

Ocular Photoscreening

Policy Number: CS378.A
Effective Date: January 1, 2025

[Instructions for Use](#)

Table of Contents	Page
Application	1
Coverage Rationale	1
Applicable Codes	2
Description of Services	4
Clinical Evidence	5
U.S. Food and Drug Administration	8
References	8
Policy History/Revision Information	9
Instructions for Use	9

Commercial Policy
<ul style="list-style-type: none"> Ocular Photoscreening

Application

This Medical Policy does not apply to the states listed below; refer to the state-specific policy/guideline, if noted:

State	Policy/Guideline
Kentucky	Ocular Photoscreening (for Kentucky Only)
Louisiana	Ocular Photoscreening (for Louisiana Only)
Mississippi	Ocular Photoscreening (for Mississippi Only)
Nebraska	Ocular Photoscreening (for Nebraska Only)
New Jersey	Ocular Photoscreening (for New Jersey Only)
New Mexico	Ocular Photoscreening (for New Mexico Only)
North Carolina	Ocular Photoscreening (for North Carolina Only)
Ohio	Ocular Photoscreening (for Ohio Only)
Pennsylvania	Ocular Photoscreening (for Pennsylvania Only)
Tennessee	Ocular Photoscreening (for Tennessee Only)

Coverage Rationale

Instrument-based ocular photoscreening is proven and medically necessary for the following:

- As a mass screening instrument for children 1-5 years of age (ends on 6th birthday); or
- In individuals 6 years of age and older who are developmentally delayed and are unable or unwilling to cooperate with routine visual acuity screening

Instrument-based ocular photoscreening is unproven and not medically necessary for all other individuals including children less than 1 year of age due to insufficient evidence of safety and/or efficacy.

Retinal birefringence scanning/retinal polarization scanning is unproven and not medically necessary for the detection of eye misalignment or strabismus due to insufficient evidence of safety and/or efficacy.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

CPT Code	Description
0469T	Retinal polarization scan, ocular screening with on-site automated results, bilateral
99174	Instrument-based ocular screening (e.g., photo screening, automated-refraction), bilateral; with remote analysis and report
99177	Instrument-based ocular screening (e.g., photo screening, automated-refraction), bilateral; with on-site analysis

CPT® is a registered trademark of the American Medical Association

Diagnosis Code	Description
For development delay, or those unable or unwilling to cooperate with routine visual acuity screening	
F70	Mild intellectual disabilities
F71	Moderate intellectual disabilities
F72	Severe intellectual disabilities
F73	Profound intellectual disabilities
F78.A1	SYNGAP1-related intellectual disability
F78.A9	Other genetic related intellectual disability
F79	Unspecified intellectual disabilities
F80.0	Phonological disorder
F80.1	Expressive language disorder
F80.2	Mixed receptive-expressive language disorder
F80.4	Speech and language development delay due to hearing loss
F80.81	Childhood onset fluency disorder
F80.82	Social pragmatic communication disorder
F80.89	Other developmental disorders of speech and language
F80.9	Developmental disorder of speech and language, unspecified
F81.0	Specific reading disorder
F81.2	Mathematics disorder
F81.81	Disorder of written expression
F81.89	Other developmental disorders of scholastic skills
F81.9	Developmental disorder of scholastic skills, unspecified
F82	Specific developmental disorder of motor function
F84.0	Autistic disorder
F84.2	Rett's syndrome
F84.3	Other childhood disintegrative disorder
F84.5	Asperger's syndrome
F84.8	Other pervasive developmental disorders
F84.9	Pervasive developmental disorder, unspecified
F88	Other disorders of psychological development
F89	Unspecified disorder of psychological development
F90.0	Attention-deficit hyperactivity disorder, predominantly inattentive type
F90.1	Attention-deficit hyperactivity disorder, predominantly hyperactive type

