Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Retinal Polarization Scan (Retinal Birefringence Scanning)

Description/Background

Amblyopia ("lazy eye") is a major public health problem, caused by misalignment of the eyes (strabismus) or defocus. If detected early in childhood, there is an excellent response to therapy, yet most children are detected too late to be treated effectively. Commercially available vision screening devices that test for the primary cause of amblyopia can detect strabismus only indirectly and inaccurately via assessment of the positions of external light reflections from the cornea. However, they cannot detect the anatomical feature of the eyes where fixation actually occurs (the fovea).[1]

The fovea, which is the most sensitive part of the retina, is known to have birefringent properties, i.e. it changes the polarization state of light upon reflection. Existing devices use this property to obtain information on the orientation of the fovea and the direction of gaze. Such devices employ specific frequency components that appear during moments of fixation on a target. To detect them, previous methods have used solely the power spectrum of the Fast Fourier Transform (FFT), which, unfortunately, is an integral method, and does not give information as to where exactly the events of interest occur. With very young patients who are not cooperative enough, this presents a problem, because central fixation may be present only during very short-lasting episodes, and can easily be missed by the FFT.

Vision screening in children is an ongoing process, with components that should occur at each well-child visit. Tests of visual acuity directly test for the presence of amblyopia. It is commonly not possible to test visual acuity with a matching or naming test until the child is 3 years old. Visual acuity testing in preverbal infants and toddlers is most commonly performed by assessing the fixation preference or by using forced preferential looking tests such as Teller cards. The basic form of the cover test, the cover-uncover test, establishes the diagnosis of manifest strabismus. An occluder is introduced in front of one eye, then removed again, re-establishing binocular viewing. If an eye moves when the other is covered, this indicates that this eye was not fixing before the cover was introduced. Any eye movement is interpreted as

"test positive" and "manifest strabismus present"; the magnitude of the movement is often categorized as small, moderate or large.

Retinal polarization scanning, also known as retinal birefringence scanning (RBS), is a method for detecting the central fixation of the eye. RBS can be used in pediatric ophthalmology screening. By simultaneously measuring the central fixation of both eyes, small- and large-angle strabismus can be detected. The method is non-invasive and requires little cooperation by the patient, allowing it to be used for detecting strabismus in young children. The method is aimed at trying to provide a reliable detection of strabismus and has also been used for detecting certain kinds of amblyopia.

Retinal birefringence scanning uses the human eye's birefringent properties (the splitting of one ray of light into two in an anisotropic medium) to identify the position of the fovea and the direction of gaze. This information is then used to measure for any binocular misalignment. The main principle behind this testing is that birefringent material has a refractive index that depends on the polarization state and propagation direction of light. The main contribution to the birefringence of the eye stems from the Henle fibers, which are photoreceptor axons that are arranged in a radial symmetric pattern that extend outward from the fovea, the most sensitive part of the retina. It has been theorized that analyzing this pattern allows the position of the fovea and direction of gaze to be determined.

Binocular retinal birefringence has been used for diagnosing strabismus (including micro-strabismus) in young children, and has also been proposed for diagnosing amblyopia by detecting strabismus and by detecting reduced fixation accuracy. It is hoped that by detecting even minor fixation inaccuracies early in young children, treatment may be started at an earlier age and prevent some of the social and physiological consequences of amblyopia and/or strabismus.

Regulatory Status

The Pediatric Vision Scanner was approved by the U.S. Food and Drug Administration Denovo approval process [DEN]1300521 on June 8, 2016.

