MEDICAL POLICY

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POLICY TITLE	RETINAL TELESCREENING FOR DIABETIC RETINOPATHY
POLICY NUMBER	MP- 2.086

Original Issue Date (Created):	**October 25, 2011**
Most Recent Review Date (Revised):	**January 28, 2014**
Effective Date:	**April 1, 2014**

I. POLICY

Retinal telescreening with digital imaging and manual grading of images may be considered **medically necessary** as a screening technique for the detection of diabetic retinopathy.

Retinal telescreening is considered **investigational** for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference

MP 2.085 Anterior Eye Segment Optical Imaging
MP-2.028 Eye Care
MP 2.056- Ophthalmologic Techniques for Evaluating Glaucoma

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[Y] SeniorBlue HMO
[Y] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

*The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

[Note: Final page is signature page and is kept on file, but not issued with Policy.]

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III. DESCRIPTION/BACKGROUND

Digital imaging systems use a digital fundus camera to acquire a series of standard field color images and/or monochromatic images of the retina of each eye. This type of retinopathy screening and risk assessment is proposed as an alternative to conventional dilated fundus examination, particularly in diabetic individuals who are not compliant with the recommended periodic retinopathy screenings. The digital images that are captured may be transmitted via the Internet to a remote center for interpretation by trained readers, storage, and subsequent comparison.

Diabetic retinopathy is the leading cause of blindness among adults aged 20–74 years in the United States. The major risk factors for developing diabetic retinopathy are duration of diabetes and severity of hyperglycemia. After 20 years of disease, almost all patients with type 1 and >60% of patients with type 2 diabetes will have some degree of retinopathy. Other important risk factors include hypertension and elevated serum lipid levels.

Diabetic retinopathy progresses, at varying rates, from asymptomatic, mild nonproliferative abnormalities to proliferative diabetic retinopathy (PDR) with new blood vessel growth on the retina and posterior surface of the vitreous. The two most serious complications for vision are diabetic macular edema and proliferative diabetic retinopathy. At its earliest stage (nonproliferative retinopathy), the retina develops microaneurysms, intraretinal hemorrhages, and focal areas of retinal ischemia. With disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses blood vessels that provide nourishment to the retina are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). The new blood vessels that occur in PDR may fibrose and contract, resulting in tractional retinal detachments with significant vision loss. Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or nonproliferative stages of the disease. Although proliferative disease is the main blinding complication of diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

The value of screening is well established since diabetic retinopathy has few visual or ocular symptoms until vision loss develops. With early detection, diabetic retinopathy can be treated with modalities that can decrease the risk of severe vision loss. Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for patients whose retinopathy is approaching the high-risk stage. Although laser photocoagulation is effective at slowing the progression of retinopathy and reducing visual loss, it results in collateral damage to the retina and does not restore lost vision. Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser

photocoagulation, while diffuse macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit vascular endothelial growth factor (VEGF) production, but are associated with serious adverse effects including cataracts and glaucoma with damage to the optic nerve. Corticosteroids also can worsen diabetes control. VEGF inhibitors (e.g., ranibizumab, bevacizumab, and pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are being evaluated for the treatment of diabetic macular edema and proliferative diabetic retinopathy.

Because treatments are aimed primarily at preventing vision loss, and retinopathy can be asymptomatic, it is important to detect disease and begin treatment early in the process. Annual dilated, indirect ophthalmoscopy coupled with biomicroscopy or 7-standard field stereoscopic 30° fundus photography have been considered to be the screening techniques of choice. Because these techniques require a dedicated visit to a competent eye care professional, typically an ophthalmologist, there is underutilization of this screening recommendation by at-risk members. The under-use has resulted in the exploration of remote retinal imaging, using film or digital photography, as an alternative to direct ophthalmic examination of the retina.

