



# CIGNA MEDICAL COVERAGE POLICY

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

**Subject Retinal Imaging for Diabetic Retinopathy**

**Effective Date ..... 1/15/2011**  
**Next Review Date ..... 1/15/2012**  
**Coverage Policy Number ..... 0080**

## Table of Contents

Coverage Policy ..... 1  
General Background ..... 1  
Coding/Billing Information ..... 4  
References ..... 4  
Policy History ..... 7

## Hyperlink to Related Coverage Policies

Telemedicine

### INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer'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 customer'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 customer'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 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 ©2011 CIGNA

## Coverage Policy

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

- standard film or digital fundus photography
- retinal telescreening
- 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.**

**CIGNA does not cover computer programs (i.e., algorithms) designed to automatically detect or diagnose diabetic retinopathy, because they are considered experimental, investigational or unproven.**

## General Background

Screening and detection of diabetic retinopathy in patients with diabetes mellitus 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. Digital photography is an accepted method of fundus photography. The gold standard for the evaluation of diabetic retinopathy is seven-field stereo fundus photography read by trained readers.

Off-site expert review of digital images is referred to as retinal telescreening or teleophthalmology. Retinal telescreening involves taking digital images of the retina and electronically transmitting them to another location where they are evaluated. Depending on the service, images may be viewed by trained, nonphysician technicians and/or ophthalmology specialists. Sending scanned images via a high-speed broadband Internet connection or via satellite to high-definition computer screens links patients in remote locations (where screening might otherwise not be available) with specialty centers. Professionals in specialty centers can then determine whether retinopathy is present and whether follow-up specialist care is needed. Retinopathy telescreening has the potential to improve compliance with retinopathy screening because it can be performed during a primary care physician office visit without referral to an ophthalmologist or optometrist (ECRI, 2010). A screening program has its greatest potential in areas where qualified eye care professionals are not available. The American Academy of Ophthalmology (AAO) notes 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 in-person exams are still necessary when the photos are unacceptable and for follow-up of abnormalities detected (ADA, 2010).

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). OCT, HRT, cSLO and RTA are types of laser scanning imaging. FA may use laser scanning or a fundus camera.

### **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. Some examples include:

Ophthalmic cameras:

- Digiscope<sup>®</sup> (EyeTel Imaging, Inc., Columbia, MD)
- RETINA DX (Eye Expert, LLC., Greenville, NC)
- Imagenet (Topcon Corp., Paramus, NJ)
- Eyecap Imaging System (Haag Streit UK Ltd., UK)

Ophthalmic image storage devices:

- Eye Q Imaging System (Canon, Inc., Lake Success, NY)
- Medilive Mindstream (Carl Zeiss Surgical GMBH, Germany)
- 

Ophthalmic image management systems:

- Opthavision Imaging System (MRP Group, Inc., Waltham, MA)

Ophthalmic image communication devices:

- Joslin Vision Network<sup>™</sup> (Joslin Diabetes Center, Boston, MA)
- Warspeed System (Image Technology Laboratories, Inc., Kingston, NY)
- DR-3DT (Inoveon Corp., Oklahoma City, OK)
- IRI<sup>™</sup> Integrated Retinal Imager System (MediVision Medical Imaging Ltd., Israel)

Scanning Laser Ophthalmoscope

- Optos Panoramic 200MA Ophthalmoscope (Optos PLC, Dunfermline, Fife, Scotland, UK)

Ophthalmoscope, AC powered

- Zeiss Confocal Laser Scanning Ophthalmoscope (Carl Zeiss, Inc. , Princeton, NJ)

Tomography, Optical Coherence

- Spectralis™ Heidelberg Retina Angiograph /Optical Coherence Tomograph (Heidelberg Engineering GmbH (Heidelberg, Germany)

There is no FDA-approved computer program (i.e., algorithm) designed to automatically detect or diagnose diabetic retinopathy.

### **Literature Review**

Retinal screening with standard fundus photography or digital imaging is safely and accurately used to identify patients with diabetic retinopathy (Rudnisky, et al., 2007; Lopez-Bastida, et al., 2007; 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 digital imaging is more sensitive in identifying 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 seen in retinopathy (Perumalsamy, et al., 2007; Rudnisky, et al., 2002; Liesenfeld, et al., 2000).

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). Retinal telescreening has not been adequately studied outside the scope of screening for diabetic retinopathy in diabetic patients.