Medical Policy Statement

The bilateral retinal polarization scan, ocular screening with on-site automated results, is experimental/investigational. It has not been scientifically demonstrated to improve long-term patient clinical outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0469T

Rationale

Amblyopia is the leading treatable cause of monocular vision loss in childhood, with a mean prevalence of 2.2% for amblyopia and 2.8% for strabismus. Even children who make regular visits to their pediatricians may not be identified early, because the signs of amblyopia and strabismus can be subtle and preschool children may be unable to cooperate successfully with an ophthalmologic examination. The consequences of not identifying and treating strabismus and amblyopia early include permanent visual impairment and adverse effects on school performance, fine motor skills, social interactions, and self-image.[1]

The fovea, which is the most sensitive part of the retina, is known to have birefringent properties, i.e. it changes the polarization state of light upon reflection. The main causes for this birefringence are the Henle fibers surrounding the fovea, arranged in a radial symmetric pattern. When illuminated or scanned with polarized light, the Henle fiber layer produces the macular polarization cross or “bow tie”, which is a windmill shaped pattern centered about the fovea. The strength and contrast of the polarization cross and the orientation of its bright parts depend on the orientation and degree of polarization of the light striking the retina, which is a function of both the instrumentation and the individual corneal properties. In recent years, the birefringent properties of the human eye have been used to identify the position of the fovea and the direction of gaze. This allows for one to check for eye alignment and strabismus (cross-sightedness), a risk factor for amblyopia (called also “lazy eye”), which can potentially lead to a loss of sight in the affected eye.[2]

A 2017 article by Gramatikov discussed the development of a novel technology for detecting accurate eye alignment directly, by exploiting the birefringence (a property that changes the polarization state of light) of the uniquely arranged nerve fibers (Henle fibers) surrounding the fovea.[3] They employed retinal birefringence scanning (RBS), a technique that uses the changes in the polarization of light returning from the eye, to detect the projection into space of the array of Henle fibers surrounding the fovea. In RBS, polarized near-infrared light is directed onto the retina in a circular scan, with a fixation point in the center, and the polarization-related changes in light retro-reflected from the ocular fundus are analyzed by means of differential polarization detection. Due to the radial symmetric arrangement of the birefringent Henle fibers, a characteristic frequency appears in the obtained periodic signal when the scan is centered on the fovea, indicating central fixation. By analyzing frequencies in the RBS signal from both eyes simultaneously, eye alignment can be measured, and thus strabismus (misaligned eyes) can be detected. RBS technology is the only known technology that can detect central fixation remotely using true anatomical information (position of the fovea). An early version of the “pediatric vision screener” (PVS) was designed and then tested at the Boston Children’s Hospital. This prototype device has been developed into a commercial

instrument that detects eye alignment (REBIScan, Boston, MA, USA). In a pilot study of children aged 2 to 18 years conducted by the team that developed the prototype retinal birefringence scanner, sensitivity was 97% and specificity was 98% for strabismus and amblyopia, suggesting that the PVS could accurately identify children who need ophthalmic care and minimize over-referral. Since the pilot study, the bulky PVS was redesigned to be smaller and lighter, making it easier to use in the physician's office.

In 2014, Jost et al published a report of a study involving three hundred consecutive preschool children (aged 2-6 years) who underwent vision screening using the PVS and the SureSight Autorefractor at 2 pediatric ophthalmology private practices.[4] Three hundred consecutive preschool children (aged 2-6 years) were screened using the PVS and the SureSight Autorefractor at 2 pediatric ophthalmology private practices. A masked comprehensive pediatric ophthalmic examination provided the gold standard for determining sensitivity and specificity for each screening device.

The objective of this study was to independently evaluate the sensitivity and specificity of the redesigned PVS in the target preschool age range, as well as the accuracy of the PVS in identifying the targeted vision disorders (strabismus and amblyopia) in a clinical setting. In addition, sensitivity, specificity, and positive and negative likelihood ratios of the SureSight Autorefractor for the targeted conditions were assessed in the same cohort of children.

Of the 300 patients, 188 had strabismus only, amblyopia only, or both, and 112 had no strabismus or amblyopia. The sensitivity of the PVS to detect strabismus and amblyopia (0.97; 95% CI, 0.94-1.00) was significantly higher than that of the SureSight Autorefractor (0.74; 95% CI, 0.66-0.83). Specificity of the PVS for strabismus and amblyopia (0.87; 95% CI, 0.80-0.95) was significantly higher than that of the SureSight Autorefractor (0.62; 95% CI, 0.50-0.73). The authors concluded that the PVS identified children with strabismus and/or amblyopia with high sensitivity, outperforming the SureSight Autorefractor. Accurate, early detection of these conditions could improve long-term vision outcomes of affected preschool children.

