Name of Policy:
Ocular Photoscreening in the Primary Care Physician’s Office as a Screening Tool to Detect Amblyogenic Factors

Policy #: 175
Category: Surgical

Latest Review Date: December 2010
Policy Grade: Effective 12/26/2012 - Active policy but no longer scheduled for regular literature reviews and update.

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:
1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
Description of Procedure or Service:
Amblyopia is a form of defective central visual processing, manifested as decreased visual acuity in one eye. It affects more than 2% of the population and is the leading cause of monocular vision loss in children and adults. However, if detected before eight to ten years of age, it can be effectively treated by patching or atropine drops applied to the sound eye. A variety of organizations have recommended routine vision screening throughout childhood. Organizations include the American Academy of Pediatrics, the US Preventive Services Task force, the American Academy of Ophthalmology, the American Optometric Association and the American Association for Pediatric Ophthalmology and Strabismus. Detection of amblyopia itself requires assessment of visual acuity, which is difficult in preverbal children. Ocular photoscreening has been investigated as an alternative screening method, not to detect amblyopia itself, but instead to detect risk factors for amblyopia, which include strabismus, high refractive errors, anisometropia, and media opacities.

Ocular photoscreening is based on the principle of photorefraction 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. Patients 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.

Several different systems are commercially available. In this country, the majority of published studies have used the Medical Technology Inc. (MTI) Photoscreener (Medical Technology, Inc., Cedar Falls, Iowa). Another company, iScreen Vision Screener was cleared by the FDA via the 510(k) process in January 2001.

Note: Ocular photoscreening can be performed in several settings. For example, photoscreening can be performed in public health setting or as part of school screening programs. In addition, photoscreening may be performed by ophthalmologists as an adjunct to an ophthalmologic exam. This policy only addresses the use of photoscreening in the setting of the primary care physician’s office, where it is performed as an adjunct or alternative to the standard visual exam. It is anticipated that the results of photoscreening would be used by the primary care physician to determine whether the patient required referral to a pediatric ophthalmologist for further evaluation.

Policy:
Ocular photoscreening in the primary care physician’s office as a screening tool to detect amblyogenic factors does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered investigational.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and
his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

**Key Points:**
As noted in the description above, this policy only addresses ocular photoscreening when performed in the primary care physician’s office, either as an adjunct or alternative to standard visual assessment. Aside from assessment of visual acuity, using Snellen charts, letters, or other techniques, primary care physicians typically assess fixation and following movements and perform the red reflex test. Specifically the red reflex test can detect visual opacities in the visual axis and abnormalities of the back of the eye, such as retinoblastoma or retinal detachment. When the red reflex is assessed simultaneously, potentially amblyopic conditions, such as asymmetric refractive errors and strabismus, can also be identified. The test is performed in a darkened room, with the direct ophthalmoscope focused on each pupil individual and then both eyes simultaneously. The family and clinical history may also identify a child at higher risk of amblyopia. For example, high-risk children include those with a family history or strabismus, amblyopia, high refractive errors or childhood eye disorders. Premature children, or those with neurologic and developmental conditions, are also at an increased risk.

It is assumed that the results of photoscreening would be used to prompt referral to an ophthalmologist for further evaluation. Therefore, assessment of photoscreening in this setting requires population based studies to determine whether the results of photoscreening result in a higher referral rate to ophthalmologists, with an associated improvement in sensitivity and specificity in detection of amblyogenic factors that lead to earlier diagnosis and treatment with a decrease in vision impairing amblyopia. To date these studies have not been performed.

The majority of the published studies have focused on the technical feasibility of ocular photoscreening, setting diagnostic parameters for interpretation of the photographs and its use in public health settings. For example, Tong and colleagues from the Wilmer Eye Institute published a series of three studies of the MTI PhotoScreener. The first study of 100 children was designed to determine whether or not healthcare professionals or lay volunteers could interpret and grade photoscreening photographs. A total of 18 volunteers including both pediatric ophthalmologists and lay personnel interpreted the photoscreening results, which included 26 children with normal ophthalmologic exams and 74 with abnormalities. Results from the graders varied, with sensitivities ranging from 37 to 88% and specificity from 40 to 80%. No single grader achieved sensitivity and specificity both greater than 70%. The authors concluded that these results reflected either inconsistent photographic interpretation skills or deficient grading criteria.

