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 BlueSM and Medicare PPO BlueSM 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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Status</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>This is not a covered service.</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare HMO BlueSM</td>
<td>This is not a covered service.</td>
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<tr>
<td>Medicare PPO BlueSM</td>
<td>This is not a covered service.</td>
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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.²³ Diagnoses 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.⁴⁵ However, early diagnosis in US remains an unmet need even though studies have demonstrated a temporal trend of decreasing mean ages at diagnosis over time.⁶⁷ 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 device 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.11

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 prospective study of clinical validity. Relevant outcomes are test validity, change in disease status, functional outcomes, and quality of life. Results of the study reported that Canvas Dx outperformed conventional autism screeners both in area under curve (AUC), sensitivity, and specificity. However, multiple limitations were noted. The major limitation is the lack of clarity on how the test fits into the current pathway.

Diagnosis of ASD in the United States generally occurs in 2 steps: developmental screening followed by comprehensive diagnostic evaluation if screened positive. To evaluate the utility of the test, an explication of how the test would be integrated into the current recommended screening and diagnostic pathway is needed. Neither the manufacturer’s website nor the FDA-cleared indication is explicit on how the test fits into the current pathway. It is unclear whether the test is meant to be used as add-on test to existing comprehensive diagnostic evaluation tests or if it could replace existing comprehensive diagnostic evaluation tests among a population of children at risk for developmental delay for confirmatory diagnosis of ASD. In addition, there is also a potential of "off-label" use of this test in the general population, either as a screening test or a diagnostic test. Second, the manufacturer asserts that Canvas Dx is intended to be used by a primary care physician to aid in the diagnosis of ASD, but the published study on clinical validity used a specialist rather than a primary care physician to complete the clinical questionnaire
module. This is likely to result in higher sensitivity and specificity and thus confounds the interpretation of published data on clinical validity.

Further testing in primary care clinics is needed to validate the accuracy of the clinician module. In addition, all published studies were conducted on children who had been preselected as having high risk of autism. No studies on children from the general population have been published. 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. 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**

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<th>Date</th>
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<tr>
<td>12/2022</td>
<td>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.</td>
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**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**


