of the studies, 80 children were randomized into those with and without attention deficit hyperactivity disorder. Significant neuropsychological improvements were observed for the 40 cases, but not for the 40 controls (Davis, 2018).

Regulatory approval for EndeavorRx was based on five studies, with a total of more than 600 participants. The primary study was a controlled trial (n = 348) of children ages eight to 12 years old. All participants were required to have a definitive diagnosis of attention deficit hyperactivity disorder, scores on several ratings scales indicating attention problems, an intelligence quotient above 80, no comorbid psychiatric conditions, and no use of medications for the disease that could not be discontinued (Kollins, 2020).

Children in the case group played the EndeavorRx video game for five five-minute sessions per day, five days a week for four weeks. The control group played a game whose objective was to find and connect letters on a grid to spell words during the same period. Major findings include:

	Cases (n = 180)	Controls (n = 168)	*P* value	
Test of Variables of Attention	47%	32%	.0058	*
Attention Performance Index	11%	4%	.033	*
ADHD Rating Scale (> 2 points)	74%	73%	.77	
ADHD Rating Scale (> 30%)	24%	19%	.23	
Impairment Rating Scale	48%	37%	.049	*
Clinical Global Impressions (< 2 post-intervention)	17%	16%	.86	
Clinical Global Impressions (1 post-intervention)	1%	1%	.96	
Self-Reported Improvement on Exit (patients)	73%	66%	.15	
Self-Reported Improvement on Exit (parents)	56%	44%	.025	*

* Significance at $P < .05$.

The percentage of patients experiencing intervention-emergent adverse effects during the study period was higher for cases (7%, n = 12) versus controls (2%, n = 3). Ten of the 12 effects on the test patients were frustration (5), headache (3), and emotional reaction (2). No serious adverse effects were experienced by either group, and there were no discontinuations (Kollins, 2020).

An update to this trial (n = 206) of children ages eight to 14 with attention deficit hyperactivity disorder taking or not taking stimulant medication assessed the impact of AKL-T01, an application and video-game-based treatment for inattention. Subjects used the game for four weeks, followed by non-use for four weeks. Inattention improved in groups taking or not taking medication, both significant at $P < .001$ after four weeks, with no side effects, and improvements persisted up to one month (Kollins, 2021).

A systematic review examined the effects of game-based therapeutics, including EndeavorRx, in randomized controlled trials on children and adolescents with attention deficit hyperactivity disorder. The investigators indirectly compared the outcomes of game-based digital therapeutics, medication, and controls. Outcomes were reported as standard mean difference (95% confidence interval). Both digital therapeutics and controls improved inattention (0.28 [0.14 to 0.41] and 0.21 [0.03 to 0.39], respectively) and hyperactivity/impulsivity (0.28 [0.03 to 0.53] and 0.30 [0.05 to 0.55], respectively). However, medication had outcomes superior to digital therapeutics for these indicators (Oh, 2024).

Video games, such as EndeavorRx, may improve treatment adherence, as they are perceived as enjoyable activities. Drop-out rates for EndeavorRx were 5.45% (Kollins, 2020) and 12.13% (Kollins, 2021), lower than most other video game-based treatments. However, long-term efficacy is uncertain (Caselles-Pina, 2023), and the effects on behavior are limited (Lee, 2025).

In 2024, we added a systematic review (Caselles-Pina, 2023) and guideline references, and deleted several older references. No policy changes are warranted.

In 2025, we updated the references and added a new prescription digital therapeutic, Prismira, to the policy. There are no published studies supporting its use. No policy changes are warranted.

In 2026, we updated the references with no policy changes warranted.

References

On July 6, 2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “attention deficit disorder with hyperactivity (MeSH),” “attention deficit and hyperactivity disorder,” “digital health (MeSH),” “digital therapeutics,” “EndeavorOTC,” “EndeavorRx,” and “Prismira.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

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U.S. Food and Drug Administration. EndeavorOTC 510(k) summary approval letter K233496 Akili Interactive Labs, Inc. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K233496. Decision date June 14, 2024.

U.S. Food and Drug Administration. Prismira 510(k) summary approval letter K243729 to Lumos Labs, Inc. https://www.accessdata.fda.gov/cdrh_docs/pdf24/K243729.pdf. Date prepared June 15, 2025.

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Policy updates

9/2020: initial review date and clinical policy effective date: 10/2020.

9/2021: Policy references updated.

9/2022: Policy references updated.

9/2023: Policy references updated.

9/2024: Policy references updated.

9/2025: Policy references updated. New product added to Coverage with no policy changes.

9/2026: Policy references updated.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1470.This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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