



Louisiana

Retinal Telescreening for Diabetic Retinopathy

Policy # 00026

Original Effective Date: 08/25/2003

Current Effective Date: 12/20/2017

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**.

Table PG1. American Diabetes Association Retinopathy Screening Recommendations

Patient Group	First Retinal Examination	Follow-Up
Adults with type 1 diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 y after the onset of diabetes	Every 2 years if no evidence of retinopathy for 1 or more annual eye exams; dilated retinal examinations at least annually if any level of retinopathy is present. ^a
Type 2 diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of diagnosis of diabetes	Every 2 years if no evidence of retinopathy for 1 or more annual eye exams; dilated retinal examinations at least annually if any level of retinopathy is present. ^a
Before pregnancy in preexisting diabetes	Before pregnancy or early in the first trimester of pregnancy	Every trimester throughout pregnancy and for 1 y postpartum

^a More frequent retinal examinations may be required if retinopathy is progressing or threatens sight.

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

DIABETIC RETINOPATHY

Diabetic retinopathy is the leading cause of blindness among adults aged 20 to 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 more than 60% of patients with

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type 2 diabetes will have some degree of retinopathy. Other factors that contribute to the risk of retinopathy 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 (DME) 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, retinal blood vessels 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 cause of blinding in diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

Screening

There is potential value in screening for diabetic retinopathy because diabetic retinopathy has few visual or ocular symptoms until vision loss develops. 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° fundus photography, has been considered the screening technique of choice. Because these techniques require a dedicated visit to a competent eye care professional, typically an ophthalmologist, retinopathy screening is underutilized. This 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.

Treatment

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 causes 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 events including cataracts and glaucoma, with damage to the optic nerve. Corticosteroids also can worsen diabetes control. VEGF inhibitors (eg, ranibizumab, bevacizumab,

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pegaptanib), which reduce permeability and block the pathway leading to new blood vessel formation (angiogenesis), are being evaluated for the treatment of DME and PDR.

Digital Photography and Transmission Systems for Retinal Imaging

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

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Several digital camera and transmission systems (see Table 1 for examples) have been cleared for marketing by the U.S. FDA through the 510(k) process and are currently available (product codes: HKI and NFJ).

Table 1. Digital Camera and Transmission Systems Cleared by FDA for Retinal Telescreening

Camera and Transmission Systems	Manufacturer	Approval Date
IRIS Intelligent Retinal Imaging System™‡ DigiScope®‡	Ora Inc. Eye Tel Imaging with Johns Hopkins Medicine	2015 1999
The Fundus Autolmager™‡ ImageNet™ ‡Digital Imaging System	Visual Pathways Topcon Medical Systems	2002 2008
Zeiss FF450 Fundus Camera and the VISUPAC®‡ Digital Imaging System	Carl Zeiss Meditec	2001

Centers for Medicare and Medicaid Services (CMS)

There is no national coverage determination.

Rationale/Source

OPTOMETRIST OR OPHTHALMOLOGIST IMAGE INTERPRETATION

7-Field Fundus Photography

The benefit of early treatment of diabetic retinopathy was established in the early 1990s in the large Early Treatment Diabetic Retinopathy Study (ETDRS), which was supported by the National Eye Institute (NEI). Local acquisition/remote interpretation technique, with interpretation by skilled readers, was used to

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consistently detect and evaluate the retinal changes of participants in the study. ETDRS used mydriatic 30° stereoscopic color fundus 35-mm photographs of 7 standard fields evaluated by a single reading center.

Seven-field fundus photography is considered the criterion standard for the detection of diabetic retinopathy and has sensitivity and specificity superior to direct and indirect ophthalmoscopy by ophthalmologists. Studies from the 1970s established the accuracy of 7-field fundus photography in the detection of diabetic retinopathy. Moss et al (1985) reported on an overall agreement of 85.7% when comparing retinopathy detection by ophthalmoscopy performed by skilled examiners with 7-standard-field stereoscopic 30° fundus photography evaluated by trained readers. A study by Kinyoun et al (1992) found fair-to-good agreement between ophthalmoscopy and evaluation of 7-standard-field stereoscopic 30° 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, which are some of the earliest manifestations of diabetic retinopathy.