In 2015, Jost et al did another study to determine the specificity of the Pediatric Vision Scanner, a binocular retinal birefringence scanner, in its intended setting, a pediatric primary care office.[5] One hundred two preschool children (age 2–6 years) were screened during a well-child pediatric visit using the Pediatric Vision Scanner and the SureSight Autorefractor and completed a masked comprehensive pediatric ophthalmic examination (gold standard examination). Based on the gold standard examination, one child had anisometropic amblyopia, and the remaining 101 had no amblyopia or strabismus. Specificity of the Pediatric Vision Scanner was 90% (95% CI, 82%–95%) while specificity of the SureSight was 87% (95%CI, 79–93%). Combining these results with the sensitivity of the devices determined in our previous study conducted in a pediatric ophthalmology office setting, the positive likelihood ratio for the Pediatric Vision Scanner was 10.2; for the SureSight, 5.0. The negative likelihood ratio for the Pediatric Vision Scanner was 0.03; for the SureSight, 0.42, a significant difference. The author concluded that the Pediatric Vision Scanner had high specificity (90%) in screening for amblyopia and strabismus as part of a pediatric well-child visit. Likelihood ratio analysis suggests that affected children have a high probability of being correctly identified by the Pediatric Vision Scanner. The high level of confidence conferred by Pediatric Vision Scanner screening may remove an important barrier to vision screening in pediatric primary care.

Shah et al (2021) reported on a prospective study of 300 eligible children 24 to 72 months of age with no known eye conditions, who were screened for amblyopia and strabismus using the Pediatric Vision Scanner.[12] A pediatric ophthalmologist, who was masked to the PVS screening results, performed a comprehensive eye examination. Sensitivity and specificity of the PVS was calculated with a 95% confidence interval. Based on the eye examination, 6 children (2%) had amblyopia and/or strabismus. The PVS detected all 6 cases, yielding a sensitivity rate of 100% (95% CI, 54%-100%). The PVS referred 45 additional children (15%) who had normal ophthalmic findings, yielding a specificity rate of 85% (95% CI, 80%-89%).

SUMMARY OF EVIDENCE

A portable, hand-held vision scanner, the Pediatric Vision Scanner (PVS) that quickly and accurately detects strabismus and amblyopia has been created. The device gives a "pass" or "refer" response, indicating whether children should be referred for further testing or treatment. The scanner requires minimal participation from the child, and can be used in a regular medical office setting with a small amount of training. The device has not yet been approved for use in Canada.

One published study showed that the PVS is better at diagnosing strabismus and amblyopia in preschool-aged children than comprehensive physical eye exams or another automated vision scanning device. Although the impact of this device on the cost of vision screening is currently unknown, because the hand-held scanner can be used and the results interpreted by non-specialists, it could result in lower testing costs. It could also make eye exams more accurate and accessible, compared with what is currently offered. However, there are no published studies showing that earlier diagnosis of strabismus/amblyopia would necessarily result in earlier intervention and potentially better outcomes for these patients.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Pediatrics[9,10]

The AAP (2016) updated October, 2021 issued a policy statement on instrument-based pediatric vision screening which states:

- Instrument-based screening devices for vision screening are available commercially and have had extensive validation, both in field studies and, more recently, in the pediatrician’s offices. Screening instruments detect amblyopia, high refractive error, and strabismus, which are the most common conditions producing visual impairment in children.
- If available, they can be used at any age but have better success after 18 months of age.
- Instrument-based screening can be repeated at each annual preventive medicine encounter through 5 years of age or until visual acuity can be assessed reliably using optotypes.
- Using these techniques in children younger than 6 years can enhance detection of conditions that may lead to amblyopia and/or strabismus compared with traditional methods of assessment.

