Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/25**
(See policy history boxes for previous effective dates)

Title: Retinal Care for Diabetic Retinopathy

Description/Background

Retinopathy telescreening and risk assessment with digital imaging systems are proposed as an alternative to conventional dilated fundus examination in diabetic individuals. 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. Captured digital images may be transmitted via the Internet to a remote center for interpretation by trained readers, storage, and subsequent comparison.

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 I and more than 60% of patients with Type II diabetes will have some degree of retinopathy.(1) 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 two 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 the 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 seven-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 production but are associated with serious adverse events including cataracts and glaucoma, with damage to the optic nerve. Corticosteroids can also worsen diabetes control. Vascular endothelial growth factor inhibitors (e.g., ranibizumab, bevacizumab, 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.

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 and has become the standard in major clinical trials. 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.

Artificial Intelligence Technology

Per the FDA news release (2018) early detection of retinopathy was emphasized as an important part of managing care for the millions of people with diabetes. However, 50% of diabetics are not adequately screened for diabetic retinopathy since they do not see their eye

doctor on a yearly basis. Artificial intelligence technology (e.g. IDx-DR) was designed to allow health care providers who may not normally be involved in eye care, to screen for diabetic retinopathy and refer accordingly during annual visits. IDx-DR is a software program that uses an artificial intelligence algorithm to analyze images of the eye taken with a retinal camera called the Topcon NW400. A doctor uploads the digital images of the patient's retinas to a cloud server on which IDx-DR software is installed. If the images are of sufficient quality, the software provides the doctor with one of two recommendations: (1) refer to an eye care professional or (2) rescreen in 12 months. IDx-DR should not be used in patients with diabetes who are pregnant. IDx-DR is only designed to detect diabetic retinopathy, including macular edema; it should not be used to detect any other disease or condition. Patients will still need to get a complete eye examination at the age of 40 and at the age of 60 and also if they have any vision symptoms (for example, persistent vision loss, blurred vision or floaters).(20)

Regulatory Status

Several digital camera and transmission systems (see Table 1 for examples) have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Digital image storage and data communication systems that are designed to be utilized with a variety of cameras have also been cleared for marketing by the FDA. FDA product codes: HKI and NFJ.

Many artificial intelligence analysis systems are in use around the world. As of February 2021, 2 have received marketing clearance from the FDA (Table 2). In 2018, the FDA gave De Novo clearance for an automated retinal analysis system (IDx-DR) that uses artificial intelligence (DEN180001). IDx-DR is indicated "for use by health care providers to automatically detect more than mild diabetic retinopathy in adults diagnosed with diabetes who have not been previously diagnosed with diabetic retinopathy. IDx-DR is indicated for use with the Topcon NW400." EyeArt retinal analysis software (Eyenuk) received marketing clearance through the FDA's 510(k) pathway in 2020. It is indicated for use with the Canon CR-2 AF and Canon CR-2 Plus AF cameras in both primary care and eye care settings. Use of automated retinal analysis of images obtained with other cameras would be considered off-label. FDA product code: PIB

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

Camera and Transmission Systems	Manufacturer	FDA Clearance	Approved
RetinaVue™ Network REF 901108 PACS Medical Image System	Welch Allyn	K181016	2018
IRIS Intelligent Retinal Imaging System™	Ora Inc.	K141922	2015
EyeSuite Imaging	Haag-Streit AG	K142423	2014
CenterVue Digital Retinography System (DRS)	Welch Allyn	K101935	2010
ImageNet™ Digital Imaging System	Topcon Medical Systems		2008
The Fundus AutoImagerä	Visual Pathways		2002
Zeiss FF450 Fundus Camera and the VISUPAC® Digital Imaging System	Carl Zeiss Meditec		2001
DigiScope®	Eye Tel Imaging with Johns Hopkins Medicine		1999

FDA: Food and Drug Administration

Table 2. Automated Analysis Systems

Automated Analysis Systems	Manufacturer	Clearance	Approved
IDx-DR Artificial Intelligence Analyzer for the Topcon NW400	IDx, LLC	FDA De Novo	2018
EyeArt™	Eyenuk™	CE	

CE: Conformite Europeenne; FDA: Food and Drug Administration

Medical Policy Statement

The safety and effectiveness of retinal telescreening with digital imaging and manual grading of images as a diagnostic screening technique and for the monitoring and management of diabetic retinopathy have been established.

The clinical utility of U.S. Food and Drug Administration approved digital retinal imaging with image interpretation by artificial intelligence software (e.g., IDX-DR, EyeArt) to screen for diabetic retinopathy has been established.

Retinal telescreening is considered experimental/investigational for all other indications.

Inclusionary and Exclusionary Guidelines

See MPS statement above

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

92227 92228 92229 92250

Other codes (investigational, not medically necessary, etc.):

N/A

Note: Established code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

OPTOMETRIST OR OPHTHALMOLOGIST IMAGE INTERPRETATION

Clinical Context and Test Purpose

The purpose of retinal telescreening with manual grading of images in patients who have diabetes is to inform a decision whether to refer to an ophthalmologist.