Digital Imaging

While 7-field fundus photography with evaluation by a skilled examiner has high sensitivity for diabetic retinopathy detection, its time-consuming nature limits its value as a screening tool. As a result, the use of digital image acquisition, with evaluation of images by an ophthalmologist who may or may not be co-located with the patient, has been evaluated for screening.

The efficacy of diabetic retinopathy detection with digital image acquisition, compared with film-based acquisition, has been reported by several investigators.

In 2015, Shi et al reported a systematic review and meta-analysis of studies that compared telemedicine (digital image acquisition) with 7-field fundus photography for the detection of diabetic retinopathy or DME. Twenty studies (total N=1960 patients) were included in the qualitative analysis; however, because 4 studies had the same primary author and reported on the same patient population, only 1 was included, leaving 17 studies for inclusion in the meta-analysis. Studies varied in the specific digital photography techniques used, the number of fields evaluated, the use of stereoscopic versus monoscopic imaging, and the use of mydriatic versus nonmydriatic techniques. In pooled analysis, the sensitivity of digital imaging with telemedicine ophthalmologic evaluation for various diabetic retinopathy states (presence/absence of diabetic retinopathy, mild, moderate, or severe nonproliferative diabetic retinopathy, high- and low-risk PDR, DME, and clinically significant macular edema) was greater than 70%, except for the detection of severe nonproliferative diabetic retinopathy (sensitivity, 53%; 95% confidence interval [CI], 45% to 62%). In pooled analysis, the specificity of digital imaging for various diabetic retinopathy states was greater than 90%, except for the detection of mild nonproliferative diabetic retinopathy (specificity, 89%; 95% CI, 88% to 91%). Summary receiver operating characteristic curves showed an area under the curve of greater than 0.9 for the detection of diabetic retinopathy and DME, across a range of severity.

One 2015 randomized clinical trial (RCT) was identified; it compared the effectiveness of a telemedicine screening program for diabetic retinopathy to traditional surveillance with an eye care professional. The trial

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randomized 567 adults with diabetes to a telemedicine program (n=296) or traditional surveillance (n=271). After 2 years of enrollment, those randomized to the traditional surveillance program were offered the opportunity to cross over to telemedicine screening. The telemedicine photography protocol involved the capture of 6 undilated 45° fundus photographs of each eye, with grading of the retinal images by 2 investigators into 5 categories of retinopathy and for the presence of DME. At 0- to 6-month follow-ups, those randomized to the telemedicine program were more likely to undergo retinopathy screening (94.6%) compared with those randomized to traditional surveillance (43.9%; risk difference [RD], 50.7%; 95% CI, 46.6% to 54.8%; p<0.001). There was also a significant difference in screening rates at 6- to 18-month follow-ups—53.0% in the telemedicine group and 33.2% in the traditional screening group (RD=19.8%; 95% CI, 16.5% to 23.1%; p<0.001). Beyond 18 months, when telemedicine was offered to all participants, there were no significant differences in screening rates between the groups. Throughout follow-up, most subjects (>90%) had a diabetic retinopathy stage within ± 1 unit of their baseline stage.

Examples of individual studies that have reported on the diagnostic accuracy of digital image acquisition include those by Liesenfeld et al (2000) and Tennant et al (2001), both of which collectively found high correlations between diabetic retinopathy diagnoses made by slit-lamp biomicroscopy performed by an ophthalmologist and by 7-field 35-mm photography. Fransen et al (2002) published comparative results of standard evaluations using film and the same fields captured and transmitted as digital images. In their study of 290 adults with diabetes, the sensitivity of digital imaging compared with 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 with contact lens biomicroscopy, Rudnisky et al (2002) found a high level of agreement in the detection of clinically significant DME in diabetic patients.

