BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 3.03.01 Digital Health Technologies: Diagnostic Applications

Effective Policy Date: October 1, 2022

Original Policy Date: September 2022

Related Policies:

None

Digital Health Technologies: Diagnostic Applications

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 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.

OBJECTIVE

The objective of this evidence review is to individually assess FDA approved prescription digital health technologies to determine whether each diagnostic application improves the net health outcome compared with standard testing.

POLICY STATEMENT

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**.

POLICY GUIDELINES

None

BENEFIT APPLICATION

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

Non-prescription digital health technologies may be excluded from coverage depending on local contract language.

FDA REGULATORY STATUS

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

FDA: U.S. Food and Drug Administration;

RATIONALE

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 U.S. Food and Drug Administration (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.

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

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.[2,]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.[20,]

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.[31,]

The UK National Screening Committee

The UK National Screening Committee[32,] 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.[33,] 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.

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.

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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 2022	New policy - Add to Digital Health section	Policy created with literature review through April 25, 2022. 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.