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Medical Policy Manual Medicine, Policy No. 175.01

Digital Health Products for Attention Deficit Hyperactivity Disorder

Effective: April 1, 2022

Next Review: September 2022
Last Review: March 2022

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. Digital therapeutic products differ from digital health products in that they are practitioner-prescribed software that delivers evidence-based therapeutic interventions to prevent, manage, or treat a medical disorder or disease. Digital therapeutic products have been proposed to supplement or replace established treatments for attention-deficit/hyperactivity disorder (ADHD).

MEDICAL POLICY CRITERIA

Note:

- Member contracts for covered services vary. Member contract language takes precedence over medical policy.
- This policy addresses the use of practitioner-prescribed software applications for therapeutic intervention.
- This policy does not address:
  - Software that is used for the function or control of an FDA-cleared or approved stand-alone medical device (e.g. external insulin pump or pacemaker).

- Applications operated by a health care practitioner for remote health monitoring.

The use of a digital health product (including digital therapeutics) for the treatment of attention-deficit/hyperactivity disorder (ADHD), either as a stand-alone treatment or as an adjunct to standard treatment, is considered **investigational,** including but not limited to EndeavorRx® (AKL-T01).

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. Digital Health Products, Medicine, Policy No. 175

BACKGROUND

ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

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.[1]

For children younger than 17 years of age, the DSM-5 requires at least six symptoms of hyperactivity-impulsivity or at least six symptoms of inattention. The combined type requires a minimum of six symptoms of hyperactivity-impulsivity plus at least six symptoms of inattention. The symptoms must 1) occur often, 2) be present in more than one setting, 3) persist for at least six months, 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

Established treatments for ADHD in children include educational, environmental, psychological, and behavioral interventions, and medication. Almost two-thirds of children with ADHD take medication, and about one half receive behavioral treatment.[1]

- Educational intervention involves discussion with parents about symptoms and access to services, environmental modifications such as seating arrangements, changes to lighting and noise, reducing distractions, and the benefit of having movement breaks and teaching assistants at school.
- Parent-child behavioral therapy teaches parenting techniques within the principles of behavior therapy. The therapy programs typically last two to three months and includes rewarding positive behavior, identifying unintentional reinforcement of negative behaviors, limiting choices, and using calm discipline.
- Medication with stimulants, such as methylphenidate, are considered first-line therapy for ADHD in school-age children. However, adverse effects of stimulants may include sleep disturbance, decreased appetite, and weight changes. Combination therapy with

medication and behavioral interventions can improve both core ADHD symptoms and non-ADHD symptoms such as social skills and parent-child relations.

REGULATORY STATUS

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).[2] EndeavorRx® is a prescription device that is indicated to "improve attention function as measured by computer-based testing in children ages 8 to 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. EndeavorRx® was referred to as "ProjectEvo" and in later evaluations as "AKL-T01."

EVIDENCE SUMMARY

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

DIGITAL THERAPIES FOR ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

Clinical Context and Therapy Purpose

The purpose of digital therapeutic products is to provide a treatment option that is an alternative to or an improvement on existing therapies for patients with attention-deficit/hyperactivity disorder (ADHD).

Attention-deficit/hyperactivity disorder is a syndrome that can include hyperactivity, impulsivity, and/or inattention, which in turn can affect cognitive, academic, behavioral, emotional, and social functioning. The symptoms of the hyperactive-impulsive presentation typically occur

together and are characterized by the inability to sit still or inhibit behavior. The inattentive presentation is characterized by reduced ability to focus attention and reduced speed of cognitive processing, which is exhibited by difficulty with maintaining attention, lack of follow through and organization, distraction, and forgetfulness. The combined presentation includes symptoms of both the hyperactive-impulsive presentation and the inattentive presentation.

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 electroencephalogram in the prefrontal cortex in older adults.[3] 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.

ADHD-specific rating scales are described in Table 1.