Diagnosis Code	Description
For development delay, or those unable or unwilling to cooperate with routine visual acuity screening	
F90.2	Attention-deficit hyperactivity disorder, combined type
F90.8	Attention-deficit hyperactivity disorder, other type
F90.9	Attention-deficit hyperactivity disorder, unspecified type
G80.0	Spastic quadriplegic cerebral palsy
G80.1	Spastic diplegic cerebral palsy
G80.2	Spastic hemiplegic cerebral palsy
G80.3	Athetoid cerebral palsy
G80.4	Ataxic cerebral palsy
G80.8	Other cerebral palsy
G80.9	Cerebral palsy, unspecified
H93.25	Central auditory processing disorder
Q05.0	Cervical spina bifida with hydrocephalus
Q05.1	Thoracic spina bifida with hydrocephalus
Q05.2	Lumbar spina bifida with hydrocephalus
Q05.3	Sacral spina bifida with hydrocephalus
Q05.4	Unspecified spina bifida with hydrocephalus
Q05.5	Cervical spina bifida without hydrocephalus
Q05.6	Thoracic spina bifida without hydrocephalus
Q05.7	Lumbar spina bifida without hydrocephalus
Q05.8	Sacral spina bifida without hydrocephalus
Q05.9	Spina bifida, unspecified
Q07.00	Arnold-Chiari syndrome without spina bifida or hydrocephalus
Q07.01	Arnold-Chiari syndrome with spina bifida
Q07.02	Arnold-Chiari syndrome with hydrocephalus
Q07.03	Arnold-Chiari syndrome with spina bifida and hydrocephalus
Q90.0	Trisomy 21, non - mosaicism (meiotic nondisjunction)
Q90.1	Trisomy 21, mosaicism (mitotic nondisjunction)
Q90.2	Trisomy 21, translocation
Q90.9	Down syndrome, unspecified
Q91.0	Trisomy 18, non - mosaicism (meiotic nondisjunction)
Q91.1	Trisomy 18, mosaicism (mitotic nondisjunction)
Q91.2	Trisomy 18, translocation
Q91.3	Trisomy 18, unspecified
Q91.4	Trisomy 13, non - mosaicism (meiotic nondisjunction)
Q91.5	Trisomy 13, mosaicism (mitotic nondisjunction)
Q91.6	Trisomy 13, translocation
Q91.7	Trisomy 13, unspecified
Q92.0	Whole chromosome trisomy, non - mosaicism (meiotic nondisjunction)
Q92.1	Whole chromosome trisomy, mosaicism (mitotic nondisjunction)
Q92.2	Partial trisomy
Q92.5	Duplications with other complex rearrangements
Q92.7	Triploidy and polyploidy
Q92.8	Other specified trisomies and partial trisomies of autosomes
Q92.9	Trisomy and partial trisomy of autosomes, unspecified

Diagnosis Code	Description
For development delay, or those unable or unwilling to cooperate with routine visual acuity screening	
Q93.0	Whole chromosome monosomy, non - mosaicism (meiotic nondisjunction)
Q93.1	Whole chromosome monosomy, mosaicism (mitotic nondisjunction)
Q93.2	Chromosome replaced with ring, dicentric or isochromosome
Q93.3	Deletion of short arm of chromosome 4
Q93.4	Deletion of short arm of chromosome 5
Q93.51	Angelman syndrome
Q93.59	Other deletions of part of a chromosome
Q93.7	Deletions with other complex rearrangements
Q93.81	Velo-cardio-facial syndrome
Q93.82	Williams Syndrome
Q93.88	Other microdeletions
Q93.89	Other deletions from the autosomes
Q93.9	Deletion from autosomes, unspecified
Q95.2	Balanced autosomal rearrangement in abnormal individual
Q95.3	Balanced sex/autosomal rearrangement in abnormal individual
Q95.5	Individual with autosomal fragile site
Q95.8	Other balanced rearrangements and structural markers
Q95.9	Balanced rearrangement and structural marker, unspecified
Q96.0	Karyotype 45, X
Q96.1	Karyotype 46, X iso (Xq)
Q96.2	Karyotype 46, X with abnormal sex chromosome, except iso (Xq)
Q96.3	Mosaicism, 45, X/46, XX or XY
Q96.4	Mosaicism, 45, X/other cell line(s) with abnormal sex chromosome
Q96.8	Other variants of Turner's syndrome
Q96.9	Turner's syndrome, unspecified
Q98.0	Klinefelter syndrome karyotype 47, XXY
Q98.1	Klinefelter syndrome, male with more than two X chromosomes
Q98.3	Other male with 46, XX karyotype
Q98.4	Klinefelter syndrome, unspecified
Q99.2	Fragile X chromosome
R41.840	Attention and concentration deficit
R62.0	Delayed milestone in childhood
Z91.198	Patient's noncompliance with other medical treatment and regimen for other reason
Z91.199	Patient's noncompliance with other medical treatment and regimen due to unspecified reason
Z91.A98	Caregiver's noncompliance with patient's other medical treatment and regimen for other reason