A number of photographic methods have been evaluated that allow images of the retina to be captured and then interpreted by expert readers who may not be located conveniently to the patient. One approach is mydriatic standard field 35-mm stereoscopic color fundus photographs. Digital fundus photography has also been evaluated as an alternative to conventional film photography. Retinal imaging can be performed using digital retinal photographs with (mydriatic) or without (nonmydriatic) dilating the pupil. Digital imaging has the advantage of easier acquisition, transmission, and storage. In addition, the potential for digital images of the retina to be acquired in a primary care setting and evaluated by trained readers in a remote location with retinal specialist consultation exists.

Several digital camera and transmission systems have received marketing clearance through the U.S. Food and Drug Administration's 510(k) process and are currently available. These include:

- The Diabetic Retinopathy Digital Disease Detection and Tracking System (Inoveon Corp., Oklahoma City, OK)
- DigiScope® (EyeTel Corp., Columbia, MD) in conjunction with the Wilmer Eye Institute at Johns Hopkins Medicine
- The Fundus AutoImager™ (Visual Pathways Inc., Prescott, AZ)
- ImageNet™ Digital Imaging System (Topcon Medical Systems Inc., Paramus, NJ)
- Zeiss FF450 Fundus Camera and the VISUPAC® Digital Imaging System (Carl Zeiss Meditech Inc., Dublin, CA)

The 2011 diabetic retinopathy screening recommendation of the American Diabetic Association includes the following:

Patient Group	First Retinal Examination	Follow-up
Type 1 diabetes	Within 5 years after diagnosis of diabetes in adults and children > 10 years	Annually*
Type 2 diabetes	Shortly after the diagnosis of diabetes	Annually*
Before pregnancy in preexisting diabetes	Before conception and early in the first trimester of pregnancy	Throughout pregnancy and for 1 year postpartum

*Less frequent exams (every 2-3 years) may be considered following one or more normal eye exams. More frequent retinal examinations may be required if retinopathy is progressing

IV. RATIONALE

The benefit of early treatment of diabetic retinopathy was established in the large Early Treatment Diabetic Retinopathy Study (ETDRS) supported by the National Eye Institute (NEI). (3, 4) Local acquisition/remote interpretation technique was used to consistently detect and evaluate the retinal changes of participants in the ETDRS. The ETDRS used mydriatic 30-degree stereoscopic color fundus 35-mm photographs of 7 standard fields evaluated by a single reading center. This is considered to be the gold standard for the detection of diabetic retinopathy and has sensitivity and specificity that is superior to direct and indirect ophthalmoscopy by ophthalmologists.

Moss et al. reported on an overall agreement of 85.7% when comparing retinopathy detection by ophthalmoscopy performed by skilled examiners to 7 standard field stereoscopic 30-degree fundus photography evaluated by trained graders. (5) A study by Kinyoun et al. found fair-to-good agreement between ophthalmoscopy and evaluation of 7-standard field stereoscopic 30-degree fundus photography by the examining ophthalmologist, as well as by trained readers. (6) Analysis of the discordance suggested that conventional ophthalmoscopy could miss up to 50% of microaneurysms, some of the earliest changes of diabetic retinopathy. Delori et al. reported more accurate visualization and documentation of the structures of the ocular fundus when using monochromatic illumination (red-free green light), as compared to the white light used to obtain color photographs. (7)

The efficacy of digital image acquisition, as compared to film-based acquisition, has been reported by several investigators. (8, 9) Fransen et al. published the results of a

comparison of standard evaluations using film to the same fields captured and transmitted as digital images. (10) In the study of 290 adult diabetic patients, the sensitivity of digital compared to film was 98.2%, and the specificity was 98.7%. Statistical analysis identified that the evaluation of film and digital images provided substantially equivalent results. When comparing high-resolution stereoscopic digital fundus photography to contact lens biomicroscopy, Rudnisky et al. found a high level of agreement regarding the detection of clinically significant macular edema in diabetic patients. (11)

In addition to the examination technique and the comparison of different photographic techniques, the results of dilated versus nonmydriatic fundus photography have been studied. (12-14) In a 2003 report, Scanlon et al. (14) compared mydriatic and nonmydriatic photo screening programs using dilated slit lamp biomicroscopy as the reference standard. In the study of 3,611 patients, the sensitivity of mydriatic digital photography was 87.8%, the specificity was 86.1%, and the technical failure rate was 3.7%. Photography through an undilated pupil was found to provide a sensitivity of 86.0%, a specificity of 76.6%, and a technical failure rate of 19.7%.