A subsequent study was published in 2000, which included 392 preverbal children who were referred to an ophthalmologist for examination; 103 had normal examinations while the remaining 284 children had conditions of interest for pediatric screening. In this study, the photographs were graded by a representative of the manufacturer, MTI PhotoScreener, and the results compared with the results of the ophthalmologic exam. The overall sensitivity was 65%
and the specificity 87%. The results were further analyzed according to the abnormality present, i.e., external examination abnormality (e.g., ptosis), media opacity, strabismus and refractive error. The sensitivity for refractive error was low (33%), while the sensitivity for strabismus was 55%. The authors conclude that while photoscreening with the MTI system is promising, further research on grading criteria, particularly to detect refractive errors, is needed.

The third study by the Wilmer Eye Institute investigated a new grading system for hyperopia, based on the conclusions from the previous study that the criteria for hyperopia indicating a failing grade were too low and would result in an undesirably high referral rate. This study reexamined the 392 photographs from the previous study and developed new grading criteria that resulted in a sensitivity and specificity of 100% and 88%, respectively.

Simons and colleagues studied the MTI PhotoScreener in 100 children, aged four months to 12 years who were recruited either from a pediatric ophthalmologic referral practice, children suspected to have developmental delay or a behavior disorder, or patients from a day care center. All 100 photographs were independently graded by six observers, including four pediatric ophthalmologists, a nurse and a research coordinator, and compared to the results of a complete ophthalmologic examination. For detecting any abnormal results, the sensitivity ranged from 80 to 91% and the specificity ranged from 20 to 67%. This study included verbal children, who presumably could participate in visual acuity tests.

It should be noted that all of the above studies recruited patients from a pediatric ophthalmology practice or other settings such that the studied population had a high incidence of patients with pathologic conditions. While these populations are useful to determine the initial sensitivity of photoscreening, this population does not duplicate the general population of children presenting to the primary care physicians’ office. Presumably, the patients in the above studies were referred to a pediatric ophthalmologist due to a clinical abnormality noted in the physical exam or a history that placed them at high risk. To determine the utility of photoscreening in the primary care physician’s office, the sensitivity and specificity of the photoscreening should be compared to the sensitivity and specificity of clinical diagnosis in this setting.

Ocular photoscreening has also been investigated in a public health care setting, where presumably the photoscreening is the only type of vision screening that is available to participants. For example, Donahue and colleagues reported on the results of a public health screening program which evaluated 15,000 preschool children in Tennessee. This program used volunteers from local Lions Clubs to take the photographs and all photographs were interpreted at a central reading station by professional photo readers. The positive predictive value ranged from 84% when a diagnosis of strabismus was suggested by the photoscreen, to 41% for astigmatism. While this public health setting is not applicable to this policy, it is anticipated that ocular photoscreening may be predominantly used in this setting.

In 2002, the American Academy of Pediatrics published a commentary on photoscreening. This document noted the following:

- Photoscreening does not represent a single technique or piece of equipment. Different optical systems can be used for photoscreening. Interpretation of screening images may
be performed in the physician’s office, office in a reading center, or with an automated system.

- Each photoscreening system may have its own advantage and disadvantages, and it appears that results published in the literature for one system are not necessarily valid for others.
- It is difficult to compare efficacies of various vision screening methods, such as stereoacuity testing, auto-refraction, red reflex testing and cover testing, and then determine if photoscreening has better positive and negative predictive values. This attributable in part to lack of uniformity in pass-fail criteria for significant refractive errors.
- Photoscreening needs to be studied more extensively. The AAP favors additional research of photoscreening devices and other vision screening methods in large, controlled studies to elucidate validity of results, efficacy, and cost effectiveness to identify amblyogenic factors in different age groups as well as subgroups of children.

In 2003, The American Academy of Pediatrics issued a policy statement on eye examination as performed by pediatricians, which included discussion of ocular photoscreening. This document noted that “photoscreening is not a substitute for accurate visual acuity measurement but can provide significant information about the presence of sight threatening conditions such as strabismus, refractive errors, media opacities (cataract) and retinal abnormalities (retinoblastoma). Photoscreening techniques are still evolving”.