Description of Services

Ocular photoscreening is a method for detection of visual impairments that involves collection and analysis of images of the eyes captured with a digital or film camera. This technique is being used for detection of visual disorders that can predispose children to amblyopia, in which the brain inactivates an eye that has a significant visual impairment. Early diagnosis and treatment of these conditions has been shown to yield better visual outcomes. Ocular photoscreening is based on the principle of photo refraction in which the refractive state of the eye is assessed via the pattern of light reflected through the pupil. The images can then be analyzed based on the position of the corneal light reflex as well as the overall reflection of light from the fundus, which provides information on the child's fixation pattern and the presence or absence of strabismus. Individuals are photographed in a darkened room while looking at the camera. The photographs

can be sent to a central laboratory for analysis, either by ophthalmologists or specifically trained personnel. Results are typically graded as pass, fail, or repeat photoscreening.

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.

Clinical Evidence

Photoscreening

Ocular photoscreening has been investigated as an alternative screening method to detect risk factors for amblyopia, strabismus, high refractive errors, anisometropia, and media opacities.

Shah et al (2021) conducted a prospective study to assess the Pediatric Vision Scanner (PVS) for the diagnosis of amblyopia and strabismus in the general pediatric population. Three hundred children, ages 24-72 months were screening using the PVS. They were then given a comprehensive eye examination from a pediatric ophthalmologist who was masked to the PVS results. "Based on the gold standard 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%). The median acquisition time for the PVS was 28 seconds." The authors concluded that "PVS detected amblyopia with high sensitivity and would allow children with amblyopia and/or strabismus to be referred to an eye care specialist as early as 2 years old".

In a prospective study (Vilà-de Muga et al. 2021) to detect amblyopia risk factors, 453 patients aged 18 to 30 months in primary care settings were examined by photoscreening. Patients were then referred to an ophthalmologist for confirmation. The main objectives were to detect amblyogenic risk factors and to assess the usefulness of a photoscreener in this type of setting. "Out of 453 patients, 42 (9.3%) presented visual alterations according to the photoscreener, with astigmatism being the most common. The instrument had good sensitivity (89%) and specificity (91%), with a positive predictive value of 76% and a negative predictive value of 96%. Overall, 38% of the patients required follow-up, and 47% needed glasses. The automated screening device allowed these children to be diagnosed at an early stage." The authors concluded that the use of a photoscreener to screen 2-year-old children in primary care settings was helpful and accurate, and that the use of instrument-based screening in children aged 18 to 30 months allows excellent detection of early amblyopia risk factors in primary care settings.

A retrospective study (Stiff et al. 2020) was performed, comparing amblyopia rates and treatment outcomes in children ages 0-2 years and ages 3-5 years, who were referred from a community based photoscreening program (Iowa KidSight), a program aimed screening of children ages 6 months to 6 years. This retrospective review included the medical records of 319 children who failed vision photoscreening through Iowa KidSight and were subsequently seen at the University of Iowa for a complete eye examination over a 13-year period. Outcome measures included the number of children obtaining normal vision, and the age at which the normal vision was attained. Also measured was the elapsed time from screening examination to first documentation of normal vision. "Of 319 subjects, 67 (21%) were 0-2 years of age and 252 (79%) were at least 3 years of age at screening. Amblyopia was found in 19% of the younger group and 30% of the older group ($p = 0.12$). Follow-up time was similar between groups. At final follow-up, 8% of children in the younger group did not attain normal vision, compared with 40% in the older group (OR = 8.92; 95% CI, 1.65-92.95; $p = 0.009$). Normal vision was attained on average at 35 months of age in the younger group and 69 months in the older group ($p < 0.0001$)." The authors concluded that children less than three years of age were found to have an equivalent rate of amblyopia compared with the children who were screened over the age of three years, concluding that those screened between the ages of 0-2 years of age were more likely to attain normal vision, and at a significantly younger age. It is however unclear how many of these were ages 6 to 11 months.

