



Louisiana

Digital Health Therapies for Attention Deficit/Hyperactivity Disorder

Policy # 00755

Original Effective Date: 11/08/2021

Current Effective Date: 11/14/2022

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers prescription digital therapy for the treatment of attention-deficit/hyperactivity disorder to be **investigational**.*

Background/Overview

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.

For children younger than 17 years of age, the DSM-5 requires at least 6 symptoms of hyperactivity-impulsivity or at least 6 symptoms of inattention. The combined type requires a minimum of 6 symptoms of hyperactivity-impulsivity plus at least 6 symptoms of inattention. The symptoms must 1) occur often, 2) be present in more than 1 setting, 3) persist for at least 6 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.

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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.

- 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 2 to 3 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration

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approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Attention-deficit/hyperactivity disorder (ADHD) is characterized by symptoms of hyperactivity, impulsivity, and inattention, which are considered excessive for the person's age. Established treatments for ADHD in children include educational, environmental, psychological, and behavioral interventions, and medication. This review will assess whether a digital therapy in the form of a computer game can improve attention in children with ADHD.

Summary of Evidence

For individuals with ADHD who receive a prescription digital therapy, the evidence includes an randomized controlled trial (RCT). 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) with 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 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 are ongoing or have recently been completed. At this time, the digital therapy cannot be 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.

Supplemental Information

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

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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.

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. 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."

U.S. Preventive Services Task Force Recommendations

Not applicable

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

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Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Ongoing</i>			
NCT04897074 ^a	A Single Arm Pivotal Trial to Assess the Efficacy of AKL-T01, a Novel Digital Intervention Designed to Improve Attention, in Adolescents, Aged 13-17 Years Old, Diagnosed With Attention Deficit Hyperactive Disorder (STARS-ADHD-Adolescents)	165	Dec 2022
NCT05183919	Software Treatment for Actively Reducing Severity of ADHD in Adults (STARS ADHD Adult)	325	Aug 2022
<i>Unpublished</i>			
NCT03649074 ^a	Software Treatment for Actively Reducing Severity of ADHD as Adjunctive Treatment to Stimulant (STARS-ADHD Adjunctive)	203	Sep 2019 (results submitted)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

References

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2. 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
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Policy History

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10/07/2021 Medical Policy Committee review

10/13/2021 Medical Policy Implementation Committee approval. New policy.

10/06/2022 Medical Policy Committee review

10/11/2022 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 10/2023

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)†, copyright 2021

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by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No specific codes
HCPCS	No specific codes
ICD-10 Diagnosis	F90-0-F90.9

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
 3. Reference to federal regulations.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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