There is 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.

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.(2,3) A local acquisition/remote interpretation technique, with interpretation by skilled readers, was used to consistently detect and evaluate the retinal changes of participants in the study. ETDRS used mydriatic 30° stereoscopic color fundus 35-mm photographs of seven standard fields evaluated by a single reading center. 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. 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.

The following PICOs were used to select literature to inform this review.

Populations

The relevant population of interest are patients with diabetes who are undergoing screening for 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.

The diabetic retinopathy screening recommendations of the American Diabetes Association (2020) are provided in Table 3.(4)

Table 3. Retinopathy Screening Recommendations

Patient Group	First Retinal Examination	Follow-up
Adults with type I diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 y after onset of diabetes	Yearly
Type II diabetes	Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of diagnosis of diabetes	Yearly
Pregnancy in preexisting diabetes	Before pregnancy or in the first trimester	Every trimester and for one year postpartum as indicated by the degree of retinopathy

Interventions

The test being considered is digital retinal imaging with manual image interpretation.

Comparators

The following tests are currently being used to screen for diabetic retinopathy: dilated retinal fundus evaluation via ophthalmoscopy and 7-field fundus photography. Seven-field fundus

photography is considered the criterion standard for the detection of diabetic retinopathy and has sensitivity and specificity that is 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 seven-standard-field stereoscopic 30° fundus photography evaluated by trained readers.(5) Kinyoun et al (1992) found fair-to-good agreement between ophthalmoscopy and evaluation of seven-standard-field stereoscopic 30° 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, which are some of the earliest manifestations of diabetic retinopathy.

Outcomes

The general outcomes of interest are test validity, change in disease status, and functional outcomes. Tests should have sufficient sensitivity and specificity to detect retinopathy in order to facilitate early treatment and prevent a loss of visual function. When used as a screening tool with referral for further evaluation by an eye care specialist, detection of retinopathy (sensitivity) is the most critical feature for referral to an eye care specialist.

The beneficial outcome of a true positive test is the early detection of diabetic retinopathy with treatment and preservation of vision. The beneficial outcome of a true negative test is continued assurance with follow-up scheduled after 1 year.

A harmful outcome of a false positive test is unnecessary referral to an ophthalmologist. A harmful outcome of a false negative test is delay in treatment potentially resulting in vision loss.

Comparison with 7-field fundus photography would be immediate. A change in retinopathy can be observed over the period of a year, while a change in vision may occur over several years.

Study Selection Criteria

For the evaluation of clinical validity of the test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient clinical characteristics were described.

Review of Evidence

The efficacy of diabetic retinopathy detection with digital image acquisition, compared with 7-field fundus photography, has been evaluated in over 20 studies (total n=1960 patients) and summarized in a systematic review by Shi et al (2015).(7) In pooled analysis, the sensitivity of digital imaging with telemedicine ophthalmologic evaluation for various diabetic retinopathy states was greater than 70%. The pooled 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.

The 7-field fundus photography technique used in ETDRS, and in some of the studies of digital photography, used dilated pupils. However, screening using undilated pupils has advantages regarding time, cost, and patient compliance. Thus, in addition to the examination technique and the comparison of different photographic techniques, the results of dilated (mydriatic) vs undilated (nonmydriatic) fundus photography have been studied. Bragge et al (2011) conducted a meta-analysis to evaluate variations in qualifications of photographers and mydriatic status.(8) 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. 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).

One 2015 RCT compared the effectiveness of a telemedicine screening program for diabetic retinopathy with traditional surveillance with an eye care professional.(9) The trial 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. At 0- to 6-month follow-up, 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, 50.7%; 95% CI, 46.6% to 54.8%; p<0.001).

Section Summary: Optometrist or Ophthalmologist Image Interpretation
Data from systematic reviews have demonstrated that there is concordance between direct ophthalmoscopy and grading by mydriatic or non-mydriatic photography and remote evaluation. An RCT that compared a telemedicine screening program with traditional surveillance found that patients who were randomized to the telemedicine arm were more likely to undergo screening (95% vs 44%). There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the Early Treatment Diabetic Retinopathy Study that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in Early Treatment Diabetic Retinopathy Study, and a randomized controlled trial 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.

AUTOMATED IMAGE INTERPRETATION

Clinical Context and Test Purpose
Early detection of diabetic retinopathy is critical to vision preservation. The telemedicine screening programs (described above) rely on human grading. Screening for diabetic retinopathy using human grading is labor intensive and requires trained personnel. Because the prevalence of diabetes has doubled since 1980 and is expected to increase even more in the future, this creates an increasing demand for professionals who are trained to screen for diabetic retinopathy.

