Ocular Photoscreening

Number: 0689

Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers one ocular photoscreening medically necessary for screening all children 3 years of age, and for screening children 4 to 5 years of age who are unable to cooperate with routine acuity screening (e.g., mental retardation, developmental delay, and severe behavioral disorders).

Aetna considers retinal birefringence scanning for the detection of eye misalignment or strabismus experimental and investigational because its effectiveness has not been established.

Background

Many children permanently lose vision each year as a result of amblyopia, media opacities, and treatable ocular disease processes. Early diagnosis and treatment of these conditions has been shown to yield better visual outcomes.

The U.S. Preventive Services Task Force (USPSTF, 2011) 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. The USPSTF concluded that the current evidence is insufficient to assess the balance of benefits and harms of vision screening for children less than 3 years of
Infants and young preverbal children are difficult to screen because they are unable to provide subjective responses to visual acuity testing and do not easily cooperate with testing of ocular alignment or stereoacuity (AAP, 2002). For similar reasons, it also is difficult to screen certain older children, such as those who are nonverbal or have developmental delays.

Ocular photoscreening has been used to screen for amblyogenic factors, such as strabismus, media opacities, and significant refractive errors, in children (AAP, 2002). An advantage of ocular photoscreening over standard methods of testing visual acuity, ocular alignment and stereoacuity is that photoscreening requires little cooperation from the child, other than having to fixate on the appropriate target long enough for photoscreening. Thus, photoscreening has the potential to improve vision screening rates in preverbal children and those with developmental delays who are the most difficult to screen. Many of the children that are most difficult to screen using conventional methods are also at highest risk of amblyopia (e.g., premature infants, children with developmental delays).

Ocular photoscreening uses a specialized camera or video system to obtain images of the pupillary reflexes and red reflexes (AAP, 2002). An evaluator, reviewing center or computer analyzes data for amblyogenic factors. Children with abnormal findings are referred for a complete eye examination.

Two types of photoscreeners are presently available: (i) those in which the screener interprets the photograph (such as MTI Photoscreener™, Medical Technology and Innovations, Inc., Lancaster, PA; Visiscreen 100™, Vision Research Corporation, Birmingham, AL) and (ii) those in which a computer interprets the photograph (such as The EyeDx System™, EyeDx, Inc., San Diego, CA).

In a position statement on instrument-based pediatric vision screening, the American Academy of Pediatrics Section on Ophthalmology and the Committee on the Practice of Ambulatory Medicine (Miller et al, 2012) stated that photoscreening and handheld autorefraction may be electively performed in
children to 3 years of age, allowing earlier detection of conditions that may lead to amblyopia, as well as in older children who are unable to cooperate with routine acuity screening. The position statement was issued in conjunction with the American Academy of Ophthalmology, the American Association for Pediatric Ophthalmology and Strabismus, and the American Association of Certified Orthoptists. The statement noted that instrument-based screening is quick, requires minimal cooperation of the child, and is especially useful in the preverbal, preliterate, or developmentally delayed child. The statement said that children younger than 4 years can benefit from instrument-based screening, and visual acuity testing can be used reliably in older children.

The U.S. Preventive Services Task Force (USPSTF, 2011) 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. The USPSTF found adequate evidence that vision screening tools have reasonable accuracy in detecting visual impairment, including refractive errors, strabismus, and amblyopia. The USPSTF found adequate evidence that early treatment for amblyopia, including the use of cycloplegic agents, patching, and eyeglasses, for children 3 to 5 years of age leads to improved visual outcomes. The USPSTF found inadequate evidence that early treatment of amblyopia for children less than 3 years of age leads to improved visual outcomes.

The U.S. Preventive Services Task Force recommendations discuss ocular photoscreening among several methods of vision screening of children. The Recommendation Statement states: “Various screening tests that are feasible in primary care are used to identify visual impairment among children. These tests include visual acuity tests, stereoacuity tests, the cover-uncover test, and the Hirschberg light reflex test (for ocular alignment/strabismus), as well as the use of autorefractors (automated optical instruments that detect refractive errors) and photoscreeners (instruments that detect amblyogenic risk factors and refractive errors)”. The USPSTF noted that potential disadvantages of using photoscreeners and autorefractors are the initial high costs
associated with the instruments and the need for external interpretation of screening results with some photoscreeners.

