Retinal Telescreening for Diabetic Retinopathy

Policy # 00026
Original Effective Date: 08/25/2003
Current Effective Date: 12/21/2016

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

<table>
<thead>
<tr>
<th>Patient Group</th>
<th>First Retinal Examination</th>
<th>Follow-Up</th>
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<tbody>
<tr>
<td>Adults with type 1 diabetes</td>
<td>Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within 5 y after the onset of diabetes</td>
<td>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.</td>
</tr>
<tr>
<td>Type 2 diabetes</td>
<td>Initial dilated and comprehensive eye examination by an ophthalmologist or optometrist at the time of diagnosis of diabetes</td>
<td>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.</td>
</tr>
<tr>
<td>Before pregnancy in preexisting diabetes</td>
<td>Before pregnancy or early in the first trimester of pregnancy</td>
<td>Every trimester throughout pregnancy and for 1 y postpartum</td>
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</table>

*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 greater than 60% of patients with type 2 diabetes will have some degree of retinopathy. Other important risk factors include hypertension and elevated serum lipid levels.
Diabetic retinopathy progresses, at varying rates, from asymptomatic, mild nonproliferative abnormalities to proliferative diabetic retinopathy (PDR), with new blood vessel growth on the retina and posterior surface of the vitreous. The 2 most serious complications for vision are diabetic macular edema and PDR. At its earliest stage (nonproliferative retinopathy), the retina develops microaneurysms, intraretinal hemorrhages, and focal areas of retinal ischemia. With disruption of the blood-retinal barrier, macular retinal vessels become permeable, leading to exudation of serous fluid and lipids into the macula (macular edema). As the disease progresses, blood vessels that provide nourishment to the retina are blocked, triggering the growth of new and fragile blood vessels (proliferative retinopathy). The new blood vessels that occur in PDR may fibrose and contract, resulting in tractional retinal detachments with significant vision loss. Severe vision loss with proliferative retinopathy arises from vitreous hemorrhage. Moderate vision loss can also arise from macular edema (fluid accumulating in the center of the macula) during the proliferative or nonproliferative stages of the disease. Although proliferative disease is the main blinding complication of diabetic retinopathy, macular edema is more frequent and is the leading cause of moderate vision loss in people with diabetes.

**Diabetic Retinopathy Screening**

The value of screening is well established, because diabetic retinopathy has few visual or ocular symptoms until vision loss develops. With early detection, diabetic retinopathy can be treated with modalities that can decrease the risk of severe vision loss. Tight glycemic and blood pressure control is the first line of treatment to control diabetic retinopathy, followed by laser photocoagulation for patients whose retinopathy is approaching the high-risk stage. Although laser photoacoagulation is effective at slowing the progression of retinopathy and reducing visual loss, it results in collateral damage to the retina and does not restore lost vision. Focal macular edema (characterized by leakage from discrete microaneurysms on fluorescein angiography) may be treated with focal laser photocoagulation, while diffuse macular edema (characterized by generalized macular edema on fluorescein angiography) may be treated with grid laser photocoagulation. Corticosteroids may reduce vascular permeability and inhibit vascular endothelial growth factor (VEGF) production but are associated with serious adverse effects including cataracts and glaucoma with damage to the optic nerve. Corticosteroids also can worsen diabetes control. VEGF inhibitors (eg, 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.

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

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

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
Several digital camera and transmission systems have been cleared for marketing by the U.S. FDA through the 510(k) process and are currently available (product codes: HKI and NFJ). Examples include:

- IRIS Intelligent Retinal Imaging System™ (Ora Inc., Andover, MA)
- The Diabetic Retinopathy Digital Disease Detection and Tracking System (now called iScan™; Inoveon, Oklahoma City, OK)
- DigiScope® (Eye Tel Imaging, Columbia, MD) in conjunction with the Wilmer Eye Institute at Johns Hopkins Medicine
- The Fundus AutoImager® (Visual Pathways, Prescott, AZ)
- ImageNet™ Digital Imaging System (Topcon Medical Systems, Paramus, NJ)
- Zeiss FF450 Fundus Camera and the VISUPAC® Digital Imaging System (Carl Zeiss Meditec, Dublin, CA).

Centers for Medicare and Medicaid Services (CMS)
There is no national coverage determination.

Rationale/Source
7-Field Fundus Photography
Seven-field fundus photography is an established technique as a screening method for diabetic retinopathy.

The benefit of early treatment of diabetic retinopathy was established in the large Early Treatment Diabetic Retinopathy Study (ETDRS) supported by the National Eye Institute (NEI). Local acquisition/remote interpretation technique, with interpretation by skilled readers, was used to consistently detect and evaluate the retinal changes of participants in the study. ETDRS used mydriatic 30-degree stereoscopic color fundus 35-mm photographs of 7 standard fields evaluated by a single reading center.

Seven-field fundus photography is considered to be 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 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 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, some of the earliest changes of diabetic retinopathy. Delori et al reported more accurate visualization and documentation of the structures of the ocular fundus when using monochromatic illumination (red-free green light), compared with the white light used to obtain color photographs.

**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 for screening. 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 diabetic macular edema. 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 of these was included, leaving 17 studies for inclusion in the meta-analysis. Studies varied in the specific digital photography techniques used; there was variability in the number of fields evaluated, the use of stereoscopic versus monoscopic imaging, and the use of mydriatic versus non mydriatic 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 proliferative diabetic retinopathy, diabetic macular edema, 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 (ROC) curves showed an area under the curve (AUC) of greater than 0.9 for the detection of diabetic retinopathy and diabetic macular edema, across a range of severity.

