BlueCross BlueShield of Louisiana

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Retinal Telescreening for Diabetic Retinopathy

Policy # 00026
Original Effective Date: 08/25/2003
Current Effective Date: 12/18/2013

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider retinal telescreening with digital imaging and manual grading of images as a screening technique for the detection of diabetic retinopathy to be **eligible for coverage.**

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

Patient Group	First Retinal Examination Recommendation	Minimum Follow-up Recommendation
Type 1 diabetes	Within five years after diagnosis of diabetes in adults 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 for 1 year postpartum

When Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers retinal telescreening for all other indications, including the monitoring and management of disease in individuals diagnosed with diabetic retinopathy to be **investigational.***

Background/Overview

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.

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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 greater than 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 2 most serious complications for vision are diabetic macular edema and PDR. 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. Vascular endothelial growth factor 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 primarily aimed 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 degree fundus photography has 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 underuse 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 conveniently located 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 of 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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
Several digital camera and transmission systems are currently available and have received FDA approval as Class II devices through the 510(k) Premarket Notification process:

- 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)

Rationale/Source

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). 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. 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. 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.

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The efficacy of digital image acquisition, as compared to film-based acquisition, has been reported by several investigators. Fransen et al. published the results of a comparison of standard evaluations using film to the same fields captured and transmitted as digital images. 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.

In addition to the examination technique and the comparison of different photographic techniques, the results of dilated versus nonmydriatic fundus photography have been studied. In a 2003 report, Scanlon et al. 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. 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. 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). 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. 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. 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.

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	92227, 92228, 92250
HCPCS	S0625
ICD-9 Diagnosis	250.00 thru 250.93
ICD-9 Procedure	No code

Policy History

Original Effective Date: 08/25/2003
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06/20/2003 Medical Policy Committee review
08/25/2003 Managed Care Advisory Council approval
11/02/2004 Medical Director review
11/16/2004 Medical Policy Committee review
Format revision. No substance change to policy.
11/29/2004 Managed Care Advisory Council approval

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10/05/2005	Medical Director review
10/18/2005	Medical Policy Committee review Format revision. FDA information added to policy. Rationale/Source added from BCBSA policy. No substance change to policy.
10/27/05	Quality Care Advisory Council approval
11/01/2006	Medical Director review
11/15/2006	Medical Policy Committee approval. Diabetic Association recommendations for diabetic retinopathy screening were added to policy.
11/07/2007	Medical Director review
11/15/2007	Medical Policy Committee approval. Policy statement unchanged.
11/05/2008	Medical Director review
11/18/2008	Medical Policy Committee approval. No change to coverage eligibility.
12/04/2009	Medical Director review
12/16/2009	Medical Policy Committee approval. No change to coverage eligibility.
12/01/2010	Medical Director review
12/15/2010	Medical Policy Committee approval. No change to coverage eligibility.
12/08/2011	Medical Policy Committee review
12/21/2011	Medical Policy Implementation Committee approval. Title changed from “Digital Imaging Systems for the Detection and Evaluation of Diabetic Retinopathy” to “Retinal Telescreening for Diabetic Retinopathy”. Eligible for coverage statement revised to adopt the new policy title. Investigational statement added for all other indications of retinal telescreening. Background/Overview, Rationale and References revised and updated.
12/06/2012	Medical Policy Committee review
12/19/2012	Medical Policy Implementation Committee approval. No change to coverage.
12/12/2013	Medical Policy Committee review
12/18/2013	Medical Policy Implementation Committee approval. No change to coverage.

Next Scheduled Review Date: 12/2014

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or “Medical Necessity”) - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and

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C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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