



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject Retinal Imaging for Diabetic Retinopathy

Effective Date 3/15/2009
Next Review Date 3/15/2010
Coverage Policy Number 0080

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Telemedicine

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans as well as benefit plans formerly administered by Great-West Healthcare. Please note, the terms of a participant's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a participant's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a participant's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2009 CIGNA

Coverage Policy

CIGNA covers the following retinal imaging technologies as medically necessary in individuals with diabetes mellitus:

- standard film or digital fundus photography
- retinal telescreening (e.g., Digiscope[®], Inoveon[™] System, Joslin Vision Network[™])
- optical coherence tomography
- fluorescein angiography
- Heidelberg Retina Tomograph
- confocal scanning laser ophthalmoscope
- retinal thickness analyzer

CIGNA does not cover retinal telescreening for any other indication because it is considered experimental, investigational or unproven.

General Background

Diabetic retinopathy typically exhibits no symptoms at its most treatable stages. Early detection of retinopathy depends on educating patients with diabetes as well as their families, and eye care providers about the importance of regular eye examination even though the patient may be asymptomatic. Patients with diabetes

mellitus without diabetic retinopathy should be encouraged to have annual dilated eye examinations to detect the onset of diabetic retinopathy. Unfortunately, according to the National Committee for Quality Assurance's Health Plan Employers Data Information Set System, the average rate of annual eye examinations for patients with diabetes in participating health plans in 2007 was 55% for commercial health plans, 62% for Medicare plans, and 51% for Medicaid plans (American Academy of Ophthalmology, 2008).

Screening and detection of diabetic retinopathy includes a comprehensive annual eye examination, including measurement of visual acuity, intraocular pressure, and an examination of the retina, usually with the pupils pharmacologically dilated (i.e. mydriatic). This is generally performed by an optometrist or ophthalmologist. Along with manual visual inspection, retinal imaging via fundus photography (using the seven standard field 35 millimeter stereoscopic color photography or digital photography) may be performed. Off-site expert review of digital images is referred to as retinal telescreening or teleophthalmology.

The American Academy of Ophthalmology (AAO) states that photographic screening programs have value when access to ophthalmic care is limited. The AAO notes that photographic screening programs are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy (AAO, 2008). The American Diabetes Association (ADA) states that examinations can be done by the taking of retinal photographs (with or without dilation of the pupil) and having these read by experienced experts in this field. In-person exams are still necessary when the photos are unacceptable and for follow-up of abnormalities detected. This technology has its greatest potential in areas where qualified eye care professionals are not available (ADA, 2009).

Additional retinal imaging tools that may aid in the diagnosis and treatment of diabetic retinopathy as well as other eye disorders include: optical coherence tomography (OCT); fluorescein angiography (FA); Heidelberg Retina Tomograph (HRT) (Heidelberg Engineering GmbH, Heidelberg, Germany); Confocal Scanning Laser Ophthalmoscope (cSLO); and Retinal Thickness Analyzer (RTA) (Talia Technology Ltd., Neve-Ilan, Israel).

U.S. Food and Drug Administration (FDA)

The FDA has approved standard and digital ophthalmic cameras, ophthalmic image storage devices, ophthalmic image management systems, and ophthalmic image communication devices.

Literature Review

According to the American Academy of Ophthalmology (AAO) Preferred Practice Patterns™ for Diabetic Retinopathy (2008), the primary prevention and screening process for diabetic retinopathy varies according to the age of onset of the disease. Several forms of retinal screening with standard fundus photography or digital imaging, with and without dilation, are being investigated as a means of detecting retinopathy. Digital imaging technology can be a sensitive and effective screening tool to identify patients with diabetic retinopathy (Rudnisky, et al., 2007; Lopez-Bastida, et al., 2007; Whited, 2006; Schiffman, et al., 2005; Williams, et al., 2004; Larsen, et al., 2003; Gómez-Ulla, et al., 2002; Fransen, et al., 2002; Bursell, et al., 2001). Some studies have found that photography is more sensitive in identifying sight-threatening retinopathy than clinical examination with ophthalmoscopy (Ahmed, et al., 2006; Lin, et al., 2002; Sharp, et al., 2003; Leese, et al., 2002). Digital cameras with stereoscopic capabilities are useful for identifying subtle neovascularization and macular edema (Perumalsamy, et al., 2007; Rudnisky, et al., 2002; Liesenfeld, et al., 2000). The AAO notes that at this time, it is not clear that photographic screening programs achieve a greater reduction in vision loss than does routine community care in areas where access to ophthalmologists is straightforward. Studies have found a positive association between participating in a photographic screening program and receiving or subsequent adherence to receiving, recommended comprehensive dilated eye examinations by a clinician (Fonda, et al., 2007; Taylor et al. 2007; Conlin, et al., 2006; Zimmer-Galler, et al., 2006; Massin, et al., 2005). However, the AAO states that "such screening programs have great value in circumstances in which access to ophthalmic care is limited" (Farley, et al., 2008). The AAO states "at this time, these technologies are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy" (AAO, 2008). There is a paucity of evidence in the peer-reviewed scientific literature supporting the use of retinal telescreening outside the scope of screening for diabetic retinopathy in diabetic patients without diabetic retinopathy.