The purpose of digital retinal imaging with automated image interpretation in patients who have diabetes is to inform a decision whether to refer to an eye care specialist. The potential benefits of an automated screening system are to reduce the burden on eye care providers and increase the rate of screening for a population that is seeing substantially increased rates of diabetes prevalence, and who may not be fully compliant with annual screening recommendations. Automated annual screening at the same time as a routine diabetes check-up could reduce the burden on eye care providers, increase compliance with annual screening recommendations, and facilitate referral to eye care specialists for patients who have detectable diabetic retinopathy. A number of automated scoring systems are being evaluated for diabetic retinopathy screening.

The following PICOs were used to select literature to inform this review.

Populations

The relevant population of interest is patients with diabetes who are undergoing screening for 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.

The diabetic retinopathy screening recommendations of the American Diabetes Association (2020) are provided in Table 3.(4)

Interventions

The test being considered is digital retinal imaging with automated image interpretation. Algorithms for retinal imaging analysis are undergoing rapid evolution and the version of the software, which can change frequently, is important for evaluating performance characteristics.

In 2018, the U.S. Food and Drug Administration gave the first marketing clearance for an automated analysis system with artificial intelligence (IDx-DR) through the De Novo classification process. The IDx-DR was previously known as the Iowa Detection Program for Referable Diabetic Retinopathy.

EyeArt (Eyenuk) automated image interpretation software received marketing clearance in 2020. The EyeArt versions evaluated here are v2.0 and v2.1.0.

Both IDx-DR and EyeArt are indicated for use with specific retinal imaging cameras. Automated image interpretation systems are also being evaluated with mobile phone cameras.

Comparators

The following tests are currently being used to screen for diabetic retinopathy: dilated retinal fundus evaluation via ophthalmoscopy and 7-field fundus photography. Fundus photography with expert evaluation of images is considered the criterion standard for the detection of diabetic retinopathy. Telescreening with digital mydriatic or non-mydriatic photography and remote human grading of images is an accepted method of diabetic retinopathy screening. Standard telescreening is limited by the number of eye care specialists for a population that is seeing dramatic increases in rates of diabetes. Screening for diabetic retinopathy may also require a separate visit to an eye care specialist, which can impact compliance with the annual screening recommendations.

Outcomes
The general outcomes of interest are the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) to detect retinopathy in order to facilitate early treatment and prevent a loss of visual function. When used as a screening tool with referral for further evaluation, detection of retinopathy (sensitivity) is the most critical feature for referral to an eye care specialist.

The beneficial outcome of a true positive test is the early detection of diabetic retinopathy with treatment and preservation of vision. The beneficial outcome of a true negative test is assurance with scheduling follow-up for 1-year.

The harmful outcome of a false positive test is unnecessary referral to an ophthalmologist for further evaluation. The harmful outcome of a false negative test is delay in treatment potentially resulting in vision loss. Annual screening would limit the harms of false negatives as more severe and treatable retinopathy could be detected in subsequent years as the disease progresses.

Comparison with fundus photography and manual grading of images would be immediate. A change in retinopathy can be observed over the period of a year, while a change in vision would occur over several years.

Study Selection Criteria
For the evaluation of clinical validity of the test, studies that meet the following eligibility criteria were considered:

- Reported on the accuracy of the marketed version of the technology (including any algorithms used to calculate scores)
- Included a suitable reference standard
- Patient clinical characteristics were described.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Review of Evidence
Study characteristics and results are shown in Tables 4 and 5. Study limitations are described in Tables 6 and 7.

The pivotal study of the IDx-DR artificial intelligence (AI) image analysis system (DEN180001) was published by Abramoff et al (2018).(10) The reference standard was expert mydriatic photography and centralized reading of images. Performance thresholds for the FDA application were set at 85.0% for sensitivity and 82.5% for specificity. Nine hundred patients with diabetes and no history of diabetic retinopathy were enrolled at primary care centers. The study was enriched with patients who had elevated hemoglobin A1C in order to increase the likelihood of enrolling patients with more serious diabetic retinopathy. The primary care staff received 4 hours of training in image capture and use of the system. The system includes an image quality algorithm, which recommended pupil dilation in 23.6% of patients when 3 attempts at nonmydriatic image capture had failed. Compared to expert mydriatic photography and centralized image assessment, the AI system had sensitivity of

87.2%, specificity of 90.7%, PPV of 74.9% and NPV of 95.7% (see Table 5). Enrichment corrected sensitivity and specificity calculated similar diagnostic performance if the study population had not been enriched with subjects with higher hemoglobin A1C levels.