In a retrospective study, Longmuir et al. (2013) reported their experience with vision screening in children and compared the results of photo screening in children younger than 3 years with those of children of preschool age and older. During the 11 years of the study, 210,695 pediatric photo screens were performed at 13,750 sites. In the < 3-year age group, the unreadable rate was 13.0%, the referral rate was 3.3%, and the overall positive-predictive value was 86.6%. In the 3- to 6-year-old children, the unreadable rate was 4.1%, the referral rate was 4.7%, and the overall positive-predictive value was 89.4%. However, in the 6-11 month age group, the unreadable rate was 25.5%, the referral rate was 3.7%, and the overall positive-predictive value was 82.5%. The authors concluded that no statistically significant difference was found in

screening children from 1 to 3 years old compared with screening children > 3 years old. According to the authors, these results confirm that early screening, before amblyopia is more pronounced, can reliably detect amblyogenic risk factors in children younger than 3 years of age, and they recommend initiation of photo screening in children aged 1 year and older. They also note that photoscreens require some cooperation, and children < 1 year of age have been previously shown to be difficult to screen and their photoscreens show a high unreadable rate.

In a cross-sectional study, Longmuir et al. (2010) reported on a cohort of preschool children screened by a photo screening program (using MTI PhotoScreener) over a 9-year period from a single, statewide vision screening effort. Children who failed the photo screening were referred to local eye care professionals who performed a comprehensive eye evaluation. Over the 9 years of the continuously operating program, 147,809 children underwent photo screens to detect amblyopic risk factors at 9,746 sites. Because of abnormal photo screen results, 6,247 children (4.2%) were referred. The overall positive predictive value (PPV) of the MTI PhotoScreener was 94.2%. For those children < 1 years of age, the unreadable rate was 21.2% and in those from 1 to 2 years of age group was 10.9%. The unreadable rate continued to decrease with increasing age, with an overall unreadable rate of 5.0%.

Clinical Practice Guidelines

American Academy of Ophthalmology (AAO)

The American Academy of Ophthalmology (AAO) Vision Screening for Infants and Children (2022) recommend that vision screening should be performed at an early age and at regular intervals throughout childhood. The elements of vision screening vary depending on the age and level of cooperation of the child. Subjective visual acuity testing is preferred to instrument-based screening in children who are able to participate reliably. Instrument-based screening is useful for some young children and those with developmental delays. Instrument-based screening techniques, such as photoscreening and autorefractometry, are useful for assessing amblyopia and reduced-vision risk factors for children ages 1 to 5 years, as this is a critical time for visual development. Instrument-based screening can occur for children aged 6 years and older when children cannot participate in optotype-based screening.

American Academy of Ophthalmology (AAO)/American Association for Pediatric Ophthalmology and Strabismus (AAPOS)/American Association of Certified Orthoptists (AACO)

The AAO, AAPOS and AACO coauthored a policy statement regarding the use of instrument-based screening devices. These devices are available commercially and have had extensive validation, both in field studies as well as 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 (Donahue and Baker, 2016a,2016b).

National Center for Children's Vision and Health (NCCVH)

(NCCVH) Recommended Practices for vision screening for children ages 36 to < 72 Months have provided the following recommendations:

- All children aged 36 months to younger than 72 months should be screened annually (best practice) or at least once (acceptable minimum standard) during the interval between their third and sixth birthdays. Exceptions to this include children with the following: readily observable ocular abnormalities, neurodevelopmental disorders, systemic conditions that have associated ocular abnormalities, first-degree relatives with strabismus or amblyopia, a history of prematurity (< 32 completed weeks), and parents who believe their child has a vision problem. These children should be referred directly to an ophthalmologist or optometrist for a comprehensive eye examination. Children who have received an eye examination from an eye care professional within the prior 12 months do not need to be screened. A vision screening program based on best practice standards should be the goal.
- Children who are unable or refuse to complete testing are considered untestable. These children are more likely to have vision problems than testable children, and thus should be rescreened either the same day or soon afterward, but in no case later than 6 months. Children with cognitive, physical, or behavioral issues likely to preclude rescreening and those unable to be rescreened in a timely manner because of administrative or other issues should be referred directly for a comprehensive eye examination.
- Currently, there are 2 best practice vision screening methods for children aged 36 to younger than 72 months: (1) monocular vision acuity testing and (2) instrument-based testing using autorefractometry:
 - For visual acuity testing, appropriately scaled (logMAR) single crowded HOTV letters or LEA Symbols surrounded by crowding bars at a 5-ft (1.5-m) test distance with the child matching or reading the optotypes aloud should be