In 2003, the American Association for Pediatric Ophthalmology and Strabismus published a position statement on photoscreening, which reads in part, “It is important to remember that photoscreening detects many problems that predispose the developing visual system to amblyopia, rather than providing a direct test of visual acuity and binocularity, and that, therefore these latter tests are preferable once a child can cooperate with such testing. For the preliterate child, however, photoscreening systems show significant potential. Current photoscreeners still suffer from relatively low sensitivity, high false positive referral rates, and relatively high usage costs. Advances in technology will eventually lead to the development of systems having higher sensitivities and positive predictive values. AAPOS encourages the development of such systems. We believe that further research may produce systems that have sufficient reliability to achieve widespread acceptance and usage, not only for children who do not receive primary medical care, but also in the primary care physician’s office.”

**June 2008 Update**

A search of the MEDLINE database was performed for the period of May 2006 through May 2007. As described above, the literature focuses on the effectiveness of community-based screening programs for preschool and elementary school-age children. A single study was identified that examined the use of photoscreening in the primary care setting. Kemper and colleagues conducted a national survey of 377 pediatricians (55% response) to determine the rate of acuity screening in preschool children. It was reported that vision screening was conducted in 35%, 73%, and 66%, of three, four, and five-year olds, respectively. Few (8%) of the respondents reported using either autorefraction or photoscreening. Based on a retrospective review, Donahue reported that younger children with anisometropia had a lower prevalence of amblyopia than older children. This retrospective study, which should be considered
preliminary, suggests that earlier detection of anisometropia might allow earlier intervention, and may prevent or retard development of amblyopia.

The National Eye Institute is sponsoring a 3-phase multicenter prospective clinical trial to evaluate screening tests for identifying preschool children in need of comprehensive eye examinations. The category of screening personnel and the specific screening tests will be determined in Phases I and II of the Vision in Preschoolers (VIP) Study. Phase III will evaluate the performance (sensitivity and specificity) of the tests in identifying specific vision disorders in 6400 Head Start preschoolers.

**June 2010 Update**

A literature search identified one study that examined the use of photoscreening in the primary care setting, and this was a survey of physicians, not a clinical trial. Kemper and colleagues conducted a national survey of 377 pediatricians (55% response) to determine the rate of acuity screening in preschool children. It was reported that vision screening was conducted in 35%, 73%, and 66%, of three, four, and five-year olds, respectively. Few (8%) of the respondents reported using either auto refraction or photoscreening.

A Cochrane review, last updated in 2008, focused on the role of screening for amblyopia in general. The investigators searched the literature and found noted that there have been no trials comparing the prevalence of amblyopia in screened versus populations, therefore it is difficult to analyze the impact of screening programs on the prevalence of amblyopia.

The Vision in Preschoolers (VIP) study, a multicenter prospective trial sponsored by the National Eye Institute, evaluated screening tests for identifying preschool children in need of comprehensive eye examination. The trial evaluated screening tests administered by eye care professionals (in Phase I), and nurses and lay screeners (in Phase II) in a community-based setting; it was not designed to evaluate testing in a primary care physician’s office. In Phase I, a total of 2,588 children aged three to five years in Head Start were screened with 11 tests, including two photoscreening tests using a mobile unit designed for the study. When overall specificity was set to either 90% or 94%, non-cycloplegic retinoscopy, Retinomax, SureSight and Lea Symbols VA performed the best in detecting children who had at least one of the targeted conditions (amblyopia, strabismus, significant refractive error and/or unexplained reduced visual acuity) as well as those with the most severe conditions. Non-cycloplegic retinoscopy, Retinomax and SureSight performed significantly better than static photoscreeners including the MTI Photoscreener and the iScreen Photoscreener. Phase II used the best performing tests from Phase I, which did not include photoscreening.

