MASSACHUSETTS

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Medical Policy

# Digital Health Technologies: Diagnostic Applications

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## Policy Number: 175

BCBSA Reference Number: 3.03.01 (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 Blue℠ and Medicare PPO Blue℠ Members

Prescription digital health technologies for diagnostic application that have received clearance for marketing by the U.S. Food and Drug Administration as a diagnostic aid for autism spectrum disorder (Canvas Dx) are considered **INVESTIGATIONAL**.

## 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℠** | This is **not** a covered service. |
| **Medicare PPO Blue℠** | 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

**Autism Spectrum Disorder**

Autism spectrum disorder (ASD) is a biologically based neurodevelopmental disorder characterized by persistent deficits in social communication and social interaction and restricted, repetitive patterns of behavior, interests, and activities. ASD can range from mild social impairment to severely impaired functioning; as many as half of individuals with autism are non-verbal and have symptoms that may include debilitating intellectual disabilities, inability to change routines, and severe sensory reactions. The American Psychiatric Association's Diagnostic and Statistical Manual, Fifth Edition (DSM-5) provides standardized criteria to help diagnose ASD.[1,]

Diagnosis of ASD in the United States generally occurs in two steps: developmental screening followed by comprehensive diagnostic evaluation if screened positive. American Academy of Pediatrics (AAP) recommends general developmental screening at 9, 18 and 30 months of age and ASD specific screening at 18 and 24 months of age.[2,3,] Diagnosis and treatment in the first few years of life can have a strong impact on functioning as it allows for treatment during a key window of developmental plasticity.[4,5,] However, early diagnosis in the US remains an unmet need even though studies have demonstrated a temporal trend of decreasing mean ages at diagnosis over time.[6,7,]. According to a 2020 study by Autism and Developmental Disabilities Monitoring (ADDM) Network, an active surveillance system that provides estimates of ASD in the US, reported median age of earliest known ASD diagnosis ranged from 36 months in California to 63 months in Minnesota.[8,]

**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. Three broad categories of software use in medical devices are:

1. Software used in the manufacture or maintenance of a medical device (example 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 (example 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) (example, 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".[9,] 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 diagnostic application (detecting presence or absence of a condition, the risk of developing a condition in the future, or treatment response [beneficial or adverse]) and meet the following 3 criterion:

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 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 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.[10.]

## 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 diagnostic application (detecting the presence or absence of a condition, the risk of developing a condition in the future, or treatment response [beneficial or adverse]) and meet the following 3 criterion- 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 either through the *de novo* premarket process or 510(k) process or pre-market approval and 3) Must be prescribed by a healthcare provider.

**Summary of Evidence**
For individuals who are in the age range of 18 to 72 months and in whom there is a suspicion of autism spectrum disorder (ASD) by a parent, caregiver, or healthcare provider and who receive Canvas Dx, the evidence includes a single, double-blind, multicenter, prospective, comparator cohort study of clinical validity. Relevant outcomes are test validity, change in disease status, functional outcomes, and quality of life. The study compared Canvas Dx output to diagnostic agreement by 2 or more independent specialists in a cohort of 18 to 72-month-olds with developmental delay concerns. The majority of study participants (68% or 290/425) were classified as “indeterminates” by Canvas DX. For the 32% of participants who received a determinate output (ASD positive or negative), sensitivity was 98.4% (95% CI, 91.6% to 100%), specificity was 78.9% (95% CI, 67.6% to 87.7%), positive predictive value (PPV) was 80.8% (95% CI, 70.3% to 88.8%) and negative predictive value (NPV) was 98.3% (95% CI, 90.6% to 100%). A major limitation in study relevance is the lack of clarity on how the test fits into the current pathway and the appropriate referral process subsequent to testing. It is unclear if Canvas Dx is a "rule-out" or "rule-in" test or perhaps both. Major limitations in the design and conduct of the study included missing data and lack of generalizability. The estimated drop out rate was 40%. Authors reported that COVID-19 control measures led to changes in study visit schedules, missed visits, patient discontinuations, and site closures (9 out of 14 sites). No clear description of reasons for discrepancy in the number of clinical sites (30 proposed sites versus 14 actual sites), characteristics of missing observations, or sensitivity analyses of missing data assumptions were provided. Issues related to the generalizability of the study findings were also noted. Data on participants stratified by enrollment sites/states and origin of primary concern for developmental delay (whether it was patient/caregiver or healthcare professional) was not reported. Other limitations include differences that may occur between the testing environments of a structured clinical trial setting versus the home setting and lack of data on usability outside of a clinical trial. More clarity on these issues is needed to understand generalizability of this study. Evidence for the Canvas Dx has not directly demonstrated that the test is clinically useful, and a chain of evidence cannot be

constructed to support its utility. 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. References added. Policy statements unchanged. |
| 12/2022 | New medical policy describing investigational indications. Prescription digital health technologies for diagnostic application that have received clearance for marketing by the FDA as a diagnostic aid for autism spectrum disorder (Canvas Dx) are considered investigational. Effective 12/1/2022. |

## 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


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