Pupil Dilation

The 7-field fundus photography technique used in ETDRS, and in some of the studies of digital photography referenced above, used dilated pupils. However, screening using undilated pupils has advantages in terms of time, cost, and patient compliance. Thus, in addition to the examination technique and the comparison of different photographic techniques, the results of dilated (mydriatic) versus undilated (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 their study of 3611 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 by Bragge et al evaluated variations in qualifications of photographers and mydriatic status. Twenty studies were included that assessed 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 also selected. 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

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were grouped 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 as compared with the reference standard. Across all selected studies, in pooled analysis, the sensitivity and specificity for diabetic retinopathy detection were 82.5% (95% CI, 75.6% to 87.9%) and 88.4% (95% CI, 84.5% to 91.4%), respectively. In a multivariable logistic regression, variations in mydriatic status alone did not significantly influence sensitivity (odds ratio [OR], 0.89; 95% CI, 0.56 to 1.41) or specificity (OR=0.94; 95% CI, 0.57 to 1.54). Variations in medical qualifications of photographers did not significantly influence sensitivity (OR=1.25; 95% CI, 0.31 to 5.12), 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 (95% CI, 1.78 to 8.37) 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 seen with nonspecialist photographers could lead to increased referrals to an eye care specialist for further examination in some patients without diabetic retinopathy. This finding might be biased, because 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.

Since publication of the Bragge systematic review, Rasmussen et al (2015) compared the concordance of diabetic retinopathy screening results obtained with ETDRS 7-field fundus photography with those obtained from single-image mydriatic wide field photography, nonmydriatic wide field photography, and mydriatic steered photography among 95 diabetic patients. Agreement within 1 level of retinopathy occurred in 99% of cases ($\kappa=0.98$; 95% CI, 0.97 to 0.99). Exact agreement between the nonmydriatic wide field photography and the 7-field fundus photography occurred in 76.3% of cases ($\kappa=0.71$; 95% CI, 0.63 to 0.78).

There is some evidence that retinal images from nonmydriatic cameras are more likely to be ungradable. Included in the 2011 Bragge review was a 2004 study by Murgatroyd et al that evaluated digital image screening with a nonmydriatic camera in 398 patients (794 eyes). Mydriasis was found to reduce the proportion of ungradable photographs from 26% to 5% ($p<0.001$). 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). Because 64% of patients had gradable images, the authors suggested the possibility of targeted mydriasis or dilating only those patients who fail initial undilated photography. In 2014, Mizrahi et al reported on a retrospective study of 6962 consecutive patients who underwent nonmydriatic digital imaging at community health centers. Although the photographer had viewed each image immediately and retaken the photograph if the original image was considered of insufficient quality, a final 85.6% of the photographs were of adequate quality for a diagnosis of diabetic retinopathy. Patients younger than 70 years of age had a greater chance of having good-quality images (93.7%) than patients older than 70 years (73.1%; $p<0.001$). In a random sample of 362 patients from the larger cohort of 6962 patients, comparison of nonmydriatic digital photographs with the reference standard

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(mydriatic retinal exams by an ophthalmologist) showed a sensitivity of 99.3%, specificity of 88.3%, and positive predictive value of 85.3%.

Section Summary: Optometrist or Ophthalmologist Image Interpretation

Data from multiple observational studies and 1 RCT have demonstrated that there is high concordance between direct ophthalmoscopy and grading by telescreening. Given findings from ETDRS that early retinopathy treatment improves outcomes, a strong chain of evidence can be made that telescreening is associated with improved health outcomes.

AUTOMATED IMAGE INTERPRETATION

The telemedicine screening programs using digital images (described above) rely on image interpretation by a trained ophthalmologist. A number of automated scoring systems are being evaluated for diabetic retinopathy screening. Many of the relevant studies have involved retrospective analyses of established datasets. The studies are described briefly below, and their diagnostic characteristics summarized in Table 1.

In 2011, Sanchez et al examined the accuracy of a computer-aided diagnosis system to diagnose diabetic retinopathy using a publicly available dataset of 1200 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, 94.5% and 91.2%; specificity, 50%). Fifty-one abnormal images were wrongly classified as normal.

Oliveira et al (2011) assessed the accuracy of another automated screening system (RetmarkerSR) in a study of nonmydriatic images from 5386 patients in a diabetic retinopathy screening program. Automated analysis classified 47.5% as having no disease and 52.5% as having disease (confidence intervals not reported). A 2-step approach, in which patients marked as diseased on the first screen had a second screening visit, improved specificity to 63.2% (95% CI, 60.8% to 65.7%) with no loss of sensitivity. The sample in this study was biased, because it did not include another 9.5% of images that a grader had identified as being of poor quality. The omission of these cases could have led to an erroneously high estimate of accuracy.