Table 1. ADHD Rating Scales

Rating Scale	Description	Scoring
ADHD Rating Scale (ADHD-RS-IV)[4]	The ADHD-RS-IV is an 18-item, clinician-administered questionnaire for which a parent respondent rates the frequency of occurrence of ADHD symptoms and behaviors as defined by criteria outlined for ADHD in the DSM-IV. Each item is scored on a 4-point scale ranging from 0 (rarely or never) to 3 (very often) with total scores ranging from 0 to 54. The 18 items are grouped into 2 subscales: hyperactivity/impulsivity and inattentiveness.	Each subscale produces a subscale score ranging from 0 to 27. A higher score indicates more severe ADHD symptoms and behaviors and a negative change in total score indicates improvement.
The Clinical Global Impression Scale – Improvement (CGI-I)[5]	The CGI-I is a clinician's comparison of the participant's overall clinical condition at follow-up to the overall clinical condition at baseline. It includes an assessment of the change from the initiation of treatment with a rating from 1 to 7.	The 7-point scale is: 1 = Very much improved, 2=Much improved, 3=Minimally improved, 4=No change, 5=Minimally worse, 6=Much worse, and 7=Very much worse. A score of 1, 2, or 3 would indicate overall improvement of ADHD severity.
Conners Comprehensive Behavior Rating Scales[6]	Parent and teacher forms are available in full (90-item, 59-item) and abbreviated (27-item, 28-item) versions.	Normative values are provided separately by gender and age.
The Vanderbilt Assessment Scales for parents and teachers[7, 8]	The Vanderbilt Assessment Scales are based on DSM-IV scales. The scale for parents has 55 questions that rate symptoms and their impact on family and school. The teacher scale includes 43	Normative data and percentile ranks are provided for each subscale by grade and gender.

Rating Scale	Description	Scoring
	questions on symptoms and school performance.	
Test of Variables of Attention (TOVA), Attention performance index[9]	TOVA® is a validated computerized continuous performance test that presents targets and non-targets as squares that either appear at the top or bottom of the screen. The task consists of two halves: the first half has a target-to-non-target ratio assessed sustained attention; the second half assesses inhibitory control. The program assesses attention consistency, attentional lapses, and processing speed.	Clinical meaningfulness for the pivotal trial was defined as: TOVA API improvement greater than 1.4 points, and post-test API score 0 or more (normative range), ADHD-RS improvement of two points or more, CGI-I post-score of one (very much improved) or two or less (very much or much improved), and any improvement in an Impairment Rating Scale.

ADHD: attention-deficit/hyperactivity disorder; ADHD-RS-IV: ADHD rating scale, version 4; CGI-I: clinical global impression scale-improvement; DSM-IV: Diagnostic and Statistical Manual of Mental Disorders 4th edition; TOVA (API): test of variables of attention (attention performance index).

Follow-up after the treatment period (1 to 3 months), at six months, and annually for three years is of interest to monitor outcomes of the effect of EndeavorRx®.

STUDY SELECTION CRITERIA

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for randomized controlled trials (RCTs);
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

REVIEW OF EVIDENCE

Randomized Controlled Trials

Key RCT characteristics and results are described in Tables 2 and 3. Limitations in study relevance and study design and conduct are described in Tables 4 and 5.

Kollins (2020) reported results of the STARS-ADHD (Software Treatment for Actively Reducing Severity of ADHD) randomized double blind trial, which compared treatment with EndeavorRx® (AKL-T01) to a digital control (EVO Words) that targets cognitive domains other than those targeted by AKL-T01.[10] AKL-T01 is a digital game played on a mobile device as described above. EVO Words requires the child to spell as many words as possible by connecting letters in a grid in a fixed amount of time. Parents and children were informed that the study was evaluating two different investigational interventions for ADHD, and only the study coordinator was aware of which video game that the children received. Compliance was monitored by study coordinators, who notified parents by email if the game was not played for more than 48 hours. After four weeks, patients were reassessed for attentional functioning, ADHD symptoms, and impairment. The primary outcome was the change in the computerized test of variable of attention, attention performance index (TOVA API). Secondary outcomes

