BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Digital Health Technologies: Diagnostic Applications

Policy #: 750
Latest Review Date: August 2022
Category: DME

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **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 are considered a **non-covered benefit** and as **investigational**.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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.

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.

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. 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. 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. 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.

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". 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.

KEY POINTS:

This evidence review was created in April 2022 with a search of the PubMed database.

Summary of Evidence:
For individuals who are in the age range of 18 to 72 months and in whom there is a suspicion of 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 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.

Practice Guidelines and Position Statements

American Academy of Pediatrics

The American Academy of Pediatrics (AAP) guidelines recommend ASD-specific universal screening in all children at ages 18 and 24 months in addition to developmental surveillance and monitoring. Toddlers and children should be referred for diagnostic evaluation when increased risk for developmental disorders (including ASD) is identified through screening and/or surveillance. Children should be referred for intervention for all identified developmental delays at the time of identification and not wait for an ASD diagnostic evaluation to take place. The AAP does not approve nor endorse any specific tool for screening purposes. The AAP has published a toolkit that provides a list of links to tools for developmental surveillance and screening for use at the discretion of the health care professional.

The American Academy of Child and Adolescent Psychiatry

The American Academy of Child and Adolescent Psychiatry recommends that the developmental assessment of young children and the psychiatric assessment of all children should routinely include questions about ASD symptomatology.

The UK National Screening Committee

The UK National Screening Committee does not recommend systematic population screening for ASD because:

- There is not currently a test that is good enough for screening the general population
- It is not known if screening would improve long term outcomes for children with autism
- There is not an established approach to screening which is acceptable to parents

These recommendations were based on a summary of evidence published in 2012. The next review is estimated to be completed in 2022.

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF) published recommendations for ASD in young children in 2016. The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for ASD in young children (children 18 to 30 months of age) for whom no concerns of ASD have been raised by their parents or a clinician.

KEY WORDS:
Canvas DX, Coagnoa App

APPROVED BY GOVERNING BODIES:
Digital health technologies that meet the current scope of review are shown in Table 1.

Table 1. Digital Health Technology for Diagnostic Applications

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Code	FDA Marketing Clearance	Year
Canvas DX (formerly known as Coagnoa App)	Cognoa	"Canvas Dx is intended for use by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (ASD) for patients ages 18 months through 72 months who are at risk for developmental delay based on concerns of a parent, caregiver, or healthcare provider. The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic	Artificial intelligence app for use by health care providers as an adjunct in the diagnosis of autism spectrum disorder for patients ages 18 to 72 months. Canvas DX includes 3 questionnaires: parent/caregiver, a video analyst, and a health care provider, with an algorithm that synthesizes the 3 inputs for use by the primary care provider.	QPF	DEN200069	2021

		process. The device is for prescription use only (Rx only)."				

FDA: U.S. Food and Drug Administration;

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

There is no specific CPT or HCPCS coding for these devices.

E1399	Durable medical equipment, miscellaneous

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POLICY HISTORY:

Adopted for Blue Advantage, August 2022
Medical Policy Group: August 2022