

Regence

Medical Policy Manual

Behavioral Health, Policy No. 38

Eye Tracking to Detect Autism Spectrum Disorder in Children

Effective: October 1, 2026

Next Review: September 2027

Last Review: September 2026

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Eye-tracking–based diagnostic aids use gaze patterns and computerized analysis to support the diagnosis and assessment of autism spectrum disorder in at-risk children. These devices are intended to aid qualified clinicians and are not stand-alone diagnostic tests.

MEDICAL POLICY CRITERIA

The use of eye tracking based diagnostic aids for autism spectrum disorder (e.g., the EarliPoint Assessment), are considered **investigational** for the diagnosis and assessment of autism spectrum disorder.

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

1. [Applied Behavior Analysis for the Treatment of Autism Spectrum Disorders](#), Behavior Health, Policy No. 18

BACKGROUND

AUTISM SPECTRUM DISORDER

Autism spectrum disorder (ASD) is a neurodevelopmental disorder characterized by persistent differences in social communication and interaction and restricted or repetitive behaviors, interests, or activities. Symptoms begin early in development but vary widely in presentation and severity and may affect language, learning, behavior, and daily functioning; some children also have intellectual, developmental, or other medical conditions. Developmental surveillance and ASD-specific screening may identify children who need further evaluation, but diagnosis is based on a comprehensive assessment by experienced clinicians using developmental history, caregiver information, direct observation, standardized tools, and established diagnostic criteria. Early identification is important because it can support timely access to interventions and services during a key period of development.^[1-7]

EYE-TRACKING–BASED DIAGNOSTIC AIDS

Eye-tracking–based diagnostic aids use cameras and computerized analysis to measure how a child looks at social and nonsocial visual content. Because children with autism spectrum disorder may show different gaze patterns, these noninvasive devices are being studied as objective tools to support, but not replace, a comprehensive clinical evaluation.^[1, 2]

EarliPoint Assessment

The EarliPoint Assessment (EarliTec Diagnostics, Inc., now operating as EarliPoint Health) consists of an eye-tracking module, an operator module, and a secure web portal that hosts the analysis algorithms and returns results. During an approximately 15-minute session, the child views a series of naturalistic social videos while an infrared eye tracker records gaze position at 120 Hz. The algorithm derives a Diagnostic Index Score (typically ranging from –30 to +30). The manufacturer states that the device is intended as an aid to qualified clinicians and is not a stand-alone diagnostic.

TECHNOLOGIES INCLUDED

Software has become an important part of product development and is integrated into digital platforms that serve both medical and non-medical purposes. Three broad categories of software use in medical devices 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".^[1] 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 policy 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 three criteria:

1. Must meet the definition of "SaMD" 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 FDA either through the de novo premarket process or 510(k) process or pre-market approval and;
3. Must be prescribed by a healthcare provider.

REGULATORY STATUS

The EarliPoint Assessment is a Class II device classified under product code QPF and regulation 21 CFR §882.1491 (Pediatric Autism Spectrum Disorder Diagnostic Aid). The device is prescription use only.

- In June 2022, the EarliPoint System received U.S. Food and Drug Administration (FDA) clearance for use in specialized developmental disabilities centers as a tool to aid clinicians in the diagnosis and assessment of autism spectrum disorder (ASD) in patients ages 16 through 30 months (K213882).^[15]
- In June 2023, the EarliPoint System received FDA clearance for the same indication in patients ages 16 through 30 months following a hardware update (K230337).^[16]
- In March 2025, the EarliPoint System received FDA clearance as a tool to aid qualified clinicians in the diagnosis and assessment of ASD in children ages 16 through 30 months who are at risk based on concerns identified by a parent, caregiver, or healthcare provider (K243891).^[17]
- In March 2026, the EarliPoint Assessment received FDA clearance as a tool to aid qualified clinicians in the diagnosis and assessment of ASD in children ages 16 through 95 months (7 years) who are at risk based on concerns identified by a parent, caregiver, or healthcare provider (K253442).^[18]

EVIDENCE SUMMARY

Evidence for any diagnostic device should establish clinical validity by showing accurate and reliable performance compared with an appropriate reference standard in the intended population and setting. To demonstrate clinical utility, studies should also show that clinicians use the device results to guide management and that this use improves net health outcomes compared with care without the device.