A 2011 meta-analysis evaluated variations in qualifications of photographers and mydriatic status. (15) Twenty studies were included that evaluated the accuracy of a diabetic retinopathy screening method that used photography- or examination-based retinopathy screening compared with a standard of either 7-field mydriatic photography or dilated fundal examination. Studies with film or digital cameras were included in the systematic review. Studies of automated analysis techniques and technologies were excluded because they were not considered current standard practice. For meta-analysis, 40 assessments of screening methods were collapsed into 6 categories: nonmydriatic camera, nonspecialist photographer (n=5); mydriatic camera, nonspecialist photographer (n=8); nonmydriatic camera, specialist photographer (n=4); mydriatic camera, specialist photographer (n=3); direct examination (n=8); method mixed or not reported (n=12). Sensitivity and specificity were assessed for the presence or absence of diabetic retinopathy in comparison with the reference standard. Variations in mydriatic status alone did not significantly influence sensitivity (odds ratio [OR]: 0.89) or specificity (OR: 0.94). Variations in medical qualifications of photographers did not significantly influence sensitivity (OR: 1.25), but the specificity of detection of any diabetic retinopathy was significantly higher for screening methods that used a photographer with specialist medical or eye qualifications. When photographs were taken by a specialist, the odds of a negative screening test when diabetic retinopathy was not evident with the reference standard were 3.86 times that when photographs were taken by nonspecialists. This was largely due to the effect of specialists or nonspecialists in photographs taken without mydriasis (OR: 5.65). The lower specificity with nonspecialist photographers may lead to increased referrals to an eye specialist for further examination in some patients without diabetic retinopathy. This finding may be biased, since 6 of 7 assessments in the specialist category were derived from a single study. Interpretation is further limited by the inclusion of both standard film and digital imaging in the meta-analysis.

The article by Scanlon et al. (discussed above) was not included in the systematic review. (14) Included in the review was a 2004 study by Murgatroyd and colleagues that evaluated digital image screening with a non-mydriatic camera in 398 patients (794 eyes). (16) Mydriasis was found to reduce the proportion of ungradable photographs from 26% to 5%. Sensitivity and specificity based on gradable photographs only were similar for undilated single field (77% and 95%, respectively) and dilated images (81% and 92%, respectively). Since 64% of patients had gradable images, the authors suggest the possibility of targeted mydriasis or dilating only those patients who fail initial undilated photography.

A number of automated scoring systems are being evaluated for diabetic retinopathy screening. A 2011 publication examined the accuracy of one such approach, which used a computer-aided diagnosis (CAD) system to diagnose diabetic retinopathy using a publicly available dataset of 1,200 digital color fundus photographs. (17) The reference standard was based on 2 diagnoses provided with the dataset. At a specificity of 50%, the automated system had a sensitivity of 92.2% to detect diabetic retinopathy, which was similar to the results of 2 expert reviewers (sensitivity of 94.5% and 91.2% and specificity of 50%). Fifty-one abnormal images were wrongly classified as normal. Research is continuing to improve the system's performance.