The pivotal study for the EyeArt 2.1.0 artificial intelligence imaging system (NCT03112005) was reported in the summary of the 510(k) application to the U.S. Food and Drug Administration.(11) In addition to 235 participants who were sequentially enrolled (described in more detail in the Tables below), an enriched cohort of 420 participants was studied. Participants were seen in either a primary care setting or an ophthalmology setting. Initial 2-field non-mydriatic images were automatically analyzed by EyeArt, which notified the operator if the image was not gradable in order to retake images. Imageability on the first attempt ranged from 83.5% to 94.2%. This was then followed with a reference standard of mydriatic 4-wide field images that were graded at a centralized reading facility. For the non-enriched cohort, prevalence of more than mild diabetic retinopathy was present in 12.2% of patients seen in primary care and 10.5% of patients seen by ophthalmologists. Sensitivity for more than mild diabetic retinopathy was 100% among primary care providers and 92.5% by ophthalmologists. Specificity was 88.5% among primary care providers and 85.7% for ophthalmologists. For the enriched cohort of 335 patients seen in primary care, disease prevalence was 15.5%, with sensitivity of 92.9%, and specificity of 85.6%. For the enriched cohort seen in ophthalmology practices, disease prevalence was 19.4% with sensitivity of 96.6% and specificity of 85.2% to detect more than mild diabetic retinopathy. Full results from the EyeArt 2.1.0 pivotal study were published in 2021 and confirmed the accuracy of the system to detect both more-than-mild diabetic retinopathy (sensitivity 95.5%; 95% CI, 92.4% to 98.5%; specificity 85.0%; 95%CI, 82.6% to 87.4%) and vision-threatening diabetic retinopahy (sensitivity 95.1%; 95% CI, 90.1% to 100%; specificity 89.0%; 95% CI, 87.0% to 91.1%) without dilation.(12)

Publication of the pivotal study was preceded by a non-concurrent study by Bhaskaranand et al (2019) of the diagnostic accuracy of EyeArt v2.0 in a real world setting.(13) Several of the authors are co-inventors of the technology and employees of Eyenuk, Inc. The REtrospective Validation of Eyeart in the REal world (REVERE) study assessed the EyeArt system v2.0 in previously obtained images from 107,001 consecutive diabetic patient visits from the EyePACS telescreening program. Patients had undergone telescreening at 404 primary care sites from 2014 to 2015. Notably, the fundoscopic images were taken with a variety of cameras, could be either mydriatic or non-mydriatic, and were not the same as the images that the artificial intelligence system had been trained on. The images that had been stored by the EyePACs program were uploaded and regraded by EyeArt v2.0 into referable or non-referable, with results compared with the original telescreening grades from the certified trained optometrist and ophthalmologist readers from EyePACs. Compared to the trained readers, the EyeArt system had sensitivity of 91.3% and specificity of 91.1%. Of the 1803 false negatives encounters, 95.4% did not meet general treatment criteria because they had moderate non-proliferative diabetic retinopathy. A subset of 192 patient encounters was randomly selected to be re-graded by a retina specialist. In this subset, the EyeArt system had a 95.1% sensitivity for referable DR and a 98.3% specificity. The sensitivity for potentially treatable diabetic retinopathy was 98.5%.

Heydon et al (2020) reported a prospective independent evaluation of the EyeArt v2.1.0 analysis system in over 30,000 patients from the English Diabetic Eye Screening Programme.(14) The purpose of the study was to assess the utility of the automated analysis

system as a screening tool when used in conjunction with human graders. The cameras used and the graders differed between the 3 sites. Images that had been previously scored by human graders were submitted for analysis by EyeArt and classified as referable (positive n=15,091) or non-referable (negative n=15,314). Images that were ungradable by EyeArt were considered referable for further evaluation. Overall, sensitivity and specificity were 95.7% and 54.0%, respectively. EyeArt classified for referral (positive) all cases that had been graded as moderate-to-severe retinopathy by human graders (sensitivity of 100%) but would not have referred 78 (10.6%) of the 739 images that were considered ungradable by the human graders. The number of false positives was high, but it was estimated that when used as a primary screening tool the software could reduce the workload of first level human graders by half.

Lee et al (2021) evaluated diagnostic accuracy to detect referable retinopathy with 7 different artificial intelligence algorithms in a sample of over 26,000 patients from 2 Veteran Affairs Health Systems.(15) The same camera (Topcon TRC-NW8) was used for all images, but the centers differed on whether the images were mydriatic or non-mydriatic. Over 16% of non-mydriatic images were ungradable compared to 2.5% of mydriatic images. For the analysis, 5 manufacturers (OpthAI, AirDoc, Eyenuk, RetinaAI Health, Retmarker) provided their locked software preloaded on a workstation; the software was identified only by letters A to G. All artificial intelligence algorithms were used clinically across the world, and 1 (EyeArt by Ayenuk) was cleared by the FDA for marketing at the time of the study. Across the 7 algorithms, sensitivity ranged from 50.98% to 85.90%, and specificity ranged from 60.42% to 83.69%, indicating that each marketed software needs to be evaluated separately. Only one of the algorithms had diagnostic performance equal to the human teleretinal graders.