used. A passing score is the correct identification of three of three, or three of four optotypes with each eye at the 20/50 level for children aged 36 through 47 months and at the 20/40 level for children aged 48 to younger than 72 months. Acceptable practices are to use the HOTV, or LEA Symbols calibrated for a 10-ft (3-m) test distance or to use a single line of these optotypes surrounded by a rectangular crowding bar on all four sides. Other optotypes like Allen pictures and the Tumbling E should not be used.

- The other best practice vision screening method is instrument-based screening using either the Retinomax autorefractor or the SureSight Vision Screener set in child mode and programmed with the VIP Study pass/fail criteria software for 90% specificity (version 2.24 or 2.25) in minus cylinder form. Using the Plusoptix photo-screener is considered acceptable practice, as is adding the PASS stereoacuity test as a supplement to one of the best practice screening methods.
- Vision screening requires training and certification of screening personnel, acquiring sufficient and appropriate space, obtaining and maintaining equipment and supplies, as well as recording and reporting the screening results to the family, primary care provider/medical home, and when indicated, the school or appropriate state agency.
- A best practice for children who fail vision screening includes documentation of the referral to, and subsequent comprehensive eye examination by an optometrist or ophthalmologist (Cotter et al., 2015).

U.S. Preventive Services Task Force Recommendations

The U.S. Preventive Services Task Force (USPSTF, 2017) concludes with moderate certainty that vision screening to detect amblyopia or its risk factors in children aged 3 to 5 years has a moderate net benefit. They also conclude that the benefits of vision screening to detect amblyopia or its risk factors in children younger than 3 years are uncertain, and that the balance of benefits and harms cannot be determined for this age group.

Retinal Birefringence Scanning/Retinal Polarization

There is currently insufficient evidence to support the use of retinal birefringence scanning; well-designed studies with larger sample sizes including the general population are needed to ascertain its clinical value.

Bosque et al. (2021) reported results of a prospective test validation study evaluating the accuracy of the blinq pediatric vision scanner for the detection of amblyopia and strabismus. Testing was performed by individuals masked to the diagnosis. Following testing, pediatric ophthalmologists performed complete examinations and were masked to the screening result. The study included 193 subjects, (53 previously treated, 140 treatment-naïve subjects), “including 65 (46%) with amblyopia or strabismus, 11 (8%) with risk factors/suspected binocular vision deficit without amblyopia/strabismus, and 64 (46%) controls. Sensitivity was 100%, with all 66 patients with referral-warranted ocular disease referred. Five patients with intermittent strabismus receiving pass results were deemed “acceptable pass” when considering patient risk factors and amblyogenic potential. Specificity was 91%, with 7 incorrect referrals. Subanalysis of children aged 2-8 years (n = 92) provided similar results (sensitivity 100%; specificity 89%). The authors concluded that very high sensitivity and specificity for detecting referral-warranted unilateral amblyopia and strabismus was detected with the blinq scanner. The authors further stated that “Implementation of the device in vision screening programs could lead to improved rates of disease detection and reduction in false referrals.” The study is limited by the use of non-standard calculations of adjusted sensitivity and specificity.

A cross-sectional study by Arnold (2020) evaluated the blinq™ binocular birefringent ocular alignment screener and the 2WIN with Corneal Reflex (CR) function (Adaptica, Padova, Italy) according to the American Association for Pediatric Ophthalmology and Strabismus (AAPOS) Uniform Guidelines. In this study, 100 adults and children were enrolled from a high-risk ophthalmology practice. Each participant was screened with the blinq screener with validation by AAPOS 2003 guidelines for amblyopia risk factors (which had a prescreening probability of 66%). Then, the blinq was compared to the Adaptica 2WIN with CR with validation by AAPOS 2003 guidelines and additional screenings to identify participants with diminished binocularity. By AAPOS 2003 guidelines, blinq had a sensitivity of 75%, specificity of 68% and positive predictive value of 81% compared to 2WIN with CR which had a sensitivity of 91%, specificity of 68% and PPV of 84%. Adding cases with presumed limited binocularity, blinq had a sensitivity of 64%, specificity of 71% and PPV of 85% while 2WIN with CR function had sensitivity of 87%, specificity 82% and PPV 93%. The authors concluded that the blinq pediatric vision scanner performed well in identifying refractive amblyopia and strabismus risk factors when compared to the AAPOS 2003 guidelines. Strengths of the study include the use of AAPOS Uniform Guidelines and that older patients were able to confirm binocular status. Weaknesses include that the study did not include an average community pediatric population, it was a single center and that there was a relatively small number of participants. Additionally, the sensitivity of the device was inferior to that of Adaptica 2WIN with CR. Clinical trials registry: NCT04195711.