The USPSTF evidence review (Chou et al, 2011) identified 26 studies, including 3 of poor quality and 23 of fair quality, that evaluated the diagnostic accuracy of various preschool vision screening tests. The USPSTF review reported, however, that none of the tests was associated consistently with both high sensitivity and high specificity (i.e., 90%) for specific amblyogenic risk factors. Vision screening tests included tests of visual acuity, stereoacuity, and ocular alignment, as well as tests using autorefractors and photoscreeners. The largest study comparing screening tests was the Vision in Preschoolers study (Schmidt et al, 2004; Ying et al, 2005), which compared 10 different screening tests. In the Vision in Preschoolers study, the Random Dot E stereoacuity test (StereoOptical Co, Chicago, IL), the Randot Stereo Smile Test II (Stereo-Optical Co, Chicago, IL), and the iScreen (iScreen, Inc, Memphis, TN) and Medical Technologies, Inc photoscreeners (Riviera Beach, FL) were associated with lower sensitivity (at a similar specificity), compared with the Lea symbols test (Precision Vision, Inc, LaSalle, IL), the HOTV visual acuity test (Precision Vision, Inc, LaSalle, IL), and the Retinomax (Nikon, Inc, Melville, NY) and Power Refractor II (Plusoptix, Nuremberg, Germany) autorefractors. The USPSTF report stated, however, that differences in likelihood ratio estimates were relatively small. The USPSTF concluded that well-designed studies are needed to identify the optimal age for initiation of screening, optimal screening methods, optimal screening frequency, and the most favorable combinations of screening tests.

Bright Futures does not recommend ocular photoscreening for vision screening (Kemper & Delmonte, 2010). Bright Future states that: “New vision screening technology (e.g., photoscreening, autorefraction) has been developed and is increasingly used in pediatric practice. Recommendations for the use of such technology will be made as evidence regarding their comparative effectiveness becomes available”.

An evidence review prepared for the Agency for Healthcare
Research and Quality (2004) found that the reports of the accuracy of ocular photoscreening are promising, but no evaluation has been done in the primary care practice setting with the tests administered as would be done by those usually responsible for screening. Additionally, little is known about how these new tests compare to the physical examination itself.

A technology assessment of preschool vision screening by the Canadian Agency for Drugs and Technologies in Health (Dunfield and Keating, 2007) found that, with photoscreening, sensitivities ranged from 27.8 % to 88 %, and specificities ranged from 40 % to 98.5 % in different studies. The technology assessment found that no single test or group of tests has been shown to be superior for preschool vision screening.

The Canadian Paediatric Society (2009) stated that "there appears to be some agreement on the cost-effectiveness as well as the efficacy of photoscreening in preschoolers". The guidelines cited large studies demonstrating positive predictive values of ocular photoscreening of over 80 % (citing Donahue et al, 2006) and over 95 % (citing Arnold et al, 2005). The guidelines noted, however, that "the negative predictive value of these rather large studies has not been clearly established; therefore, the safety of this promising technology remains unknown compared with conventional methods". The guidelines state that ocular photoscreening "is not appropriate for office-based primary care and assessment of infants and children."

In a multi-center, randomized controlled study, Salcido et al (2005) compared the usefulness of traditional vision screening and photoscreening of 3- and 4-year-old children in the pediatrician's office. Following training of pediatricians and office staff, 6 pediatric clinics used both the MTI PhotoScreener (Medical Technology Industries, LLC, Riviera Beach, FL) and traditional acuity and stereopsis screening materials (HOTV charts/Random Dot E tests as recommended by established AAP-MCHB-PUPVS guidelines) during well-child examinations. Clinics used one testing method for a 6-month period and switched to the other for the following 6 months, in a randomized manner. Referred children received a complete eye examination with
cycloplegic refraction by local ophthalmologists or optometrists who forwarded the results to Vanderbilt Ophthalmology Outreach Center. Amblyogenic factors were defined using standardized published criteria. A total of 605 children were screened with the photoscreener and 447 were screened with traditional techniques. Mean time for screening was less with the photoscreener: 2.5 versus 5.9 minutes (p < 0.01). Untestable rates were similar (18 % versus 10%, respectively p = NS), but higher with the photoscreener due to one clinic’s 70 % unreadable rate. Referral rates were also similar: 3.8 % versus 4.5 %. The positive predictive value (PPV) rate differed greatly. With follow-up results obtained from 56 % of referred children, 73 % of photoscreening referred children (8/11 examined) had amblyogenic factors confirmed on formal eye examinations, whereas all children referred using traditional screening methods (10/10 examined) were normal. These authors concluded that photoscreening is more time efficient than traditional screening and has a significantly higher PPV in 3- and 4-year-old children. However, this study was unable to validate traditional screening techniques in this pre-school age group. The authors further stated that if these results can be replicated, support for traditional vision screening must undergo intense scrutiny, and attention should be turned toward making photoscreening feasible for widespread implementation.