Optical coherence tomography (OCT) and fluorescein angiography (FA) are standard of care for the diagnosis and treatment of some patients with diabetic retinopathy. OCT of the posterior segment of the eye can be useful for quantifying retinal thickness, monitoring macular edema, and identifying vitreomacular traction in selected

patients with diabetic macular edema. OCT allows direct visualization of retinal pathology on a morphologic level, providing information that complements information supplied by fundus photography and fluorescein angiography. FA is commonly used to guide treatment of CSME and to evaluate unexplained visual loss. FA is occasionally used to identify suspected but clinically obscure retinal neovascularization and is not used to screen a patient with no or minimal diabetic retinopathy. (AAO, 2008; McDonald, et al., 2007; Virgili, et al., 2007; Srinivasan, et al., 2006; Goebel and Franke, 2006; Kang, et al., 2004; Sánchez-Tocino, et al., 2002; Goebel, et al., 2002; Razvi, et al., 2001).

The HRT and the RTA can measure retinal thickness. There is a high degree of correlation between retinal thicknesses determined by OCT and the RTA. However, the RTA may produce falsely elevated retinal thickness measurements. The HRT also appears to be an accurate instrument for measuring retinal thickness. These techniques provide quantitative information that has not been previously available with standard methods that have been used for macular assessment. The AAO notes that “at this time, it is reasonable to conclude that the imaging instruments discussed here are accurate, reproducible, and reliable. There is not enough evidence to make meaningful comparisons between the technologies. Laser scanning imaging provides additional information that is helpful in managing macular disease by allowing objective serial quantitative measurements of retinal thickness and anatomy” (McDonald, 2007).

Professional Societies/Organizations

American Academy of Ophthalmology (AAO): The AAO Preferred Practice Patterns™ for Diabetic Retinopathy (2008) make these retinopathy screening recommendations:

- Type 1 (Diabetes onset usually before age 30 years): Ophthalmic examinations should be performed beginning three to five years after the diagnosis of type 1 diabetes and will discover the vast majority of type 1 patients who require therapy at that time. Follow-up yearly.
- Type 2 (Diabetes Onset Usually at Age 30 Years or Older): be referred for ophthalmologic examination at the time of diagnosis. Follow-up yearly.
- Diabetes Associated with Pregnancy: Patients with diabetes who are planning to become pregnant should be encouraged to have their eyes examined prior to conception, should be counseled on the risk of development and/or progression of diabetic retinopathy, and should be told to make every attempt to lower their blood glucose levels to as near normal as possible for their own health and the health of the fetus. During the first trimester, another eye examination should be performed; subsequent follow-up will depend on the level of retinopathy found. Women who develop gestational diabetes do not require an eye examination during pregnancy because such individuals are not at increased risk for diabetic retinopathy during pregnancy.

The AAO states that photographic screening programs have value when access to ophthalmic care is limited. The AAO notes that photographic screening programs are not considered a replacement for a comprehensive eye evaluation by an ophthalmologist experienced in managing diabetic retinopathy (AAO, 2008).