USPSTF Vision Screening Recommendations-for Children 1-5 Yrs of Age (2017)[11]

- The USPSTF recommends vision screening for all children at least once between the ages of 3 and 5 years, to detect the presence of amblyopia or its risk factors. This recommendation is a grade B recommendation.
- The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of vision screening for children <3 years of age. This statement is an "I" statement.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT		Number of Participants	Completion Date
Unpublished			
NCT03919708	Amblyopia and Strabismus Detection Using Retinal Birefringence Imaging	0	May 2023

NCT: national clinical trial

Government Regulations

National/Local:

There is no national coverage determination for CPT code 0469T.

LCD: Category III Codes (L35490) effective on or after 03/28/2024.
CPT code 0469T does not appear in the covered category III codes. There is no fee listed for 0469T.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Optical Coherence Tomography Imaging, Anterior Eye

References

1. Irsch K, Gramatikov BI, Wu YK, Guyton DL. New pediatric vision screener employing polarization-modulated, retinal-birefringence-scanning-based strabismus detection and bull's eye focus detection with an improved target system: opto-mechanical design and operation. J Biomed Opt. 2014 Jun;19(6):067004.
2. Gramatikov BI. Detecting central fixation by means of artificial neural networks in a pediatric vision screener using retinal birefringence scanning. Biomed Eng Online. 2017 Apr 27;16(1):52.

3. Gramatikov, BI. Detecting fixation on a target using time-frequency distributions of a retinal birefringence scanning signal. BioMedical Engineering OnLine 2013, 12:41. Available at http://www.biomedical-engineering-online.com/content/12/1/41
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6. Irsch K, Gramatikov BI, Wu YK and Guyton DL. Improved eye-fixation detection using polarization-modulated retinal birefringence scanning, immune to corneal birefringence. Optics Express. Vol 22. Issue ppl 7972, Issue 7, pp. 7972-7988 (2014). Available at https://www.osapublishing.org/oe/abstract.cfm?uri=oe-22-7-7972
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8. Gramatikov B, Irsch K, Wu YI, Guyton DL. New pediatric vision screener, part II: electronics, software, signal processing and validation. Gramatikov et al. BioMed Eng OnLine (2016) 15:15. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4743136/
9. American Academy of Pediatrics (AAP). Policy Statement. Visual system assessment in infants, children, and young adults by pediatricians. https://www.aap.org. Published January 2016. Updated October 2021.
10. American Academy of Pediatrics. Clinical Report. Procedures for the Evaluation of the Visual System by Pediatricians. Pediatrics Volume 137, Number 1, January 2016. Available at https://publications.aap.org/pediatrics/article/137/1/e20153597/52806/Procedures-for-the-Evaluation-of-the-Visual-System
11. USPSTF Vision Screening Recommendations for Children ages 6 months to 5 Years. Screening. Available at https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/vision-in-children-ages-6-months-to-5-years-screening#:~:text=Recommendation%20Summary&text=The%20USPSTF%20recommends%20vision%20screening,amblyopia%20or%20its%20risk%20factors.&text=The%20USPSTF%20concludes%20that%20the,children%20younger%20than%203%20years. September 05, 2017.
12. Shah SS, Jimenez JJ, Rozema EJ, et al. Validation of the pediatric vision scanner in a normal preschool population. Journal of American Association for Pediatric Ophthalmology and Strabismus. 2021 Aug;25(4):216.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 31, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/17	8/15/17	8/15/17	Joint policy established
11/1/18	8/21/18	8/21/18	Routine policy maintenance, no change in status.
11/1/19	8/20/19		Routine policy maintenance, no change in policy status.
11/1/20	8/18/20		Routine policy maintenance, no change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Routine maintenance Ref 12 added
11/1/23	8/15/23		Routine maintenance Vendor: N/A (ky)
11/1/24	8/20/24		Routine maintenance Vendor: N/A (ky)

Next Review Date: 3rd Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RETINAL POLARIZATION SCAN (RETINAL BIREFRINGENCE SCANNING)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

Not covered