In a case series study, Teed et al (2010) examined the effectiveness of amblyopia treatment in children identified through a community photoscreening program. These researchers included 125 children diagnosed with amblyopia after referral from a photoscreening program. Treatment regimens included spectacles, patching, and/or atropine penalization. Successful treatment was defined as greater than or equal to 3 Snellen line equivalent improvement in visual acuity (VA) and/or 20/30 VA in the amblyopic eye in literate children. Successful treatment in initially pre-literate children was defined as 20/30 or better VA in the amblyopic eye. Main outcome measure was percentage of successfully treated amblyopic children. Of 901 children evaluated after being referred from photoscreening, 551 had amblyopiogenic risk factors without amblyopia, 185 were diagnosed with amblyopia, and 165 were false-positives. Of 185
children with amblyopia, 125 met inclusion criteria for analysis and 78 % (97 of 125) were successfully treated. The authors concluded that the success rate of amblyopia treatment in children identified through the authors' photoscreening program is high. They noted that these findings support the role of photoscreening programs in the prevention of amblyopia-related vision loss. Such early screening may translate to true VA improvement. The drawbacks of this study include (i) non-standardized VA measurements, (ii) variability in amblyopic treatment, and (iii) uncertainty in the diagnosis and treatment of amblyopia in pre-literate children.

Yanovitch and colleagues (2010) determined the sensitivity, specificity, and positive and negative predictive values of photoscreening in detecting treatable ocular conditions in children with Down syndrome (DS). Photoscreening and complete ophthalmologic evaluations were performed in 50 consecutive 3- to 10-year-old children with DS. Sensitivity, specificity, and positive and negative predictive values were calculated with the use of ophthalmologic examination findings as the reference standard. Most children were able to complete photoscreening (94 % with Medical Technology and Innovations [MTI] and 90 % with Visiscreen OSS-C [VR]). Many children had an identified diagnosis on ophthalmologic examination (n = 46, 92 %). Of these, approximately one-half (n = 27, 54 %) had one or more condition(s) requiring treatment. Both the MTI and VR photoscreening devices had a sensitivity of 93 % (95 % confidence interval [CI]: 0.76 to 0.99) for detecting treatable ocular conditions. The specificities for the MTI and VR photoscreening were 0.35 (CI: 0.18 to 0.57) and 0.55 (CI: 0.34 to 0.74), respectively. The authors concluded that photoscreening is sensitive but less specific at detecting treatable ocular conditions in children with DS. In specific instances, the use of photoscreening in the DS population has the potential to save time and expense related to routine eye examinations, especially in children with a normal baseline comprehensive examination.

Retinal Birefringence Scanning:

Retinal birefringence scanners (RBS) (e.g., the Pediatric Vision
Scanner (PVS) are hand-held instruments that measure the changes in the polarization of light returning from the eye to detect eye misalignment or strabismus during a brief scan of the eye.

Nassif and associates (2006) evaluated the clinical performance of the PVS in children in a pediatric ophthalmology office setting. A total of 77 subjects between 2 and 18 years of age received gold-standard orthoptic examinations and were classified as at risk for amblyopia if strabismus or anisometropia (greater than 1.50 diopters) was present. Strabismus was sub-classified as variable or constant. The subjects were then tested with the PVS, which produced a pass or refer recommendation based on a binocularity score. The PVS also produced a yield score to indicate the subject's interest in the target. Sensitivity and specificity for amblyopia risk detection were calculated. 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 authors concluded that PVS identified strabismus, when present, in all subjects and identified 3 subjects with anisometropia as well. They stated that the instrument showed potential as a screening device for amblyopia risk factors in pre-school children for use by primary care physicians and nurses. They stated that future studies will better characterize its performance in subjects with anisometropia, mono-fixation syndrome, and uncomplicated, symmetric refractive error.

Loudon and co-workers (2011) evaluated the ability of the PVS to identify patients with amblyopia or strabismus, particularly anisometropic amblyopia with no measurable strabismus. The PVS test, administered from 40 cm and requiring 2.5 seconds of attention, generated a binocularity score (BIN, 0 % to 100 %). These investigators tested 154 patients and 48 controls between the ages of 2 and 18 years; BIN scores of amblyopic children and controls were measured, and 21 children received sequential PVS measurements to detect any changes in BIN resulting from amblyopia treatment. With the pass/refer threshold set at BIN 60.
sensitivity and specificity were 96 % for the detection of amblyopia or strabismus. Assuming a 5 % prevalence of amblyopia or strabismus, the inferred positive and negative predictive values of the PVS were 56 % and 100 %, respectively. Fixation accuracy was significantly reduced in amblyopic eyes. In anisometropic amblyopia patients treated successfully, the BIN improved to 100 %. The authors concluded that the PVS identified children with amblyopia or strabismus with high sensitivity and specificity, while successful treatment restored normal BIN scores in amblyopic patients without strabismus. They stated that these findings supported the hypothesis that the PVS detects strabismus and amblyopia directly. They stated that future strategies for screening by non-specialists may thus be based on diagnostic detection of amblyopia and strabismus rather than the estimation of risk factors, allowing for rapid, accurate identification of children with amblyopia early in life when it is most amenable to treatment. The drawbacks of this study included small sample size (n = 21 received PVS measurements), single-center, as well as engagement of patients with known risk factors.

