



FEP Medical Policy Manual

FEP 3.03.03 Digital Health Technologies for Attention Deficit/Hyperactivity Disorder

Effective Policy Date: October 1, 2023

Original Policy Date: October 2021

Related Policies:

None

Digital Health Technologies for Attention Deficit/Hyperactivity Disorder

Description

Description

Digital health technologies is a broad term that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device, and include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics). The scope of this review includes only those digital technologies that are intended to be used for therapeutic application and meet the following 3 criteria: 1) Must meet the definition of "Software as a medical device" which states that software is intended to be used for a medical purpose, without being part of a hardware medical device or software that stores or transmits medical information. 2) Must have received marketing clearance or approval by the U.S. Food and Drug Administration (FDA) either through the *de novo* premarket process or 510(k) process or pre-market approval and 3) Must be prescribed by a healthcare provider. This review will assess whether a digital therapy in the form of a computer game can improve attention in children with ADHD.

OBJECTIVE

The objective of this evidence review is to individually assess FDA-approved prescription digital health technologies to determine whether each therapeutic application improves the net health outcome in individuals with ADHD.

POLICY STATEMENT

The use of EndeavorRx is considered **investigational** for all indications including attention-deficit/hyperactivity disorder.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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

Summary of Evidence

For individuals who are children ages 8 to 12 years with Attention-deficit/hyperactivity disorder (ADHD) who receive EndeavorRx, the evidence includes a pivotal randomized controlled trial (RCT) and an open label study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The pivotal RCT compared outcomes of EndeavorRx (AKL-T01) with a word game that targeted different cognitive abilities (digital control intervention). 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 second open label study compared EndeavorRx plus stimulant medication with EndeavorRx alone. This study design does not permit conclusions about the adjunctive treatment effect of EndeavorRx as both study arms received EndeavorRx. An appropriate study design would be comparing EndeavorRx plus stimulant medication versus stimulant medication alone. 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 have recently been completed but not yet published. 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.

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.³

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.

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.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
September 2021	New policy	Policy created with literature review through June 9, 2021. Considered investigational
September 2022	Replace Policy	Policy updated with literature review through June 23, 2022. No references added; policy statements unchanged.
September 2023	Replace Policy	Policy updated with literature review through May 5, 2023. Reference added. Policy statements revised from "Prescription digital therapy is considered investigational for the treatment of attention-deficit/hyperactivity disorder" to "The use of EndeavorRx is considered investigational for all indications including attention-deficit/hyperactivity disorder"; intent unchanged.