In a comparative study, Jost et al. (2014) evaluated the diagnostic accuracy of the Pediatric Vision Scanner (PVS) in identifying strabismus and amblyopia and compared PVS to the SureSight Autorefractor, a widely used automated pediatric screening device. Three hundred consecutive preschool children (aged 2-6 years) were screened. A masked

comprehensive pediatric ophthalmic examination provided the gold standard for determining sensitivity and specificity for each screening device. The primary outcome was sensitivity and specificity of the PVS device for detecting strabismus and amblyopia. Secondary outcomes included the positive and negative likelihood ratios of the PVS for identifying the targeted conditions. 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. The sensitivity and specificity of the PVS to detect strabismus and amblyopia was significantly higher than that of the SureSight Autorefractor. This study was performed in a clinical setting with a cohort of children referred for suspected visual impairments resulting in higher incidences than what would be seen in the general population.

Loudon et al. (2011) performed a prospective study to investigate whether the PVS could detect anisometropic amblyopia as well as strabismus. The authors also followed patients during treatment to determine whether the improvements gained from treatment would be reflected in improved vision test results. A total of 154 patients and 48 controls between the ages of 2 and 18 years participated in the study with 21 children followed longitudinally to detect changes in their binocularity (BIN) scores. The control group consisted of subjects with no strabismus, amblyopia, or anisometropia. The authors concluded that PVS identified children with amblyopia or strabismus with high sensitivity and specificity, while successful treatment restored normal BIN scores in amblyopic patients without strabismus. Study limitations again include small size, single center, and engagement of patients with known risk factors; it was also noted in this study that there was a lack of racial diversity with 74% of the participants identified as Caucasian.

Nassif et al. (2006) evaluated the clinical performance of the PVS in children in a pediatric ophthalmology office setting. Seventy-seven children between 2 and 18 years of age received gold-standard orthoptic examinations and were classified as at risk for amblyopia if strabismus or anisometropia was present. Binocularity as determined by the PVS was greater than 65% for all controls and less than 20% for all subjects with constant strabismus. Binocularity ranged from 0% to 52% in subjects with variable strabismus. All subjects with anisometropia and no strabismus had binocularity scores less than 10%. The PVS identified strabismus, when present, in all subjects and identified 3 subjects with anisometropia. The PVS shows potential to address a lack of screening instrumentation appropriate for use with preschool-aged children.

A 3-year, prospective clinical trial evaluating the PVS in a community pediatric setting was completed in January 2019 with results submitted to ClinicalTrials.gov on April 7, 2020, and were last updated on July 1, 2020; however, the results of the study have not yet been published ([NCT02536963](https://clinicaltrials.gov/ct2/show/study/NCT02536963)).

Clinical Practice Guidelines

The American Association for Pediatric Ophthalmology and Strabismus (AAPOS) uniform guidelines for instrument-based pediatric vision screen validation 2021, Arnold et al. regarding instruments such as blinq, only state that “a novel instrument-based device using bilateral birefringent foveal scanning recently became commercially available and shows promise for screening for amblyopia per se”.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Ocular screening is a procedure and, therefore, not regulated by the FDA.