Jost and colleagues (2015) examined the specificity of the PVS, a binocular retinal birefringence scanner, in its intended setting, a pediatric primary care office. A total of 102 pre-school children (aged 2 to 6 years) were screened during a well-child pediatric visit using the PVS and the SureSight Auto-refractor and completed a masked comprehensive pediatric ophthalmic examination (gold standard examination). Based on the gold standard examination, 1 child had anisometropic amblyopia, and the remaining 101 had no amblyopia or strabismus. Specificity of the PVS was 90 % (95 % CI: 82 % to 95 %) while specificity of the SureSight was 87 % (95 % CI: 79 % to 93 %). Combining these results with the sensitivity of the devices determined in a previous study conducted in a pediatric ophthalmology office setting, the positive likelihood ratio for the PVS was 10.2; for the SureSight, 5.0. The negative likelihood ratio for the PVS was 0.03; for the SureSight, 0.42, a significant difference. The authors concluded that the PVS had high specificity (90 %) in screening for amblyopia and strabismus as part of a pediatric well-child visit. Likelihood ratio analysis suggested that affected children have a
high probability of being correctly identified by the PVS. The high level of confidence conferred by PVS screening may remove an important barrier to vision screening in pediatric primary care.

Gramatikov and associates (2016) noted that many devices for eye diagnostics and some devices for eye therapeutics require the patient to fixate on a small target for a certain period of time, during which the eyes do not move and data from substructures of 1 or both eyes are acquired and analyzed. With pediatric patients, a monotonously blinking target is not sufficient to retain attention steadily. These researchers developed a method for modulating the intensity of a point fixation target using sounds appropriate to the child's age and preference. The method was realized as a subsystem of a PVS that employs RBS for detection of central fixation. In this study, a total of 21 subjects, aged 2 to 18 years, were studied. Modulation of the fixation target using sounds ensured the eye fixated on the target, and with appropriate choice of sounds, performed significantly better than a monotonously blinking target accompanied by a plain beep. The method was particularly effective with children of ages up to 10 years, after which its benefit disappeared. Typical applications of target modulation would be as supplemental subsystems in pediatric ophthalmic diagnostic devices, such as scanning laser ophthalmoscopes, optical coherence tomography units, RBS, fundus cameras, and perimeters. This was a small study; and its findings need to be validated by well-designed studies.

In a systematic review on “Vision screening in children ages 6 months to 5 years”, Jonas et al (2017), on behalf of the USPSTF, found 34 fair-quality studies (n = 45,588 observations) that evaluated the accuracy of various screening tests: visual acuity tests (6 studies), stereo-acuity tests (4 studies), ocular alignment tests (1 study), a combination of clinical tests (4 studies), auto-refractors (16 studies), photo-screeners (11 studies), and RBS (1 study).

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.
### CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

#### CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>99174</td>
<td>Instrument-based ocular screening (e.g., photoscreening, automated-refraction), bilateral; with remote analysis and report</td>
</tr>
<tr>
<td>99177</td>
<td>with on-site analysis</td>
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#### ICD-10 codes covered if selection criteria are met (not all-inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>H52.00 - H52.7</td>
<td>Disorders of refraction and accommodation</td>
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<tr>
<td>H53.001 - H54.8</td>
<td>Visual disturbances, blindness and low vision</td>
</tr>
<tr>
<td>P07.00 - P07.32</td>
<td>Disorders of newborn related to short gestation and low birth weight, not elsewhere classified</td>
</tr>
<tr>
<td>Z00.129</td>
<td>Encounter for routine child health examination without abnormal findings</td>
</tr>
<tr>
<td>Z01.00 - Z01.01</td>
<td>Encounter for examination of eyes and vision</td>
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<tr>
<td>Z02.0 - Z02.3</td>
<td>Encounter for administrative examination</td>
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<td>Z02.89</td>
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<tr>
<td>Z13.5</td>
<td>Encounter for screening for eye and ear disorders</td>
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</tbody>
</table>

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The above policy is based on the following references:


40. Loudon SE, Rook CA, Nassif DS, et al. Rapid, high-accuracy detection of strabismus and amblyopia using the pediatric


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Amendment to
Aetna Clinical Policy Bulletin Number: 0689 Ocular Photoscreening

There are no amendments for Medicaid.