included a number of clinician and parent reported measures such as the ADHD rating scale, Impairment Rating Scale, and Clinical Global Impressions-Improvement. Out of 348 patients who were randomly assigned, five were lost to follow-up, four were withdrawn by the parent or investigator, and 10 had invalid test results, resulting in a final sample of 329 children for the primary outcome measure. The two children who received the incorrect allocation were included in the intention-to-treat population. The mean change from baseline on the TOVA API was 0.93 in the AKL-T01 group and 0.03 in the control group (p<.05). However, there were no between-group differences for secondary measures, which included the clinician and parent ratings of ADHD symptoms; both groups showed improvement in ADHD ratings from baseline to post-treatment. Treatment-related adverse events AKL-T01 group included frustration (5 [3%] of 180) and headache (3 [2%] of 180) with a mean number of completed sessions of 83%, compared to 96% compliance in the EVO Words group. The study was well-designed and conducted, but there are a number of limitations in study relevance due to the limited age range, limited follow-up, and most importantly the uncertainty of the association of computerized tests with observable behavior. There are also questions regarding the most effective treatment schedule and characteristics of patients who might benefit from this intervention. The trial authors conclude "the results of the current trial are not sufficient to suggest that AKL-T01 should be used as an alternative to established and recommended treatments for ADHD." This study was funded by Akili Interactive Labs and multiple study authors have a financial interest in the funding company.

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Kollins (2020); STARS-ADHD[10]	US	20	2016 to 2017	348 pediatric patients aged 8 to 12 years, with confirmed ADHD, TOVA API scores -1.8 and below, without or with washout of disorder-related medication.	AKL-T01 (EndeavorRx®) for 25 min a day on 5 days per week for 4 weeks (n=180)	EVO Words for 25 min a day on 5 days per week for 4 weeks (n=168)

ADHD: attention-deficit/hyperactivity disorder; RCT: randomized controlled trial; STARS-ADHD: Software Treatment for Actively Reducing Severity of ADHD; TOVA API: test of variables of attention, attention performance index.

Table 3. Summary of Key RCT Results

Study	TOVA API mean improvement (SD)	TOVA API Improvement >1.4 points n/N (%)	ADHD-Rating Scale Improvement ≥2 points n/N (%)	Impairment Rating Scale n/N (%)	Clinical Global Impressions ≤2 n/N (%)
Kollins (2020); STARS-ADHD[10]					
N	329	329	337	332	339
AKL-T01	0·93 (3.15)	79/169 (47%)	128/173 (74%)	82/171 (48%)	29/175 (17%)
EVO Words	0·03 (3.16)	51/160 (32%)	119/164 (73%)	60/161 (37%)	26/164 (16%)
p-value	<0.05	0.006	0.77	0.049	0.86

ADHD: attention deficit/hyperactivity disorder; RCT: randomized controlled trial; SD: standard deviation; STARS-ADHD: Software Treatment for Actively Reducing Severity of ADHD; TOVA API: test of variables of attention, attention performance index.

Tables 4 and 5 display notable limitations identified in each study.

Table 4. Title

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Kollins (2020)[10]	4. The study population was limited to children 8 to 12 years of age.			6. Improvement on computerized tests of attention is weakly associated with classroom attention.	1. There was no follow-up after the 4 week intervention period.

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4.Not the intervention of interest.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. No CONSORT reporting of harms; 4. Not establish and validated measurements; 5. Clinical significant difference not prespecified; 6. Clinical significant difference not supported.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms.

Table 5. Title

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]
Kollins (2020)[10]				2. Missing data was not included in the intention-to-treat analysis.	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias.
[b] Blinding key: 1. Not blinded to treatment assignment; 2. Not blinded outcome assessment; 3. Outcome assessed by treating physician.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials).
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated.

Nonrandomized Studies

In 2021, Kollins published the results of an additional open-label study of the effectiveness of EndeavorRx® as an adjunct to pharmacotherapy in 8 to 14-year-old children with ADHD on stimulant medication (n = 130) or not on any ADHD medication (n = 76). Study participants were instructed to use the EndeavorRx® (approximately 25 min/day, five days/week) followed by a treatment break of four weeks and a second treatment period of four weeks. The primary study outcome was change in ADHD-related impairment as assessed by the Impairment Rating Scale (IRS) after four weeks. Secondary outcomes included changes in IRS, ADHD Rating Scale (ADHD-RS) and Clinical Global Impressions Scale—Improvement (CGI-I) on