Use of the EyeArt image analysis software was also tested in a study of 69 patients from a retina clinic who were screened using a smartphone-based camera (RetinaScope) by non-ophthalmic personnel.(16) Compared to the gold standard evaluation by a retina specialist, automated interpretation of images had a sensitivity of 87.0% and specificity of 78.6%; grader 1 had a sensitivity of 96.3% and specificity of 42.9%; grader 2 had a sensitivity of 92.5% and specificity of 50.0%. Further study in a larger, more diverse, sample is needed.

Table 4. Study Characteristics of Clinical Validity

Study	Study Population	Design	Reference Standard	Threshold for Positive Index Test	Timing of Reference	Blinding of Assessors	Comment
Abramoff et al (2018)	900 patients with diabetes and no history of DR seen at primary care sites	Multicenter prospective non-inferiority design with intent-to-screen	Expert Mydriatic photography and centralized image assessment	Diagnostic algorithm based on multiple detectors	Not specifically stated but images appear to be taken at the same time	Yes	23.6% required pupil dilation for adequate image quality
Bhaskaranand et al (2019)	107,001 consecutive patient encounters from prior telescreening for DR	Non-concurrent analysis with EyeArt v2.0 on stored images	Original retinal grades with a subset graded by retina specialists	Any level of referable retinopathy	Previously scored images were analyzed within 45 hours	Yes	Images could be mydriatic or non-mydriatic.
EyeArt 510(k) Summary (2020)	Sequential enrollment of 45 patients seen in primary care and 180 seen in	Multicenter prospective concurrent with EyeArt 2.1.0	Centralized evaluation of mydriatic 4-wide field images	More than mild retinopathy from 2-field retinal photography (not dilated)	Mydriatic wide-field images were taken following the non-mydriatic 2-field images	Yes	Feedback given to operator if image quality is insufficient

	ophthalmology centers, and an enriched cohort						
Heydon et al (2020)	30,405 patients with diabetes who were seen in the English Diabetic Eye Screening Programme	Non-concurrent analysis with EyeArt 2.1.0 on stored images	Human graders according to a standard national protocol	Any level of referable retinopathy	Previously scored images for each center were analyzed on a single day	Yes	
Lee et al (2021)	Sampled from 26,436 patients from 2 VA systems undergoing routine diabetic retinopathy screening	Non-concurrent prospective analysis comparing 7 imaging algorithms	Original VA retinal grades and arbitrated blinded grading by retina specialists	Any level of referable retinopathy, including mild non-proliferative retinopathy	Previously stored images from 2006 to 2018	Yes	16.2% of non-mydriatic images were ungradable compared to 2.5% of mydriatic images (Topcon TRC-NW8 camera)

DR: diabetic retinopathy; VA: veteran affairs health systems

Table 5. Clinical Validity

Study	Initial N	Final N	Excluded Samples	Prevalence of Condition	Clinical Validity (95% Confidence Interval)			
					Sensitivity	Specificity	PPV	NPV
Abramoff et al (2018)	900	819	33 not evaluable by AI	24.2%	87.2% (81.8% to 91.2%)	90.7% (88.3% to 92.7%)	74.9% (NR)	95.7% (NR)
Bhaskaranand et al (2019)	107,001	107,001	None - all non-evaluable images were considered positive for referral		91.3% (90.9% to 91.7%)	91.1% (90.9% to 91.3%)	72.5% (71.9% to 73.0%)	97.6% (97.5% to 97.7%)
EyeArt 510(k) Summary (2020)	45 in primary care sites	45	4 ungradable included	12.2% (4.4% to 20.0%)	100% (75.1% to 100%)	88.5% (80.0% to 95.8%)	64.7% (40.0% to 86.7%)	100% (94.7% to 100.0%)
EyeArt 510(k) Summary (2020)	190 in ophthalmology sites	190	8 ungradable included	10.5% (6.6% to 15.0%)	92.5% (82.6% to 100%)	85.7% (80.9% to 89.7%)	45.7% (31.8% to 58.3%)	96.6% (94.1% to 98.6%)
Heydon et al (2020)	30,405	30,405	None - all non-evaluable images were considered positive for referral	462 (1.5%)	95.7% (94.8% to 96.5%)	54% (53.4% to 54.5%)		
Lee et al (2021)	26,436	23,724		14.79% to 29.95% with approx 1% severe DR	50.98% to 85.90%	60.42% to 83.69%	36.46% to 50.80%	82.72% to 93.69%

AI: artificial intelligence; NPV: negative predictive value; NR: not reported; PPV: positive predictive value.

Table 6. Relevance Limitations

Study	Population [a]	Intervention [b]	Comparator [c]	Outcomes [d]	Duration of Follow-up[e]
Abramoff et al (2018)	4. Study population was enriched for increased likelihood of more serious retinopathy, although sensitivity analysis for enrichment was performed.				

