Medical Coverage Policy | Digital Health Technologies: Diagnostic Applications

EFFECTIVE DATE: 02|01|2023
POLICY LAST UPDATED: 08|02|2023

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 30months 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 to63 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, 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% to100%). 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 dropout 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.

CODING

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

RELATED POLICIES

Digital Health Technologies - Therapeutic Applications
Digital Health Technologies for Attention Deficit Hyperactivity Disorder
Digital Health Therapeutics for Substance Abuse Disorders
Unlisted Procedures

PUBLISHED

Provider Update, October 2023
Provider Update, December 2022

REFERENCES:

1. American Psychiatric Association. Diagnostic and Statistical Manual of Mental Disorders (DSM-5), 5th ed. Washington, DC: American Psychiatric Association; 2013
2. Lipkin PH, Macias MM, Norwood KW, et al. Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders ThroughDevelopmental Surveillance and Screening. Pediatrics. Jan 2020; 145(1). PMID 31843861
3. Hyman SL, Levy SE, Myers SM, et al. Identification, Evaluation, and Management of Children With Autism Spectrum Disorder. Pediatrics. Jan 2020; 145(1). PMID31843864
4. Dawson G, Bernier R. A quarter century of progress on the early detection and treatment of autism spectrum disorder. Dev Psychopathol. Nov 2013; 25(4 Pt 2): 1455-72. PMID 24342850
5. Dawson G, Rogers S, Munson J, et al. Randomized, controlled trial of an intervention for toddlers with autism: the Early Start Denver Model. Pediatrics. Jan 2010;125(1): e17-23. PMID 19948568
6. Hertz-Picciotto I, Delwiche L. The rise in autism and the role of age at diagnosis. Epidemiology. Jan 2009; 20(1): 84-90. PMID 19234401
7. Leigh JP, Grosse SD, Cassady D, et al. Spending by California's Department of Developmental Services for Persons with Autism across Demographic andExpenditure Categories. PLoS One. 2016; 11(3): e0151970. PMID 27015098
8. Maenner MJ, Shaw KA, Bakian AV, et al. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8 Years - Autism and DevelopmentalDisabilities Monitoring Network, 11 Sites, United States, 2018. MMWR Surveill Summ. Dec 03 2021; 70(11): 1-16. PMID 34855725
9. International Medical Device Regulators Forum. Software as a Medical Device (SaMD): Key Definitions. 2013. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf. Accessed June 6, 2023.
10. National Institute for Health and Care Excellence (NICE). Evidence standards framework for digital health technologies. 2021.nice.org.uk/corporate/ecd7/chapter/section-a-evidence-for-effectiveness-standards. Accessed June 6, 2023.
11. Zwaigenbaum L, Bauman ML, Choueiri R, et al. Early Intervention for Children With Autism Spectrum Disorder Under 3 Years of Age: Recommendations for Practiceand Research. Pediatrics. Oct 2015; 136 Suppl 1(Suppl 1): S60-81. PMID 26430170
12. Zwaigenbaum L, Bryson S, Lord C, et al. Clinical assessment and management of toddlers with suspected autism spectrum disorder: insights from studies of high-riskinfants. Pediatrics. May 2009; 123(5): 1383-91. PMID 19403506
13. Kleinman JM, Ventola PE, Pandey J, et al. Diagnostic stability in very young children with autism spectrum disorders. J Autism Dev Disord. Apr 2008; 38(4): 606-15.PMID 17924183
14. Canvas Dx Website. Available at https://canvasdx.com/ Accessed on June 6, 2023.
15. Abbas H, Garberson F, Liu-Mayo S, et al. Multi-modular AI Approach to Streamline Autism Diagnosis in Young Children. Sci Rep. Mar 19 2020; 10(1): 5014. PMID32193406
16. Randall M, Egberts KJ, Samtani A, et al. Diagnostic tests for autism spectrum disorder (ASD) in preschool children. Cochrane Database Syst Rev. Jul 24 2018; 7(7):CD009044. PMID 30075057
17. Megerian JT, Dey S, Melmed RD, et al. Evaluation of an artificial intelligence-based medical device for diagnosis of autism spectrum disorder. NPJ Digit Med. May 052022; 5(1): 57. PMID 35513550
18. Autism Spectrum Disorder: Links to Commonly Used Screening Instruments and Tools (AAP Toolkits). American Academy of Pediatrics. Available athttps://publications.aap.org/toolkits/pages/asd-screening-tools. Accessed on June 6, 2023.
19. Volkmar F, Siegel M, Woodbury-Smith M, et al. Practice parameter for the assessment and treatment of children and adolescents with autism spectrum disorder. J AmAcad Child Adolesc Psychiatry. Feb 2014; 53(2): 237-57. PMID 24472258
20. UK National Screening Committee. Child screening program. Autism. Available at https://view-health-screening-recommendations.service.gov.uk/autism/. Accessed onJune 6, 2023.
21. Siu AL, Bibbins-Domingo K, Grossman DC, et al. Screening for Autism Spectrum Disorder in Young Children: US Preventive Services Task Force RecommendationStatement. JAMA. Feb 16 2016; 315(7): 691-6. PMID 26881372

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