



MASSACHUSETTS

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Medical Policy

Digital Health Technologies for Attention Deficit /Hyperactivity Disorder

Table of Contents

- [Policy: Commercial](#)
- [Policy: Medicare](#)
- [Authorization Information](#)
- [Coding Information](#)
- [Description](#)
- [Policy History](#)
- [Information Pertaining to All Policies](#)
- [References](#)

Policy Number: 947

BCBSA Reference Number: 3.03.03 (For Plan internal use only)

NCD/LCD: N/A

Related Policies

None

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

The use of EndeavorRx is considered [INVESTIGATIONAL](#) for all indications including attention-deficit/hyperactivity disorder.

Prior Authorization Information

Inpatient

- For services described in this policy, precertification/preauthorization **IS REQUIRED** for all products if the procedure is performed **inpatient**.

Outpatient

- For services described in this policy, see below for products where prior authorization **might be required** if the procedure is performed **outpatient**.

	Outpatient
Commercial Managed Care (HMO and POS)	This is not a covered service.
Commercial PPO and Indemnity	This is not a covered service.
Medicare HMO Blue SM	This is not a covered service.
Medicare PPO Blue SM	This is not a covered service.

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

There are not any specific codes for this service.

Description

Scope of Review

Software has become an important part of product development and is integrated widely into digital platforms that serve both medical and non-medical purposes. The 3 broad categories of software use in medical devices are:

1. Software used in the manufacture or maintenance of a medical device (eg, software that monitors x-ray tube performance to anticipate the need for replacement),
2. Software that is integral to a medical device or software in a medical device (eg, software used to "drive or control" the motors and the pumping of medication in an infusion pump),
3. Software, which on its own is a medical device referred to as "Software as a Medical Device" (SaMD) (eg, software that can track the size of a mole over time and determine the risk of melanoma).

The International Medical Device Regulators Forum, a consortium of medical device regulators from around the world led by the U.S. Food and Drug Administration (FDA) defines SaMD as "software that is intended to be used for one or more medical purposes that perform those purposes without being part of a hardware medical device".¹ Such software was previously referred to by industry, international regulators, and health care providers as "standalone software," "medical device software," and/or "health software," and can sometimes be confused with other types of software.

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" (SaMD) 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. 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.

BCBSA Evaluation Framework for Digital Health Technologies

SaMDs, as defined by the FDA, are subject to the same evaluation standards as other devices. The Blue Cross and Blue Shield Association Technology Evaluation Criterion are as follows:

1. The technology must have final approval from the appropriate governmental regulatory bodies.
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes.
3. The technology must improve the net health outcome.^a
4. The technology must be as beneficial as any established alternatives.
5. The improvement must be attainable outside the investigational settings.^b

^a The technology must assure protection of sensitive patient health information as per the requirements of The Health Insurance Portability and Accountability Act of 1996 (HIPAA).

^b The technology must demonstrate usability in a real-world setting.

Other regulatory authorities such as the United Kingdom's National Institute for Health and Care Excellence (NICE) have proposed standards to evaluate SaMD.²

Summary

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.

Summary of Evidence

For individuals who are children ages 8 to 12 years with 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 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.

Policy History

Date	Action
9/2023	Annual policy review. Policy statements clarified 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.
9/2022	Annual policy review. Description, summary, and references updated. Policy statements unchanged.
12/2021	New policy describing investigational indications for treatment of attention deficit/hyperactivity disorder. Effective 12/1/2021.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

- [Medical Policy Terms of Use](#)
- [Managed Care Guidelines](#)
- [Indemnity/PPO Guidelines](#)
- [Clinical Exception Process](#)
- [Medical Technology Assessment Guidelines](#)

References

1. International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Key Definitions. 2013. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf>. Accessed May 9, 2023.
2. National Institute for Health and Care Excellence (NICE). Evidence standards framework for digital health technologies. 2021. [nice.org.uk/corporate/ecdf7/chapter/section-a-evidence-for-effectiveness-standards](https://www.nice.org.uk/corporate/ecdf7/chapter/section-a-evidence-for-effectiveness-standards). Accessed May 9, 2023.

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13. Kollins, S.H., Childress, A., Heusser, A.C. et al. Effectiveness of a digital therapeutic as adjunct to treatment with medication in pediatric ADHD. *npj Digit. Med*. 4, 58 (2021). <https://doi.org/10.1038/s41746-021-00429-0>