MEDICAL POLICY

Excellus

SUBJECT: OCULAR PHOTOSCREENING	EFFECTIVE DATE: 10/17/13 REVISED DATE: 09/18/14
POLICY NUMBER: 9.01.16 CATEGORY: Technology Assessment	PAGE: 1 OF: 4

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

Based upon our criteria and assessment of peer-reviewed literature, ocular photoscreening in the primary care physician's office has not been medically proven to be effective and is considered **investigational** as a screening tool to detect amblyogenic factors in children.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Amblyopia is a disorder of visual development, 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 8 to 10 years of age, it can be effectively treated by occlusion of the sound eye.

The U.S. Preventive Services Task Force 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. 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. 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 investigated as an alternative screening method, not to detect amblyopia but 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.

An advantage of ocular photoscreening over standard methods of testing visual acuity 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 can be performed in several settings. For example, photoscreening can be performed in a 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. Photoscreening in the setting of the primary care physician's office, is usually 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.

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 individually 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 of strabismus, amblyopia, high refractive errors, or childhood eye disorders. Children born prematurely, or those with neurologic and developmental conditions, are also at higher risk.

RATIONALE:

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 compared to standard visual assessment, with an associated improvement in sensitivity and specificity for detection of amblyogenic factors that lead to earlier diagnosis and treatment with a decrease in vision-impairing amblyopia.

Overall, no studies have been found that evaluate whether the results of ocular photoscreening leads to higher referral rates to ophthalmologists, earlier diagnosis and treatment or a decrease in vision-impairing amblyopia, compared to a standard visual assessment. The evidence is insufficient to determine whether ocular photoscreening in the primary care physician's office improves the net health outcome.

In April 1994, the MTI Photoscreener (Medical Technology and Innovations Inc.; Cedar Falls, IA) was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use as an ophthalmic camera. In January 2001, the iScreen Vision Screener was cleared for marketing by the FDA through the 510(k) process. The FDA determined that this device was substantially equivalent to existing devices for use in screening vision problems.

Several studies have evaluated the accuracy of ocular photoscreening. 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 examinations. 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. In Phase I, a total of 2,588 children aged 3 to 5 years in Head Start were screened with 11 tests, including 2 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.

Matta, et al. (2010) evaluated photoscreening using an infrared camera (the Plusoptix S04) in children between 3 and 5 years of age seen at one pediatric ophthalmology practice in the U.S. Chart review for a 6-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 6 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 in 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. Longmuir and colleagues (2010) described findings from a photoscreening program in Iowa in which lay volunteers screened 147,809 children who were at least 6 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 4,781, the evaluation took place and findings were recorded. The additional evaluation found that 3,925 of the 4,781 (82%) children had an amblyopia risk factor.

In a retrospective case series, Teed, et al. (2010) reported on outcomes in children identified in the Tennessee screening program and subsequently treated. Of 901 children referred to a pediatric ophthalmology practice; 551 had amblyopiogenic risk factors without amblyopia, 185 were diagnosed with amblyopia, and 165 had false-positive screenings. (14) Of the 185 children with amblyopia, 125 met inclusion criteria (lack of developmental delay and/or organic eye disease and sufficient documentation in clinical records). Ninety-seven of the 125 (78%) children were successfully treated (at least 3 lines of improvement in reading and/or 20/30 or better vision in the amblyopic eye). While the vision screening took place in a public health setting, and thus these studies are not applicable to the policy, it is anticipated that ocular photoscreening may be predominantly used in a community-based or public health setting.

A Cochrane review (Powell, et al., 2009) focused on the role of screening for amblyopia in general. The investigators noted that there have been no trials comparing the prevalence of amblyopia in screened versus unscreened populations; therefore it is difficult to analyze the impact of screening programs on the prevalence of amblyopia.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	99174 **(E/I)**	Ocular photoscreening, interpretation and report

ICD9:	V72.0	Examination of eyes and vision
	V80.2	Special screening for other eye conditions
ICD10:	Z01.00-Z01.01	Encounter for examination of eyes and vision (code range)
	Z13.5	Encounter for screening for eye and ear disorders

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* key article

KEY WORDS:

Amblyopia, Ocular photoscreening, Photoscreener, Vision screener

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon our review, ocular photoscreening is not addressed in National or regional CMS coverage determinations or policies.