Oliveira et al. assessed the accuracy of another automated screening system (RetmarkerSR) in a study of non-mydriatic images from 5,386 patients in a diabetic retinopathy screening program. (18) Automated analysis classified 47.5% as having no disease and 52.5% as having disease. When compared with an experienced ophthalmologist grader who graded 8.7% with referable retinopathy, the sensitivity was 96.1% and specificity was 51.7%. A 2-step approach in which patients marked as diseased on the first screen had a second screening visit improved specificity to 63.2% with no loss of sensitivity. The sample in this study was biased, as it did not include another 9.54% of images that a grader had identified as being of poor quality. The omission of these cases may have led to a falsely high estimate of accuracy.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 2 academic medical centers while this policy was under review in 2011. The input supported the medical necessity of retinal telescreening when performed either with or without dilation. Input was mixed regarding the use of retinal telescreening for monitoring and management of disease in individuals diagnosed with diabetic retinopathy. One

reviewer commented that retinal telescreening could be useful for monitoring patients with stable disease, particularly in outlying areas where access to this technology exceeds access to ophthalmologists.

Summary

A number of studies have reported on the agreement regarding the presence and stage of retinopathy based on ophthalmoscopy versus photography or standard film versus digital imaging. The studies generally found a high level of agreement between retinal examination and imaging. Several studies suggested that retinal imaging through a dilated pupil was equivalent or superior to ophthalmic examination regarding the detection of diabetic retinal changes. Although evidence indicates that digital imaging without mydriasis leads to an increase in the proportion of ungradable photographs, practice guidelines and clinical input supports the use of both dilated and undilated retinal telescreening. At this time, it is unclear whether non-specialist photographers would evaluate undilated photographs at the point-of-care and, if needed, repeat photography with dilation.

Overall, the published medical literature is adequate to conclude that digital imaging systems are safe and effective alternatives to the gold standard of dilated indirect ophthalmoscopy coupled with biomicroscopy or stereoscopic fundus photography. Additional advantages of digital imaging systems include short examination time and the ability to perform the test in the primary care physician setting.

Practice Guidelines and Position Statements

In 2010 the American Diabetes Association (ADA) updated their position statement on standards of medical care in diabetes. (2, 19) Included in the guidelines are specific recommendations for initial and subsequent examinations to screen for retinopathy (see Policy Guidelines). The ADA states that examinations can be done with retinal photographs (with or without dilation of the pupil) read by experienced experts. In-person exams are still necessary when the photos are unacceptable and for follow-up of detected abnormalities.

The American Association of Clinical Endocrinologists (AACE) published guidelines on diabetes mellitus comprehensive care in 2011. (20) Guidelines for the first retinal screening exam and subsequent annual dilated eye examination by an ophthalmologist are consistent with the ADA's 2010 position statement. (2) The AACE guidelines state that based on level 3 evidence (observational studies), "the use of nonmydriatic fundus cameras, equipped with digital transmission technology, enables large-scale, point-of-care screening for retinopathy. Patients with abnormal retinal photographs are then triaged to full examination by an ophthalmologist. This 2-step approach can be an efficient strategy for retinopathy screening at the population level, particularly in remote areas. However, the system is still under development and does not replace the current recommendation for annual dilated eye examination."

The 2008 Preferred Practice Patterns from the American Academy of Ophthalmology (AAO) updated their 2003 guidelines and provide the following information on screening for diabetic retinopathy, "Several forms of retinal screening with standard fundus photography or digital imaging, with and without dilation, are being investigated as a means of detecting retinopathy. Appropriately validated digital imaging technology can be a sensitive and effective screening tool to identify patients with diabetic retinopathy for referral for ophthalmic evaluation and management." (21, 22) The AAO further states that it is not clear that photographic screening programs achieve a greater reduction in vision loss than routine care by an ophthalmologist, and these technologies are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy. The recommended eye examination schedule is consistent with the screening schedule described in the 2004 ADA position statement (minor modifications to the 2010 ADA screening guidelines). (2, 19)

The AAO also published clinical statements on screening for diabetic retinopathy in 2006 and screening for retinopathy in the pediatric patient with type 1 diabetes mellitus in 2008. (23, 24) The AAO "recognizes that screening for diabetic retinopathy using appropriately validated digital image technology can be a sensitive and effective methodology. Such technology has not been demonstrated to be as effective, however, at detecting and quantifying the spectrum of other ophthalmic pathology that can accompany diabetic retinopathy, including cataract and glaucoma, which are more prevalent in patients with diabetes mellitus, and which can be medically significant. It also does not mitigate the need for periodic comprehensive ophthalmic examinations." For pediatric patients with type 1 diabetes, the AAO found that appropriate screening strategies are not adequately implemented. The AAO states that the usefulness of digital photography in detecting retinopathy has been demonstrated but is unlikely to become widely used until it can be performed rapidly, simply, and at a reasonable cost.