Bhaskaranand et al (2019)		2. Results were compared with trained readers. A small subset was compared with retina specialists.
EyeArt 510(k) Summary (2020)11,	2. It appears that repeat imaging may have been either mydriatic or non-mydriatic depending on the center.	
Heydon et al (2020)		1. No information was provided on the cameras used or whether they included mydriatic or non-mydriatic images.
Lee et al (2021)	2. Not all commercially available systems were able to be assessed. Those assessed were not identified.	

PPV: positive predictive value: NPV: negative predictive value
The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Population key: 1. Intended population unclear; 2. Clinical context is unclear; 3. Study population is unclear; 4. Study population not representative of intended use.
[b] Intervention key: 1. Classification thresholds not defined; 2. Version used unclear; 3. Not intervention of interest..
[c] Comparator key: 1. Classification thresholds not defined; 2. Not compared to credible reference standard; 3. Not compared to other tests in use for same purpose.
[d] Outcome key: 1. Study does not directly assess a key health outcome; 2. Evidence chain or decision model not explicated; 3. Key clinical validity outcomes not reported (sensitivity, specificity and predictive values); 4. Reclassification of diagnostic or risk categories not reported; 5. Adverse events of the test not described (excluding minor discomforts and inconvenience of venipuncture or noninvasive tests).
[e] Follow-Up key: 1. Follow-up duration not sufficient with respect to natural history of disease (true-positives, true-negatives, false-positives, false-negatives cannot be determined).

Table 7. Study Design and Conduct Limitations

Study	Selection[a]	Blinding[b]	Delivery of Test[c]	Selective Reporting[d]	Data Completeness[e]	Statistical[f]
Abramoff et al (2018)						1. confidence intervals for PPV and NPV not reported
Bhaskaranand et al (2019)			2. Automated analysis was performed on previously obtained images			
EyeArt 510(k) Summary (2020)						
Heydon et al (2020)			2. Automated analysis was performed on previously obtained images			
Lee et al (2021)			2. Automated analysis was performed on previously obtained images		1. Discrepancy between the abstract and text in the number of patients included	

PPV: positive predictive value: NPV: negative predictive value.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive limitations assessment.
[a] Selection key: 1. Selection not described; 2. Selection not random or consecutive (i.e., convenience).
[b] Blinding key: 1. Not blinded to results of reference or other comparator tests.
[c] Test Delivery key: 1.Timing of delivery of index or reference test not described; 2.Timing of index and comparator tests not same; 3. Procedure for interpreting tests not described; 4.Expertiseof evaluators not described.
d Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication.
[e] Data Completeness key: 1. Inadequate description of indeterminate and missing samples; 2.Highnumber of samples excluded; 3. High loss to follow-up or missing data.
[f] Statistical key: 1. Confidence intervals and/or p-values not reported; 2. Comparison to other tests not reported.

Clinically Useful

A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Review of Evidence

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from RCTs. No RCTs with automated image analysis systems were identified.

Chain of Evidence
Indirect evidence for clinical utility rests on clinical validity. When used for screening as an alternative to human graders with referral to eye care specialists for patients who screen positive, detection of retinopathy (sensitivity) is the most critical feature and is highest in patients who have treatable disease. For patients with moderate diabetic retinopathy who do not screen positive (false negatives), annual screening in subsequent years would allow the detection of treatable retinopathy as the disease progresses and mitigate potential harms. Automated annual screening at the same time as a routine diabetes check-up can improve health outcomes of patients with diabetes by increasing screening in accordance with the annual screening recommendation, thereby allowing earlier detection and treatment of diabetic retinopathy. A chain of evidence can be constructed based on the sensitivity of automated image analysis systems to detect more than mild diabetic retinopathy, referral to eye care specialists for patients who screen positive, and the established benefit of early treatment to reduce vision loss in patients with diabetes.

Section Summary: Automated Image Interpretation
Diagnostic performance of 7 artificial intelligence image analysis systems was evaluated in a large cohort of patients who had been screened for diabetic retinopathy in the U.S. Veteran Administration Healthcare System. Across the 7 algorithms, sensitivity ranged from 50.98% to 85.90% and specificity ranged from 60.42% to 83.69%, indicating that each marketed software needs to be evaluated separately, in a diverse population, and with the specific camera and use of dilation specified. The version of the software, which can change frequently, will also be key to evaluating performance characteristics. Two automated artificial intelligence system for evaluating diabetic retinopathy in primary care have received DeNovo or 510(k) marketing clearance from the U.S. Food and Drug Administration. The pivotal study for the IDx-DR system met its predefined threshold (85.0% for sensitivity and 82.5% for specificity) when compared to the criterion standard of expert photography and image evaluation from a centralized site with sensitivity of 87.2% and specificity of 90.7%. EyeArt version 2.0 and 2.1.0 automated artificial intelligence system have been evaluated in a prospective pivotal study and 2 large non-concurrent trials (30,000 and 100,00 encounters) that analyzed images from prior screenings for diabetic retinopathy. Sensitivity ranged from 91% to 100% and specificity ranged from 54% to 91% when compared to trained human graders. However, a chain of evidence can be constructed based on the sensitivity of automated image analysis systems to detect more than mild diabetic retinopathy, referral to eye care specialists for patients who screen positive, and the established benefit of early treatment to reduce vision loss in patients with diabetes. Automated annual screening at the same time as a routine diabetes check-up

can improve health outcomes of patients with diabetes by increasing screening in accordance with the annual screening recommendation, thereby allowing earlier detection and treatment of diabetic retinopathy.