American Diabetes Association (ADA): The ADA Position Statement Standards in Medical Care in Diabetes (2009) Retinopathy Screening recommendations are as follows:

- Adults and children aged 10 years or older with type 1 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist within five years after the onset of diabetes.
- Patients with type 2 diabetes should have an initial dilated and comprehensive eye examination by an ophthalmologist or optometrist shortly after the diagnosis of diabetes.
- Subsequent examinations for type 1 and type 2 diabetic patients should be repeated annually by an ophthalmologist or optometrist. Less frequent exams (every two to three years) may be considered following one or more normal eye exams. Examinations will be required more frequently if retinopathy is progressing.
- Women with pre-existing diabetes who are planning pregnancy or who have become pregnant should have a comprehensive eye examination and should be counseled on the risk of development and/or progression of diabetic retinopathy. Eye examination should occur in the first trimester with close follow-up throughout pregnancy and for one year postpartum.

The ADA stated that examinations can also be done by the taking of retinal photographs (with or without dilation of the pupil) and having these read by experienced experts in this field. In-person exams are still necessary

when the photos are unacceptable and for follow-up of abnormalities detected. This technology has its greatest potential in areas where qualified eye care professionals are not available (ADA, 2009).

American Association of Clinical Endocrinologists (AACE): The AACE Medical Guidelines for Clinical Practice for the Management of Diabetes Mellitus (2007) states the following points under Microvascular Complications – Retinopathy:

- refer the patient to a trained examiner (ophthalmologist and/or retinal specialist) for annual dilated retinal examination at the time type 2 diabetes mellitus (T2DM) is diagnosed, or five years after type 1 diabetes mellitus (T1DM) is diagnosed; annual examinations should be performed thereafter.
- alternatively, the results from 7-field stereo color fundus photography or digital retinal imaging may be read by a qualified reading center, as long as the center operates under the direction of a medical director who is a retinal specialist.
- promptly refer the patient to a retinal specialist if there is evidence that early retinopathy is progressing or if advanced retinopathy exists.

Treating retinopathy entails using laser and vitrectomy for specific indications. Digital retinal imaging system and 7-field stereo color fundus photography may be useful screening tools for diabetic retinopathy (Schiffman, et al., 2005) (Rodbard, et al., 2007).

Summary

In patients with known diabetes mellitus, annual screening for diabetic retinopathy should include clinical examination with stereo fundus photography. Digital photography is an accepted method of fundus photography. Telescreening programs should not be considered a replacement for a comprehensive eye evaluation, but do encourage participation in screening programs and provide value where access to ophthalmic care is limited. There is insufficient evidence in the peer-reviewed scientific literature supporting the use of retinal telescreening outside the scope of screening for diabetic retinopathy. Fluorescein angiograms and laser scanning imaging (i.e., optical coherence tomography [OCT], Heidelberg Retina Tomograph [HRT], confocal scanning laser ophthalmoscope [cSLO], and retinal thickness analyzer [RTA]) may provide clinically valuable information for selected diabetic retinopathy patients.

The use of the above imaging procedures for any other indication (e.g., glaucoma, macular degeneration) is not addressed in this Coverage Policy.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Covered when medically necessary:

CPT® Codes	Description
92135	Scanning computerized ophthalmic diagnostic imaging, posterior segment, (eg, scanning laser) with interpretation and report, unilateral
92235	Fluorescein angiography (includes multiframe imaging) with interpretation and report
92250	Fundus photography with interpretation and report

HCPCS Codes	Description
S0625	Retinal telescreening by digital imaging of multiple different fundus areas to screen for vision-threatening conditions, including imaging, interpretation and report

ICD-9-CM Diagnosis Codes	Description
249.00 –	Secondary diabetes mellitus

249.91	
250.00 – 250.93	Diabetes mellitus
362.01 – 362.07	Diabetic retinopathy

***Current Procedural Terminology (CPT®) © 2008 American Medical Association: Chicago, IL.**

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	3/15/2008	0080	Retinal Imaging for Diabetic Retinopathy
Great-West Healthcare	8/23/2007	05.301.02	Diabetic Retinopathy Telescreening with Digital Imaging Systems

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Connecticut General Life Insurance Company has acquired the business of Great-West Healthcare from Great-West Life & Annuity Insurance Company (GWLA). Certain products continue to be provided by GWLA (Life, Accident and Disability, and Excess Loss). GWLA is not licensed to do business in New York. In New York, these products are sold by GWLA's subsidiary, First Great-West Life & Annuity Insurance Company, White Plains, N.Y.