In 2011, the American Telemedicine Association (ATA) published guidelines for clinical, technical, and operational performance standards for diabetic retinopathy screening. (25) Recommendations from the ATA are based on reviews of current evidence, medical literature, and clinical practice. The ATA states that ETDRS 30°, stereo 7-standard field, color, 35-mm slides are an accepted standard for evaluating diabetic retinopathy. Although no standard criteria have been widely accepted as performance measurements of digital imagery used for diabetic retinopathy evaluation, current clinical trials sponsored by the National Eye Institute have transitioned to digital images for diabetic retinopathy assessment. Telehealth programs for diabetic retinopathy should demonstrate an ability to compare favorably with ETDRS film or digital photography as reflected in kappa values for agreement of diagnosis, false-positive and false-negative readings, positive predictive value, negative predictive value, sensitivity and specificity of diagnosing levels of retinopathy, and macular edema. Inability to obtain or read images should be considered a positive finding, and patients with unobtainable or unreadable images should be promptly re-imaged or referred for evaluation by an eye care specialist.

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V. DEFINITIONS

ANTERIOR SEGMENT is the front third of the eye that includes the structures in front of the vitreous humour: the cornea, iris, ciliary body, and lens. Within the anterior segment are two fluid-filled spaces: the anterior chamber between the posterior surface of the cornea (i.e. the corneal endothelium) and the iris. The posterior chamber between the iris and the front face of the vitreous. Aqueous humor fills these spaces within the anterior segment and provides nutrients to the surrounding structures

CUP/DISC RATIO in ophthalmology is the mathematic relationship between the horizontal or vertical diameter of the physiologic cup and the diameter of the optic disc.

DIABETIC RETINOPATHY is a disorder of retinal blood vessels characterized by capillary microaneurysms, hemorrhage, exudates, and the formation of new vessels and connective tissue.

INTRAOCULAR PRESSURE refers to the internal pressure of the eye regulated by resistance to the flow of aqueous humor through the fine sieve of the trabecular meshwork.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

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VIII. REFERENCES

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Other:

Novitas Medicare Services Local Coverage Determination (LCD) L27498: Fundus Photography. Effective 04/02/12.[Website]: https://www.novitas-solutions.com/policy/mac-ab/l27498-r9.html Accessed October 23, 2013.

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
92227	92250							

ICD-9-CM Diagnosis Code*	Description
250.00 – 250.03	Diabetes mellitus without mention of complication, type II or unspecified type, not stated as uncontrolled. Code range
250.50 – 250.53	Diabetes with ophthalmic manifestations, type II or unspecified type, not stated as uncontrolled Code range
362.01-362.06	Diabetic retinopathy Code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

Investigational; therefore not covered:

CPT Codes ®							
92228							

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The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
E08.00 - E13.9	Diabetes mellitus; code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

X. POLICY HISTORY

MP 2.086	**CAC 10/25/11** New policy. Adopt BCBSA. Information related to digital imaging systems extracted from MP 2.056 and a new, separate policy created. Minor wording changes in policy statement. Remains medically necessary as a screening technique for the detection of diabetic retinopathy. Added statement indicating retinal telescreening for other indications is investigational including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy.
	CAC 1/29/13 Consensus review. References updated; no changes to the policy statements. Codes reviewed. 11/28/12 klr
	Admin change 1/2014 deleted retired LCD, Novitas Medicare Services Local Coverage Determination LCD L27498 Fundus Photography.
	CAC 1/28/14 Consensus review**.** References updated; no changes to the policy statements. Rationale added.