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 systematic reviews and a randomized controlled trial. Relevant outcomes include test validity, change in disease status, and functional outcomes. Data from systematic reviews have demonstrated that there is concordance between direct ophthalmoscopy and grading by mydriatic or non-mydriatic photography and remote evaluation. An RCT that compared a telemedicine screening program with traditional surveillance found that patients who were randomized to the telemedicine arm were more likely to undergo screening (95% vs 44%). There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given evidence from the Early Treatment Diabetic Retinopathy Study that early retinopathy treatment improves outcomes, coupled with studies showing high concordance between the screening methods used in Early Treatment Diabetic Retinopathy Study, and a randomized controlled trial 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 studies comparing the validity of automated scoring of digital images to human image grading. Relevant outcomes include test validity, change in disease status, and functional outcomes. Early detection of diabetic retinopathy is critical to vision preservation. The primary benefit of an automated screening system is to reduce the burden on eye care providers and increase the rate of screening for a population that is seeing substantially increased rates of diabetes. A 2021 study found wide variability in diagnostic performance across 7 different artificial intelligence algorithms, indicating that each marketed software needs to be evaluated separately, in a diverse population, and with the specific camera and dilation specified. The version of the software, which can change frequently, is also key to evaluating performance characteristics. The pivotal study for the IDx-DR system met its predefined threshold when compared to the criterion standard of expert photography and image evaluation from a centralized site. The EyeArt versions 2.0 and 2.1.0 artificial intelligence software have been evaluated in a prospective pivotal trial and 2 large non-concurrent trials (30,000 and 100,000 encounters) in patients who had previously been screened as part of diabetic retinopathy screening programs. When used as an alternative to human grading, the sensitivity to detect diabetic retinopathy was above 90%. Detection of retinopathy (sensitivity) is the most critical feature for referral to an eye care specialist and is highest in patients who have treatable disease. Annual screening would detect retinopathy as the disease progresses, mitigating the impact of false negatives. Automated annual screening at the same time as a routine diabetes check-up will improve health outcomes of patients with diabetes by increasing the rate of

screening in accordance with the annual screening recommendation, thereby allowing earlier detection and treatment of diabetic retinopathy. This method minimizes delays in screening patients with diabetes, reduces strains on a limited resource of eye care specialists, and encourages referral to specialists for patients who screen positive for retinopathy. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Ophthalmology
A 2019 Preferred Practice pattern from the American Academy of Ophthalmology has provided the following on screening for diabetic retinopathy: “The purpose of an effective screening program for diabetic retinopathy is to determine who needs to be referred to an ophthalmologist for close follow-up and possible treatment and who may simply be screened annually. Some studies have shown that screening programs using digital retinal images taken with or without dilation may enable early detection of diabetic retinopathy along with an appropriate referral.”(17)

American Diabetes Association
In 2020 the American Diabetes Association (ADA) updated its position statement on standards of medical care in diabetes.(4) Included in the guidelines were specific recommendations for initial and subsequent screening examinations for retinopathy.

- "Adults with type I diabetes should have an initial eye examination by an ophthalmologist or optometrist within five years after the onset of diabetes. (B)"
- "Patients with type II diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of the diabetes diagnosis. (B)"
- "Eye examinations should occur before pregnancy or in the first trimester in patients with preexisting type I or type II diabetes, and then these patients should be monitored every trimester and for one year postpartum as indicated by the degree of retinopathy. (B)"
- "If there is no evidence of retinopathy for one or more annual eye exams and glycemia is well controlled, then screening every 1–2 years may be considered. (B)"
- "Programs that use retinal photography (with remote reading or use of a validated assessment tool) to improve access to diabetic retinopathy screening can be appropriate screening strategies for diabetic retinopathy. Such programs need to provide pathways for timely referral for a comprehensive eye examination when indicated. (B)"

"Artificial intelligence systems that detect more than mild diabetic retinopathy and diabetic macular edema authorized for use by the FDA represent an alternative to traditional screening approaches. However, the benefits and optimal utilization of this type of screening have yet to be fully determined."

The American Diabetic Association noted that "Retinal photography, with remote reading by experts, has great potential to provide screening services in areas where qualified eye care professionals are not readily available."