References

- American Academy of Ophthalmology (AAO). Vision Screening for Infants and Children October 2022.
- Arnold RW. Comparative AAPOS Validation of the birefringent amblyopia screener with isolated small-angle strabismus. *Clin Ophthalmol.* 2020; 14:325–329. Published 2020 Jan 31.
- Arnold RW, Donahue SP, Silbert DI et al.; AAPOS Vision Screening and Research Committees. AAPOS uniform guidelines for instrument-based pediatric vision screen validation 2021. *J AAPOS.* 2022 Feb;26(1):1.e1-1.e6.
- Bosque LE, Yamarino CR, Salcedo N, et al. Evaluation of the blinq vision scanner for detection of amblyopia and strabismus. *J AAPOS.* 2021 Aug;25(4):214.e1-214.e7.
- Cotter SA, Cyert LA, Miller JM, et al. for the National Expert Panel to the National Center for Children’s Vision and Eye Health. Vision screening for children 36 to < 72 months: recommended practices. *Optom Vis Sci* 2015;92(1): 6-16.
- Donahue S, Baker C. Committee on Practice and Ambulatory Medicine, Section on Ophthalmology, American Association of Certified Orthoptists, American Association for Pediatric Ophthalmology and Strabismus, American Academy of Ophthalmology. Visual system assessment in infants, children, and young adults by pediatricians. *Pediatrics* 2016b;137;1.

Donahue SP, Baker CN; Committee on Practice and Ambulatory Medicine, American Academy of Pediatrics; Section on Ophthalmology, American Academy of Pediatrics; American Association of Certified Orthoptists; American Association for Pediatric Ophthalmology and Strabismus; American Academy of Ophthalmology. Procedures for the evaluation of the visual system by pediatricians. *Pediatrics*. 2016a Jan;137(1).

Hayes, Inc. Medical Technology Directory Report. Photoscreening for the Detection of Amblyopia Risk Factors in Children. Lansdale, PA: Hayes Inc.; October 2013. Updated September 2016.

Jost RM, Yanni SE, Beauchamp CL et al. Beyond screening for risk factors: Objective detection of strabismus and amblyopia. *JAMA Ophthalmol* 132:814-820, 2014.

Longmuir SQ, Boese EA, Pfeifer W, et al. Practical community photo screening in young children. *Pediatrics*. 2013 Mar;131(3): e764-9.

Longmuir SQ, Pfeifer W, Leon A, et al. Nine-year results of a volunteer lay network photo screening program of 147 809 children using a photoscreener in Iowa. *Ophthalmology*. 2010 Oct;117(10):1869-75.

Loudon SE, Rook CA, Nassif DS, et al. Rapid, high-accuracy detection of strabismus and amblyopia using the pediatric vision scanner. *Invest Ophthalmol Vis Sci*. 2011 Jul 7;52(8):5043-8.

Nassif DS, Piskun NV, Hunter DG. The Pediatric Vision Screener III: detection of strabismus in children. *Arch Ophthalmol*. 2006;124(4):509-513.

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 [JAAPOS]*, Volume 25, Issue 4, 216.e1 - 216.e4.

Stiff H, Dimenstein N, Larson SA. Vision screening outcomes in children less than 3 years of age compared with children 3 years and older. *J AAPOS*. 2020 Oct;24(5):293.e1-293.e4. doi: 10.1016/j.jaapos.2020.05.016. Epub 2020 Oct 9. PMID: 33045377.

U.S. Preventive Services Task Force (USPSTF). Final Recommendation Statement: Vision in children ages 6 months to 5 years: screening. U.S. Preventive Services Task Force. September 2017.

Vilà-de Muga M, Van Esso D, Alarcon S, et al. BCN PASS Study Group. Instrument-based screening for amblyopia risk factors in a primary care setting in children aged 18 to 30 months. *Eur J Pediatr*. 2021 May;180(5):1521-1527. doi: 10.1007/s00431-020-03904-0. Epub 2021 Jan 7. PMID: 33410941.

Policy History/Revision Information

Date	Summary of Changes
03/01/2025	<p>Application Louisiana</p> <ul style="list-style-type: none"> Added reference link to state-specific policy version
02/01/2025	<p>Application Kentucky</p> <ul style="list-style-type: none"> Added reference link to state-specific policy version
01/01/2025	<p>Template Update</p> <ul style="list-style-type: none"> Created service-specific policy version for content previously included in the Medical Policy titled <i>Omnibus Codes</i> (no change to coverage guidelines) <p>Supporting Information</p> <ul style="list-style-type: none"> Added <i>Description of Services</i> and <i>FDA</i> sections Updated <i>Clinical Evidence</i> section to reflect the most current information Archived previous policy version CS087.AX

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to

modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the InterQual[®] criteria, to assist us in administering health benefits. The UnitedHealthcare Medical Policies are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.