The Iowa Detection Program (IDP), an automated screening system, uses standardized algorithms to detect various retinal findings. This system was evaluated with a publicly available sample of digital color photographs from 1748 eyes (874 patients with diabetes) who were at risk for diabetic retinopathy. The photographs were taken in primary care diabetic retinopathy clinics from 3 hospitals in France and then graded by 3 masked retinal specialists. The prevalence of referable diabetic retinopathy (more than mild nonproliferative retinopathy and/or macular edema) was 21.7% (95% CI, 19.0% to 24.5%). The diagnostic characteristics of the IDP, compared with expert consensus standard, are summarized in Table 1. The area under the receiver operating curve was 0.937.

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In 2016, the same study group reporting on the algorithm evaluated a deep learning algorithm add-on to the IDP algorithm, using the same dataset as in their 2013 study. The updated diagnostic characteristics for referable diabetic retinopathy of the deep learning algorithm are summarized in Table 1.

Also in 2016 and 2017, Tufail et al reported on the screening performance of 4 automated retinal image analysis systems in a retrospective, observational study, which included 20,258 patients seen for diabetes eye screening, run by the National Health Service from 2012 to 2013. The manual images were graded by a team of 18 optometrists and nonoptometrists who had undergone prestudy training and evaluation. The automated scoring systems identified included EyeArt (Eyenuk, Woodland Hills, CA), Retmarker (Retmarker, Coimbra, Portugal), iGradingM (Medalytix Group, now EMIS UK, Leeds, England), and IDx-DR (IDx, Iowa City, IA). However, the iGradingM was determined to be unable to process disc-centered images, and IDx withdrew from the study, so details on their test performance are not discussed here further. The overall prevalence of referable diabetic retinopathy (defined as ungradable images, maculopathy, and preproliferative and proliferative retinopathy) was 2767 (13.7%) of 20,212. Compared with manual grading, referable diabetic retinopathy using the EyeArt and Retmarker systems was associated with likelihood ratios of 1.375 (95% CI, 1.354 to 1.4) and 1.63 (95% CI, 1.59 to 1.66), respectively. The sensitivities of automated test scoring for referable diabetic retinopathy, compared with manual image review, are summarized in Table 1.

Table 1: Detection of Referable Diabetic Retinopathy With Automated Screening

Study	N	Reference Standard	Sens (95% CI), %	Spec (95% CI), %	PPV (95% CI), %	NPV (95% CI), %
Sanchez et al (2011)	1200 patients	2 expert reviewers	92.2%	Set at 50%		
Oliveira et al (2011)	5386 patients	Experienced ophthalmologist	96.1% (94.4 to 97.8)	51.7% (50.3 to 53.1)		
Abramoff et al (2013)	1748 eyes	3 retina specialists	96.8% (94.4 to 99.3)	59.4% (55.7 to 63.0)	39.8% (35.2 to 44.3)	98.5% (97.4 to 99.7)
Abramoff et al (2016)	1748 eyes	3 retina specialists	96.8% (93.3 to 98.8)	87.0% (84.2 to 89.4)	67.4% (61.5 to 72.9)	99.0% (97.8 to 99.6)
Tufail et al (2016)	20,258 patients	Trained optometrist and nonoptometrist graders				
EyeArt			99.6% (97 to 99.9)			
Retmarker			85.0% (83.6 to 86.2)			

CI: confidence interval; NPV: negative predictive value; PPV: positive predictive value; Sens: sensitivity; Spec: specificity.

In 2015, Walton et al compared manual interpretation of nonmydriatic fundus images with the Intelligent Retinal Imaging System (IRIS), an automated computer algorithm–based interpretation system, in a large retrospective study of 15,015 individuals with diabetes who were a subset of 18,025 patients with fundus

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photographs obtained as part of a county screening program, an automated computer algorithm–based interpretation system, in the detection of sight-threatening diabetic eye disease (STDED; severe nonproliferative diabetic retinopathy or PDR). Compared with centralized manual interpretation, in the screening population, the IRIS algorithm had the following sensitivity, specificity, and positive and negative predictive values for STDED: 66.4% (95% CI, 62.8% to 69.9%), 72.8% (95% CI, 72.0% to 72.5%), 10.8% (95% CI, 9.6% to 11.9%), and 97.8% (95% CI, 96.8% to 98.6%), all respectively.