days 28, 56, and 84. Significantly improved ADHD-related impairment as measured by clinician-rated IRS was found after the first 4-week treatment in both cohorts; mean changes from Baseline to Day 28 in IRS overall severity score was −0.7 (95% confidence interval (CI): [−0.86, −0.50]; DOF: 127; Cohen's d: .65; $p < 0.001$) in the On Stimulants cohort and −0.5 (95% CI: [−0.73, −0.32]; DOF: 73; Cohen's d: .59; $p < 0.001$) in the No Stimulants cohort. Participants with an improvement of ≥1 point on the IRS total score from Baseline to Day 28 were considered responders, and 55.5% of the On Stimulants cohort and 40.5% of the No Stimulants cohort were IRS responders. Significant improvement also was found in both cohorts for all secondary endpoints. Mean change from baseline to Day 56 in IRS overall severity score, ADHD-RS total score, and Inattention and Hyperactivity-Impulsivity subscale scores remained significantly improved for participants in both cohorts (all $p < 0.001$), indicating stability of treatment effects over this timeframe. While this study provides valuable information regarding longer-term treatment effects and observations in an expanded population not available from the pivotal trial discussed above, there are considerable limitations to the study. This study was conducted without randomization did not include a blinded control condition, which precludes evaluation of a possible placebo effects. The manufacturer of the application, Akili Interactive Labs, provided research support and was involved in trial conceptualization. Multiple study authors have a financial interest in the study product. There was no clear effort to mitigate the potential for bias resulting from these possible conflicts of interest.

SUMMARY OF EVIDENCE

For individuals with ADHD who receive a prescription digital therapy, the evidence includes an RCT and an open-label, uncontrolled study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single RCT that has been identified compared outcomes of the predecessor of the FDA-cleared EndeavorRx® (AKL-T01) to a word game that targeted different cognitive abilities. Although the experimental treatment group had significantly greater improvement on a computerized test of attention, both the experimental and control groups improved to a similar extent on parent and clinician assessments. 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 single-arm, open-label study evaluating the EndeavorRx® in patients with ADHD with and without current pharmaceutical intervention provided additional information regarding the effectiveness of the intervention in a broader population. However, the lack of a control group or randomization limit interpretation of study findings. Several questions remain concerning the efficacy of this treatment. At this time, the digital therapy is not recommended as an alternative or adjunct to established treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF PEDIATRICS

In 2019, the American Academy of Pediatrics (AAP) updated their 2011 clinical practice guideline on the diagnosis, evaluation, and treatment of attention-deficit/hyperactivity disorder (ADHD) in children and adolescents.[1]

The guidelines were based on a systematic evidence review by the Agency for Healthcare Research and Quality. The AAP gave strong recommendations based on level A evidence for medications and training and behavioral treatment for ADHD implemented with the family and school.

SOCIETY FOR DEVELOPMENTAL AND BEHAVIORAL PEDIATRICS

In 2020, the Society for Developmental and Behavioral Pediatrics published a clinical practice guideline for the assessment and treatment of children and adolescents with complex ADHD.[11] Complex ADHD is defined by age (<4 years or presentation >12 years), presence of coexisting conditions, moderate to severe functional impairment, diagnostic uncertainty, or inadequate response to treatment. The society gave a strong recommendation based on grade B evidence for psychoeducation and evidence-based behavioral and educational interventions (eg, parent training, classroom management, behavioral peer interventions, organizational skills training). The society gave a recommendation based on grade C to B evidence for the frequent need to combine behavioral approaches with pharmacological treatments, and that "treatment should focus on areas of functional impairment and not just symptom reduction, by incorporating developmentally appropriate strategies for self-management, skill building, and prevention of adverse outcomes."

SUMMARY

There is not enough research to show that digital health products for the treatment of attention-deficit/hyperactivity disorder (ADHD) improves net health outcomes. No clinical guidelines based on research recommend digital health products for the treatment of attention-deficit/hyperactivity disorder (ADHD). Therefore, digital health products (including digital therapeutics) for the treatment of attention-deficit/hyperactivity disorder (ADHD) are considered investigational.

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CODES

NOTE: Not all digital health products will have a specific code. These are examples of codes that may be relevant.

Codes	Number	Description
CPT	0702T	Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; supply and technical support, per 30 days
	0703T	;management services by physician or other qualified health care professional, per calendar month
	99199	Unlisted special service, procedure or report [when specified as a digital health management software application]
HCPCS	A9291	Prescription digital behavioral therapy, FDA cleared, per course of treatment
	E1399	Durable medical equipment, miscellaneous [when specified as a digital health management software application]

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