

EFFECTIVE DATE: 02|01|2023

POLICY LAST UPDATED: 10|19|2022

OVERVIEW

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.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Not applicable

POLICY STATEMENT

Medicare Advantage Plans

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) is not covered as the evidence is insufficient to determine the effects of the technology on health outcomes.

Commercial Products

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) is considered not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND

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 overtime.

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.

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.

CODING

There is no specific code for this procedure. Claims should be filed with an unlisted code.

RELATED POLICIES

Prescription Digital Therapeutics for Substance Abuse
Digital Health Therapeutics for Substance Abuse Disorders
Unlisted Procedures

PUBLISHED

Provider Update, December 2022

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