Section Summary: Automated Image Interpretation

The available studies on automated image interpretation have generally reported high sensitivity with moderate specificity, but with variability across studies, leading to uncertainty about the accuracy of automated scoring systems in practice.

SUMMARY OF EVIDENCE

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with optometrist or ophthalmologist image interpretation, the evidence includes retrospective studies comparing the accuracy of digital screening with standard methods, systematic reviews of these studies, and 1 RCT. Relevant outcomes include test accuracy and validity, change in disease status, and functional outcomes. A number of studies have reported on the agreement between direct ophthalmoscopy and photography and between standard film and digital imaging in terms of the presence and stage of retinopathy. The studies have generally found high levels of agreement between retinal examination and imaging. There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the large ETDRS that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in ETDRS and 1 RCT demonstrating higher uptake of screening with a telescreening strategy, a strong chain of evidence can be made that telescreening is associated with improved health outcomes. Digital imaging systems have the additional advantages of short examination time and the ability to perform the test in the primary care physician setting. For individuals who cannot or would not be able to access an eye care professional at the recommended screening intervals, the use of telescreening has low risk and is very likely to increase the likelihood of retinopathy detection. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have diabetes without known diabetic retinopathy who receive digital retinal imaging with automated image interpretation, the evidence includes retrospective studies comparing the accuracy of automated scoring of digital images with standard methods. Relevant outcomes include test accuracy and validity, change in disease status, and functional outcomes. The available studies have tended to report high sensitivity with moderate specificity, although there is variability across studies. In addition, available studies have reported on different automated interpretation systems. These scoring systems have potential to improve screening in the primary care setting. However, given the variability in test characteristics across different systems, there is uncertainty about the accuracy of automated scoring systems in practice. The evidence is insufficient to determine the effects of the technology on health outcomes.

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Policy History

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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 |
| 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. |
| 10/27/2005 | 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. |

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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.
12/04/2014	Medical Policy Committee review
12/17/2014	Medical Policy Implementation Committee approval. No change to coverage.
12/03/2015	Medical Policy Committee review
12/16/2015	Medical Policy Implementation Committee approval. No change to coverage.
12/01/2016	Medical Policy Committee review
12/21/2016	Medical Policy Implementation Committee approval. No change to coverage. Chart revised.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
12/07/2017	Medical Policy Committee review
12/20/2017	Medical Policy Implementation Committee approval. No change to coverage.
Next Scheduled Review Date:	12/2018

Coding

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Code Type	Code				
CPT	92228				
HCPCS	No codes				
ICD-10 Diagnosis	C92.01	C92.41	C92.51	C92.61	C92.A1
	E08.3211-E08.3299	E08.3311-E08.3399	E08.3411-E08.3499	E08.3511-E08.3599	E08.37X1-E08.37X9
	E09.3211-E09.3299	E09.3311-E09.3399	E09.3411-E09.3499	E09.3511-E09.3599	E09.37X1-E09.37X9
	E10.10-E10.29	E10.311-E10.319	E10.3211-E10.3299	E10.36-E10.39	E10.40-E10.49
	E10.51-E10.59	E10.610-E10.618	E10.620-E10.628	E10.630-E10.638	E10.641-E10.649
	E10.65-E10.69	E10.8	E11.00-E11.01	E11.21-E11.29	E11.311-E11.319
	E11.3311-E11.3399	E11.3411-E11.3499	E11.3511-E11.3599	E11.36-E11.39	E11.37X1-E11.37X9
	E11.40-E11.49	E11.51-E11.59	E11.610-E11.649	E11.65-E11.69	E11.8-E11.9
	E13.00-E13.319	E13.3211-E13.3299	E13.3311-E13.3399	E13.3411-E13.3499	E13.3511-E13.3599
	E13.36-E13.59	E13.37X1-E13.37X9	E13.610-E13.9		

*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. 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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