**December 2010 Update**

A recent study evaluated photoscreening using an infrared camera (the Plusoptix S04) in children between three and five years of age seen at one pediatric ophthalmology practice in the U.S. Chart review for a six-month period identified 153 patients who had received screening and a comprehensive pediatric ophthalmology examination on the same day; all children also had a cycloplegic refraction procedure within the previous six months. Photoscreening was done by either a certified orthoptist or an ophthalmic technician before the patient was examined. The ophthalmologist was not blinded to findings from the photoscreening. No
amblyopia risk factors and no amblyopia were found in 60 of 153 (39%) by photoscreening and 72 (47%) by examination. The photoscreener was found to have a sensitivity of 99% specificity of 82%, false-positive rate of 18%, false negative rate of 1.2%, and positive predictive value of 86%. The authors noted that the population in this study likely had a higher prevalence of amblyopia than the general population which would result in a higher positive predictive value.

The largest studies conducted in the community setting report on programs sponsored by Lions clubs. Recently, Longmuir and colleagues describe findings from a photoscreening program in Iowa in which lay volunteers screened 147,809 children who were at least six months old at 9,746 sites using the MTI PhotoScreener. The screenings were conducted by lay volunteers and the program was supervised by a volunteer pediatric ophthalmologist. The mean age of children screened was 4.7 years. Photoscreens were evaluated in a central location by professional photo readers and children who failed the screen were referred to an ophthalmic professional. A total of 6,247 of 147,809 children (4.2%) were referred for additional testing and, for 4781, the evaluation took place and findings were recorded. The additional evaluation found that 3925 of the 4781 (82%) had an amblyopia risk factor.

**Technology Assessments, Guidelines, and Position Statements**

*American Academy of Pediatrics (AAP):*

In 2008, the AAP reaffirmed its policy statement on photoscreening which was originally issued in 2002. The document noted the following:

- Photoscreening does not represent a single technique or piece of equipment. Different optical systems can be used for photoscreening. Interpretation of screened images may be performed in the physician’s office, office in a reading center, or with an automated system.
- Each photoscreening system may have its own advantages and disadvantage, and it appears that results published in the literature for one system are not necessarily valid for others.
- It is difficult to compare efficacies of various vision-screening methods, such as stereoacuity testing, autorefraction, red reflex testing, and cover testing, and then determine if photoscreening has better positive and negative predictive values. This is attributable in part to a lack of uniformity in pass-fail criteria for significant refractive errors.
- Photoscreening needs to be studied more extensively. The AAP favors additional research of photoscreening devices and other vision-screening methods in large, controlled studies to elucidate validity of results, efficacy, and cost effectiveness to identify amblyogenic factors in different age groups as well as subgroups of children.

*American Association for Pediatric Ophthalmology and Strabismus (AAPOS) and American Academy of Ophthalmology (AAO):*

In 2007, the organizations issued a joint statement on vision screening for infants and children. The statement recommends screening for vision problems and says that photoscreening may be “a valuable adjunct to the traditional screening process, particularly in preliterate children.” The statement did not recommend any particular venue for photoscreening.
**Key Words:**
Ocular photoscreening, MTI PhotoScreener, photoscreening, ocular

**Approved by Governing Bodies:**
MTI PhotoScreener was reviewed by the FDA on 12/02/1994.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.
Pre-certification/Pre-determination requirements: Not applicable

State or federal mandates (i.e., the FEP) may dictate that all devices approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these devices may be assessed only on the basis of their medical necessity.

**Current Coding:**
CPT:

99174 Instrument based ocular screening (e.g., photoscreening, automated-refraction), bilateral *(Effective 01/01/2008)*

**Previous Coding:**

0065T Ocular photoscreening, interpretation and report *(Deleted 01/01/2008)*

**References:**


**Policy History:**
Medical Policy Group, June 2004 (3)
Medical Policy Administration Committee, September 2004
Available for comment September 7-October 21, 2004
Medical Policy Group, June 2006 (1)
Medical Policy Group, June 2008 (1)
Medical Policy Group, June 2010 (1): Key Points updated, policy statement remain unchanged
Medical Policy Group, December 2010 (1): Key Points updated, reference list updated
Medical Policy Group, December 2012 (3): 2013 Coding Updates: Verbiage change to Code 99174 (effective 01/01/2013)
Medical Policy Group, December 2012 (3): Effective 12/26/2012 - Active policy but no longer scheduled for regular literature reviews and update
Medical Policy Group, October 2013 (1): Removed ICD-9 Diagnosis codes; no change to policy statement.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.