Examples of individual studies that report on the diagnostic accuracy of digital image acquisition include those by Liesenfeld et al (2000) and Tennant et al (2001), which report high correlation between diabetic retinopathy diagnoses made by slit-lamp biomicroscopy performed by an ophthalmologist or by 7-field 35-mm photography, respectively. Fransen et al published the results of a comparison of standard evaluations using film to the same fields captured and transmitted as digital images. In a study of 290 adult diabetic patients, 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 found a high level of agreement regarding the detection of clinically significant macular edema in diabetic patients.
One randomized clinical trial (RCT) was identified that evaluated the effectiveness of a telemedicine screening program for diabetic retinopathy compared with traditional surveillance with an eye care professional. The study randomized 567 adult patients 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 macular edema. At 0- to 6-month follow-up, those randomized to the telemedicine program were more likely to undergo retinopathy screening compared with those randomized to traditional surveillance: 94.6% versus 43.9% (risk difference, 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-up: 53.0% in the telemedicine group vs 33.2% in the traditional screening group (risk difference, 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 2 groups. Throughout follow-up, most subjects (greater than 90%) had a diabetic retinopathy stage within ±1 unit of their baseline stage.

**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 the 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 evaluated the accuracy of a diabetic retinopathy screening method that used photography- or examination-based retinopathy screening compared with a standard of either 7-field mydriatic photography or dilated fundal examination. Studies with film or digital cameras were included in the systematic review. Studies of automated analysis techniques and technologies were excluded because they were not considered current standard practice. For meta-analysis, 40 assessments of screening methods were 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 in comparison with the reference standard. Across all included 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 for OR, 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 may lead to increased referrals to an eye care specialist for further examination in some patients without diabetic retinopathy. This finding may 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 the publication of the Bragge systematic review, Rasmussen et al 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. Exact agreement between the nonmydriatic wide field photography and the 7-field fundus photography occurred in 76.3% of cases (κ=0.71; 95% CI, 0.63 to 0.78). However, agreement within 1 level of retinopathy occurred in 99% of cases (κ=0.98; 95% CI, 0.97 to 0.99).

There is some evidence that retinal images from nonmydriatic cameras are more likely to be ungradable. Included in the 2011 review by Bragge 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, Mizrachi 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 retook the photograph if the original image was considered to be 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 a good-quality image than patients older than 70 years (93.7% vs 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 of mydriatic retinal exams by an ophthalmologist showed sensitivity of 99.3%, specificity of 88.3%, and positive predictive value of 85.3%.

Automated Scoring
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. A 2011 publication examined the accuracy of 1 such approach, which used 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 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). When compared with an experienced ophthalmologist grader who graded 8.7% with referable retinopathy, the sensitivity was 96.1% (95% CI, 94.39% to 97.89%) and specificity was 51.7% (95% CI, 50.27% to 53.07%). 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, as it did not include another 9.5% of images that a grader had identified as being of poor quality. The omission of these cases may have led to a falsely high estimate of accuracy.

The Iowa Detection Program is an automated screening system that 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%). When compared with the expert consensus standard, the Iowa Detection Program had sensitivity of 96.8% (95% CI, 94.4% to 99.3%) and specificity of 59.4% (95% CI, 55.7% to 63.0%; there were 278 false-positive results). The positive predictive value was 39.8% (95% CI 35.2% to 44.3%) and the negative predictive value was 98.5% (95% CI, 97.4% to 99.7%). The area under the receiver operating curve was 0.937.

In a large retrospective study including 15,015 individuals with diabetes who were a subset of 18,025 patients with fundus photographs obtained as part of a county screening program, 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 the detection of sight-threatening diabetic eye disease (STDED; severe nonproliferative diabetic retinopathy or proliferative diabetic retinopathy). 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.

**Ongoing and Unpublished Clinical Trials**
A search of ClinicalTrials.gov in March 2016 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**
The evidence for digital retinal photography with optometrist or ophthalmologist image interpretation for individuals who have diabetes without known diabetic retinopathy includes retrospective studies reporting on the accuracy of digital screening compared with standard methods, systematic reviews of these studies, and 1 RCT. Relevant outcomes include test accuracy, test 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 generally found a high level of agreement between retinal examination and
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imaging. There is limited direct evidence related to visual outcomes for patients evaluated with a strategy of retinal telescreening. However, given the 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for digital retinal photography with automated image interpretation for individuals who have diabetes without known diabetic retinopathy includes retrospective studies reporting on the accuracy of automated scoring of digital images compared with standard methods. Relevant outcomes include test accuracy, test validity, change in disease status, and functional outcomes. The available studies tend to report high sensitivity with moderate specificity, although there is variability across studies. In addition, the available studies report on a variety of 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.

References

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08/25/2003 Managed Care Advisory Council approval
11/02/2004 Medical Director review
11/16/2004 Medical Policy Committee review
11/29/2004 Managed Care Advisory Council approval
10/05/2005 Medical Director review
10/18/2005 Medical Policy Committee review

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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
11/05/2008 Medical Director review
11/18/2008 Medical Policy Committee approval. No change to coverage eligibility.
12/04/2009 Medical Director review
12/16/2009 Medical Policy Committee approval. No change to coverage eligibility.
12/01/2010 Medical Director review
12/15/2010 Medical Policy Committee approval. No change to coverage eligibility.
12/08/2011 Medical Policy Committee review
12/06/2012 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

Next Scheduled Review Date: 12/21/2017

Coding

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<table>
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<th>Code Type</th>
<th>Code</th>
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<tbody>
<tr>
<td>CPT</td>
<td>92227, 92228</td>
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<tr>
<td>HCPCS</td>
<td>No codes</td>
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*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.

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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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