EYE TRACKING TO DETECT AUTISM SPECTRUM DISORDER

Non-randomized Studies for Diagnostic Accuracy

Jones (2023) reported a prospective, double-blind, multicenter study (NCT03469986) pivotal study completed at six U.S. specialty autism centers between April 2018 and May 2019 to assess the diagnostic performance of the EarliPoint Assessment device.^[2] Of 499 children ages 16 through 30 months enrolled, 475 (95.2%) successfully completed the eye-tracking index test and were included in the primary analysis. ASD prevalence in the evaluable sample

was 46.5% (221/475). Reference-standard diagnosis was clinician best-estimate using the ADOS-2, the Mullen Scales of Early Learning, medical and developmental history, and DSM-5 criteria. Diagnostic accuracy estimates for the full evaluable cohort and for the prespecified subgroups defined by expert clinician-rated diagnostic certainty are reported in Table 4. Eye-tracking-derived severity indices correlated with expert clinician-administered assessments of social disability ($r = -0.75$; 95% CI, -0.79 to -0.71), verbal ability ($r = 0.65$; 95% CI, 0.59 to 0.70), and nonverbal cognitive ability ($r = 0.65$; 95% CI, 0.59 to 0.70). Additionally, the authors reported that performance-based eye-tracking results were not statistically associated with parent-selected race or ethnicity categories, while reference-standard clinician diagnoses were associated with both, however this finding has not been replicated. Of note, there was a precipitous decline in diagnostic accuracy for the clinically uncertain subgroup which convolutes any conclusions that can be drawn regarding the clinical validity as it is precisely in such diagnostically ambiguous presentations that an adjunctive test would be expected to provide the greatest clinical value. This pattern may potentially reflect the continuum nature of ASD, in which children whose presentations are mild, atypical, or overlap with co-occurring non-ASD developmental delays are intrinsically difficult to classify, but nevertheless this finding precludes what incremental value, if any, this diagnostic aid would provide. Notable limitations include, but are not limited to, enrollment restricted to specialty autism centers with ASD prevalence enriched, use of an imperfect reference standard (clinician best-estimate diagnosis), and absence of longitudinal follow-up.

Jones (2023) published paired discovery and replication studies designed to develop and independently validate the eye-tracking-based assay underlying the EarliPoint Assessment device to diagnosis ASD in children younger than 3 years of age.^[3] Both studies were prospective, double-blind, and used clinician best-estimate diagnosis informed by the ADOS-2 and the Mullen Scales of Early Learning as the reference standard. The discovery study ($N=711$ evaluable; 16–30 months; ASD prevalence 46.3%) was conducted in a single academic medical center laboratory and was used to derive the test positivity threshold via the Youden index. The replication study ($N=361$ evaluable; 16–45 months; ASD prevalence 50.3%) applied the locked discovery-derived threshold to an independent sample collected in an academic medical center and a community clinic using a single prototype standalone device. The replication-study performance largely consistent with the discovery cohort despite the broader age range and second testing environment. Convergent validity between the eye-tracking indices and reference-standard dimensional measures was strongest and most stable for the social disability index against the ADOS-2 total score (discovery $r = -0.736$; replication $r = -0.720$). The verbal ability index against the Mullen verbal age-equivalent (discovery $r = 0.714$; replication $r = 0.589$) and the nonverbal ability index against the Mullen nonverbal age-equivalent (discovery $r = 0.659$; replication $r = 0.525$) were weaker and showed meaningful attenuation between cohorts, suggesting that the categorical diagnostic signal generalizes more reliably than the dimensional ability estimates. Notable limitations include, but are not limited to, reliance on a single prototype device in two controlled testing environments, predominantly White enrollment in both cohorts (approximately 64% discovery; approximately 66% replication), and the use of an imperfect reference standard (clinician best-estimate diagnosis) that sets a ceiling on apparent device accuracy.

Section Summary:

For children at risk for autism spectrum disorder, evidence from two prospective diagnostic accuracy studies suggests that an eye-tracking diagnostic aid can distinguish autism spectrum

disorder in controlled settings; however, accuracy declined among children with clinically uncertain presentations, and the studies did not evaluate the full intended age range or diverse clinical populations. Because no studies compared management or health outcomes with and without testing, clinical utility has not been demonstrated and the evidence is insufficient to determine that these devices improve net health outcomes.

PRACTICE GUIDELINE SUMMARY

AMERICAN ACADEMY OF PEDIATRICS

The American Academy of Pediatrics (AAP) guidelines recommend autism spectrum disorder (ASD)-specific universal screening in all children at age 18 and 24 months in addition to developmental surveillance and monitoring.^[4] 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 healthcare professional.^[5]

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.^[6]

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

The U.S. Preventive Services Task Force (USPSTF) published recommendations for ASD in young children in 2016.^[7] 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.

SUMMARY

There is not enough research to show that eye-tracking–based diagnostic aids improve health outcomes for children being evaluated for autism spectrum disorder. No clinical guidelines based on research recommend these diagnostic aids. Therefore, eye-tracking–based diagnostic aids (e.g., the EarliPoint Assessment) are considered investigational.

REFERENCES

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2. Jones W, Klaiman C, Richardson S, et al. Eye-Tracking-Based Measurement of Social Visual Engagement Compared With Expert Clinical Diagnosis of Autism. *JAMA*. 2023;330(9):854-65. PMID: 37668621
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6. 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*. 2014;53(2):237-57. PMID: 24472258
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CODES

Codes	Number	Description
CPT	None	
HCPCS	G0685	Algorithm-based assessment of likelihood of autism spectrum disorder (asd), derived from validated analysis of eye-gaze data or other technology

Date of Origin: September 2026