DRAFT Medical Coverage Policy | Digital Health Technologies: Diagnostic Applications

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 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 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

PUBLISHED

Provider Update, December 2022

REFERENCES:

1. Lipkin PH, Macias MM, Norwood KW, et al. Promoting Optimal Development: Identifying Infants and Young Children With Developmental Disorders Through Developmental Surveillance and Screening. Pediatrics. Jan 2020; 145(1). PMID 31843861
2. Hyman SL, Levy SE, Myers SM, et al. Identification, Evaluation, and Management of Children With Autism Spectrum Disorder. Pediatrics. Jan 2020; 145(1). PMID 31843864
3. 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
4. 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
5. Hertz-Picciotto I, Delwiche L. The rise in autism and the role of age at diagnosis. Epidemiology. Jan 2009; 20(1): 84-90. PMID19234401
6. Leigh JP, Grosse SD, Cassady D, et al. Spending by California's Department of Developmental Services for Persons with Autism across Demographic and Expenditure Categories. PLoS One. 2016; 11(3): e0151970. PMID 27015098
7. Maenner MJ, Shaw KA, Bakian AV, et al. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8Years - Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2018. MMWR Surveill Summ. Dec 032021; 70(11): 1-16. PMID 34855725
8. 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 December 27, 2021.
9. 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 December 26, 2021.
10. Zwaigenbaum L, Bauman ML, Choueiri R, et al. Early Intervention for Children With Autism Spectrum Disorder Under 3 Years of Age: Recommendations for Practice and Research. Pediatrics. Oct 2015; 136 Suppl 1: S60-81. PMID 26430170
11. Zwaigenbaum L, Bryson S, Lord C, et al. Clinical assessment and management of toddlers with suspected autism spectrum disorder: insights from studies of high-risk infants. Pediatrics. May 2009; 123(5): 1383-91. PMID 19403506
12. 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
13. Canvas Dx Website. Accessed on April 25, 2022. Available at https://canvasdx.com/
14. 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. PMID 32193406
15. 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: CD009044. PMID 30075057
16. Dumont-Mathieu T, Fein D. Screening for autism in young children: The Modified Checklist for Autism in Toddlers (M-CHAT) and other measures. Ment Retard Dev Disabil Res Rev. 2005; 11(3): 253-62. PMID 16161090
17. Robins DL, Casagrande K, Barton M, et al. Validation of the modified checklist for Autism in toddlers, revised with follow-up (M-CHAT-R/F). Pediatrics. Jan 2014; 133(1): 37-45. PMID 24366990
18. DuBay M, Watson LR, Mendez LI, et al. Psychometric Comparison of the English and Spanish Western-Hemisphere Versions of the Modified Checklist for Autism in Toddlers-Revised. J Dev Behav Pediatr. Dec 01 2021; 42(9): 717-725. PMID 34840315
19. Autism Spectrum Disorder: Links to Commonly Used Screening Instruments and Tools (AAP Toolkits). American Academy of Pediatrics. Accessed on April 27, 2022. Available at https://publications.aap.org/toolkits/pages/asd-screening-tools
20. Stone WL, Coonrod EE, Ousley OY. Brief report: screening tool for autism in two-year-olds (STAT): development and preliminary data. J Autism Dev Disord. Dec 2000; 30(6): 607-12. PMID 11261472
21. Stone WL, Coonrod EE, Turner LM, et al. Psychometric properties of the STAT for early autism screening. J Autism Dev Disord.Dec 2004; 34(6): 691-701. PMID 15679188
22. Robins DL, Dumont-Mathieu TM. Early screening for autism spectrum disorders: update on the modified checklist for autism in toddlers and other measures. J Dev Behav Pediatr. Apr 2006; 27(2 Suppl): S111-9. PMID 16685177

23. Stone WL, McMahon CR, Henderson LM. Use of the Screening Tool for Autism in Two-Year-Olds (STAT) for children under 24months: an exploratory study. Autism. Sep 2008; 12(5): 557-73. PMID 18805947
24. Berument SK, Rutter M, Lord C, et al. Autism screening questionnaire: diagnostic validity. Br J Psychiatry. Nov 1999; 175: 444-51.PMID 10789276
25. Chandler S, Charman T, Baird G, et al. Validation of the social communication questionnaire in a population cohort of children with autism spectrum disorders. J Am Acad Child Adolesc Psychiatry. Oct 2007; 46(10): 1324-1332. PMID 17885574
26. Eaves LC, Wingert H, Ho HH. Screening for autism: agreement with diagnosis. Autism. May 2006; 10(3): 229-42. PMID 16682396
27. Wetherby AM, Brosnan-Maddox S, Peace V, et al. Validation of the Infant-Toddler Checklist as a broadband screener for autism spectrum disorders from 9 to 24 months of age. Autism. Sep 2008; 12(5): 487-511. PMID 18805944
28. Pierce K, Gazestani V, Bacon E, et al. Get SET Early to Identify and Treatment Refer Autism Spectrum Disorder at 1 Year and Discover Factors That Influence Early Diagnosis. J Pediatr. Sep 2021; 236: 179-188. PMID 33915154
29. Salisbury LA, Nyce JD, Hannum CD, et al. Sensitivity and Specificity of 2 Autism Screeners Among Referred Children Between 16and 48 Months of Age. J Dev Behav Pediatr. Apr 2018; 39(3): 254-258. PMID 29570569
30. 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 Am Acad Child Adolesc Psychiatry. Feb 2014; 53(2): 237-57. PMID 24472258
31. UK National Screening Committee. Child screening programme. Autism. Accessed on April 27, 2022 Availableathttps://view-health-screening-recommendations.service.gov.uk/autism/
https://www.bcbsaoca.com/eps/_w_ba08f8f6/bcbsa_html//BCBSA/html/pol_3.03.01.html 16/16
32. Siu AL, Bibbins-Domingo K, Grossman DC, et al. Screening for Autism Spectrum Disorder in Young Children: US Preventive Services Task Force Recommendation Statement. JAMA. Feb 16 2016; 315(7): 691-6. PMID 26881372