3.03.03	Digital Health Therapies for Attention Deficit/Hyperactivity Disorder		
Original Policy Date:	June 1, 2022	**Effective Date:**	June 1, 2022
Section:	3.0 Mental Health	**Page:**	Page 1 of 11

Policy Statement

Prescription digital therapy is considered **investigational** for the treatment of attention-deficit/hyperactivity disorder.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Effective April 1, 2022, there is a new CPT code that represents reSET by Pear Therapeutics. Per the manufacturer, reSET is prescription digital therapeutics and is a cognitive behavioral therapy, indicated for patients 18 years of age and older who are enrolled in outpatient treatment under the supervision of a clinician.

- **A9291**: Prescription digital behavioral therapy, FDA-cleared, per course of treatment

Description

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.

Related Policies

- N/A

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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). 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

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 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.[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 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.

Literature Review

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, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 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 therapies 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.[2,] 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.

The question addressed in this evidence review is: Does the use of EndeavorRx improve the net health outcome in children with ADHD?

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is children with ADHD, with primarily inattentive or combined type ADHD.

Interventions

The therapy being considered is EndeavorRX. EndeavorRx is a digital therapy (software-as-a-medical device) in the form of an interactive video game that requires the child to navigate a character through a game-like space while collecting objects. It is designed to be played on a mobile device at home for approximately 25 minutes a day, 5 days a week, and has reminders to both the child and parent to encourage compliance. Typical treatment would be for a period of 1 month, with extension up to 3 months allowed per license.

EndeavorRx uses a proprietary technology platform that adjusts the difficulty level based on the user's prior performance. The adaptive algorithm is intended to encourage the patients to surpass their previous performance, so that the user would gradually increase their ability to focus attention. No claims are made for behavioral symptoms such as hyperactivity.

Version 1.5 was reviewed by the U.S. Food and Drug Administration for De Novo marketing clearance. Earlier non-prescription versions were called ProjectEvo and AKL-T01, which was released under the Enforcement Policy for Digital Health Devices For Treating Psychiatric Disorders During the COVID-19 Public Health Emergency.

EndeavorRx is intended to be used as part of a therapeutic program. EndeavorRx is not intended to be used as a stand-alone treatment

Comparators

The following therapies are currently used to treat ADHD, either individually or in combination:

- Educational programs
- Clinician-directed behavioral and psychological therapy
- Stimulant or non-stimulant medications

Outcomes

The general outcomes of interest are change in symptoms of inattention, ability to function at school and home, quality of life, and treatment-related adverse effects.

ADHD-specific rating scales are described in Table 1.

Table 1. ADHD Rating Scales

Rating Scale	Description	Scoring
ADHD Rating Scale[3,]	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[4,]	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[5,]	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[6,7,]	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[8,]	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	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

Rating Scale	Description	Scoring
	half assesses inhibitory control. The program assesses attention consistency, attentional lapses, and processing speed.	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).

Follow-up after the treatment period (1 to 3 months), at 6 months, and annually for 3 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 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 et al (2020) reported results of the STARS-ADHD (Software Treatment for Actively Reducing Severity of ADHD) randomized double blind trial, which compared treatment with AKL-T01 to a game (EVO Words) that targets cognitive domains other than those targeted by AKL-T01.[9,] 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 2 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 4 weeks, patients were reassessed for attentional functioning, ADHD symptoms, and impairment. The primary outcome was the change in the 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, 5 were lost to follow-up, 4 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 2 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 what might be the most effective treatment schedule and characteristics of the patients who might benefit from this intervention. As was also noted by the trial authors "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."

Table 2. Summary of Key RCT Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					Active	Comparator
Kollins et al (2020); STARS-ADHD[9,]	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 et al (2020); STARS-ADHD[9,]					
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.
Tables 4 and 5 display notable limitations identified in each study.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Kollins et al (2020)[9,]	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. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Kollins et al (2020)[9,]				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.

Section Summary: Digital Therapies for Attention-Deficit/Hyperactivity Disorder
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.

Summary of Evidence
For individuals with ADHD who receive a prescription digital therapy, the evidence includes an 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) 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 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 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.

Supplemental Information
The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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.

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. [10,] 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 (e.g., 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 6.

Table 6. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
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 (ADHD)	165	Dec 2022
Unpublished			
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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8. 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
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Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description
CPT®	None	
HCPCS	A9291	Prescription digital behavioral therapy, FDA-cleared, per course of treatment ***(Code effective 4/1/2022)***

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
06/01/2022	New policy.

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	**AFTER** **Blue font: Verbiage Changes/Additions**
New Policy **Policy Statement:** N/A	**Digital Health Therapies for Attention Deficit/Hyperactivity Disorder 3.03.03** **Policy Statement:** Prescription digital therapy is considered **investigational** for the treatment of attention-deficit/hyperactivity disorder.