BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Digital Health Therapies for Attention Deficit/Hyperactivity Disorder

Policy #: 742
Latest Review Date: August 2022
Category: Medical

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat prescription digital therapy as a **non-covered benefit** and as **investigational** for the treatment of attention deficit/hyperactivity disorder.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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

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.

Table 1. ADHD Rating Scales

Rating Scale	Description	Scoring
ADHD Rating Scale	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	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 to7.	The 7-point scale is: 1 = Very much improved, 2=Much improved, 3=Minimally improved, 4=No change, 5=Minimally worse, 6=Much worse, and7=Very much worse. A score of 1, 2, or 3 would indicate overall improvement of ADHD severity.
Conner's Comprehensive Behavior Rating Scales	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	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 questions on symptoms and school performance.	Normative data and percentile ranks are provided for each subscale by grade and gender.
Test of Variables of Attention, Attention performance index	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 2 points or more, CGI-I post-score of 1 (very much improved) or 2 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).

KEY POINTS:

This evidence review was created in July 2021 with a search of the PubMed database. The most recent literature update was performed through June 23, 2022.

Author, year, country	Study Design	Population Characteristics	Interventions	Comparators
Kollins et al (2020);STARS-ADHD, US	RCT	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) for25 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.

Study	TOVA API mean improve-ment (SD)	TOVA API Improvement >1.4points n/N (%)	ADHD-Rating Scale Improvement > 2points n/N (%)	Impairment Rating Scale n/N (%)	Clinical Global Impressions < 2 n/N (%)
Kollins et al (2020);STARS-ADHD					
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	<.05	.006	.77	.049	.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.

Study Limitations

- The study population was limited to children 8 to 12 years of age.
- Improvement on computerized tests of attention is weakly associated with classroom attention.
- There was no follow-up after the 4 week intervention period.
- Missing data was not included in the intention-to-treat analysis.

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.

Practice Guidelines and Position Statements
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 >12years), 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 (e.g., parent training, classroom management, behavioral peer interventions, and 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.

KEY WORDS:
EndeavorRx, ADD, ADHD, video game

APPROVED BY GOVERNING BODIES:
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.

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:
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 (Effective 01/01/2022)
0703T	Remote therapeutic monitoring of a standardized online digital cognitive behavioral therapy program ordered by a physician or other qualified health care professional; management services by physician or other qualified health care professional, per calendar month (Effective 01/01/2022)

HCPCS:

E1399	Durable Medical Equipment Miscellaneous

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POLICY HISTORY:

Adopted for Blue Advantage, July 2021
Medical Policy Group, July 2021
Medical Policy Group, November 2021: 2022 Annual Coding Update. Added CPT 0702T-0703T.
Medical Policy Group, August 2022