American Telemedicine Association

The American Telemedicine Association (2020) published guidelines on the clinical, technical, and operational performance standards for ocular telehealth for diabetic retinopathy.(18) Recommendations were based on reviews of evidence, medical literature, professional consensus, and a review that included open public comment. The guidelines state that Early Treatment Diabetic Retinopathy Study 30°, stereo 7-standard field, color 35-mm slides have been the gold standard for evaluating diabetic retinopathy, but with the migration away from film photography, digital retinal images have become the norm for major clinical trials. ATA recommends that telehealth programs for diabetic retinopathy should demonstrate an ability to compare favorably with Early Treatment Diabetic Retinopathy Study film or digital photography as reflected in κ values for agreement of diagnosis, false-positive and false-negative readings, positive predictive value, negative predictive value, sensitivity and specificity of referral thresholds.

The ATA notes limitations in sensitivity and specificity of smartphone platforms with a lack of standardization and a short product life cycle that create significant operational issues. Portable handheld imaging devices may suffer from some of the same limitations. ATA considers computer algorithms to enhance digital retinal image quality or provide automated identification of retinal pathology to be emerging technologies.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 8.

Table 8. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT04699864[a]	The Use of Artificial Intelligence in the Early Detection and the Follow-Up of Diabetic Retinopathy of Diabetic Patients Followed at the CHUM: Evaluation of NeoRetina Automated Algorithm (DIAGNOS Inc.)	630	Dec 2026
NCT03076697	Smartphone Screening for Eye Diseases	550	Aug 2028
Unpublished			
NCT04612868[a]	Pivotal Prospective Clinical Trial to Demonstrate the Efficacy and Safety of AEYE-DS Software Device for Automated Diabetic Retinopathy Detection From Digital Fundoscopic Images	350	Dec 2021
NCT04732208	Validation of an Artificial Intelligence Model for Diabetic Retinopathy Screening Using a Smartphone-based Fundus Camera in the UK Population	410	Aug 2022

NCT: national clinical trial.
[a] Industry sponsored or co-sponsored trial.

Government Regulations National:

There is no National Coverage Determination for retinal telescreening.

There is an NCD on intraocular photography with an effective date of 1979, which states:(19)

> "Intraocular photography is covered when used for the diagnosis of such conditions as macular degeneration, retinal neoplasms, choroid disturbances and diabetic retinopathy, or to identify glaucoma, multiple sclerosis and other central nervous system abnormalities. Make Medicare payment for the use of this procedure by an ophthalmologist [sic] in these situations when it is reasonable and necessary for the individual patient to receive these services."

Local:

There is a retired Local Coverage Determination (L32787), "Posterior Segment Imaging (Extended Ophthalmoscopy and Fundus Photography)" **retired July 2013,** states the following:

- Fundus photography (CPT codes 92250 and 92228) are bilateral services on the Medicare Physician Fee Schedule Data Base. Services performed unilaterally are subject to a reduction in fee.
- Fundus photography is not a substitute for an annual dilated examination by a qualified professional (e.g., in diabetic patients). Fundus photographs taken by a non-eye professional and sent (trans-telephonically, via internet, or by other means) to a qualified professional for interpretation are covered for the monitoring and management of active retina disease. The interpretation of tests done with remote imaging must be performed by a physician or qualified non-physician practitioner.
- Remote imaging for detection of retina disease (CPT code 92227) is considered screening and will be denied as noncovered.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Ophthalmologic Techniques for Evaluating Glaucoma
Optical Coherence Tomography Imaging, Anterior Eye
Telemedicine Services

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through July 31, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
9/1/11	6/21/11	6/21/11	Joint policy established
9/1/12	6/12/12	6/19/12	Routine maintenance
11/1/13	8/20/13	9/3/13	Routine maintenance; removed Inclusion/Exclusion pertaining to pupil dilation requirement; updated references and rationale.
3/1/15	12/12/14	12/29/14	Routine maintenance; adopted BCBSA's policy text; title changed from "Diabetic Retinal Telescreening" to current title; no change in policy position; references updated.
7/1/16	4/19/16	4/19/16	• Routine maintenance • Updated references • Denied for retirement
11/1/16	8/16/16	8/16/16	• Routine maintenance • Code update • Inclusions and exclusions are based on BCBSA policy but include part of the rationale r/t "Study seven-standard fields (DRS7)" (continuation from prior JUMP policies)
11/1/17	8/15/17	8/15/17	Routine maintenance
11/1/18	8/21/18	8/21/18	Routine maintenance
11/1/19	8/20/19		Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance

1/1/22	10/19/21		• Artificial intelligence software added as EST for the detection of diabetic retinopathy • 92229 added (EST) • Title changed from: Retinal Telescreening for Diabetic Retinopathy • Clarification of “automated” systems for telescreening
1/1/23	10/18/22		• Routine maintenance (slp)
1/1/24	10/17/23		• Routine maintenance (slp) • Vendor managed: N/A
1/1/25	10/15/24		• Routine maintenance (slp) • Vendor managed: N/A

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: RETINAL CARE FOR DIABETIC RETINOPATHY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria apply
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.