Computer programs or algorithms for automated detection or diagnosis of diabetic retinopathy may be referred to computer-assisted detection or diagnosis (CAD). The application of algorithms to transmitted digital images compared to visual inspection of digital images is being studied. Ongoing large, diagnostic cohort studies compare versions of a single program (i.e., algorithm) or different existing programs (Abràmoff, et al., 2010; Fleming, et al., 2010; Abràmoff, et al., 2008; Philip, et al., 2007). Numerous programs are in development. There is a lack of consensus regarding which algorithm should be utilized as well as any derived clinical utility (e.g., reduction in manual grading workload, earlier identification of diabetic retinopathy resulting in improved outcomes). The incremental diagnostic utility of using such technologies has not yet been demonstrated therefore the role of these programs in patient management is unproven at this time.

OCT and 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).

The HRT and the RTA can accurately measure retinal thickness. There is a high degree of correlation between retinal thicknesses determined by OCT and the RTA. These techniques provide quantitative information that has not been previously available with standard methods that have been used for macular assessment. The AAO notes the technologies 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**

The American Diabetes Association, the American Academy of Ophthalmology, and the American Association of Clinical Endocrinologists all recommend screening for diabetic retinopathy. Their respective guidelines provide various frequency recommendations by diabetes type (i.e., type 1, type 2, pregnancy).

### **Summary**

Evidence in the published, peer-reviewed, scientific literature supports the clinical utility of screening individuals with diabetes mellitus for diabetic retinopathy. Telescreening programs are not considered a replacement for a comprehensive eye evaluation, but do encourage participation in screening programs and provide particular value where access to ophthalmic care is limited. The use of computer programs for automated detection or diagnosis of diabetic retinopathy remains unproven at this time.

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. There is insufficient evidence in the published, peer-reviewed, scientific literature supporting the use of retinal telescreening outside the scope of screening for diabetic retinopathy.

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
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve (Code effective 1/1/2011)
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina (Code effective 1/1/2011)
92135	Scanning computerized ophthalmic diagnostic imaging, posterior segment, (eg, scanning laser) with interpretation and report, unilateral (Code deleted 1/1/2011)
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 – 249.91	Secondary diabetes mellitus
250.00 – 250.93	Diabetes mellitus
362.01 – 362.07	Diabetic retinopathy

\*Current Procedural Terminology (CPT®) © 2010 American Medical Association: Chicago, IL.

## References

1. Abràmoff MD, Niemeijer M, Suttorp-Schulten MS, Viergever MA, Russell SR, van Ginneken B. Evaluation of a system for automatic detection of diabetic retinopathy from color fundus photographs in a large population of patients with diabetes. *Diabetes Care*. 2008 Feb;31(2):193-8. Epub 2007 Nov 16.
2. Abràmoff MD, Reinhardt JM, Russell SR, Folk JC, Mahajan VB, Niemeijer M, Quellec G. Automated early detection of diabetic retinopathy. *Ophthalmology*. 2010 Jun;117(6):1147-54.
3. Ahmed J, Ward TP, Bursell SE, Aiello LM, Cavallerano JD, Vigersky RA. The sensitivity and specificity of nonmydriatic digital stereoscopic retinal imaging in detecting diabetic retinopathy. *Diabetes Care*. 2006 Oct;29(10):2205-9.
4. American Academy of Ophthalmology (AAO). Clinical Statement. Screening for Diabetic Retinopathy. November 2006. Accessed December 2010. Available at URL address: <http://one.aao.org/CE/PracticeGuidelines/default.aspx>
5. American Academy of Ophthalmology (AAO). Clinical Statement, Frequency of Ocular Examinations. November 2009. Accessed December 2010. Available at URL address: <http://one.aao.org/CE/PracticeGuidelines/default.aspx>
6. American Academy of Ophthalmology (AAO). Preferred Practice Patterns™ Diabetic Retinopathy. Approved September 2008. Accessed December 2010. Available at URL address: <http://one.aao.org/CE/PracticeGuidelines/default.aspx>
7. American Diabetes Association. Standards of Medical Care in Diabetes – January 2010. Accessed December 2010. Available at URL address: [http://professional.diabetes.org/CPR\\_search.aspx](http://professional.diabetes.org/CPR_search.aspx)
8. Bursell SE, Cavallerano JD, Cavallerano AA, Stereo nonmydriatic digital-video color retinal imaging compared with Early Treatment Diabetic Retinopathy Study seven standard field 35-mm stereo color photos for determining level of diabetic retinopathy. *Ophthalmology* 2001;108:572–585.
9. Conlin PR, Fisch BM, Cavallerano AA, et al. Nonmydriatic teleretinal imaging improves adherence to annual eye examinations in patients with diabetes. *J Rehabil Res Dev* 2006;43:733-40.
10. ECRI Institute. Hotline Response [database online]. Plymouth Meeting (PA): ECRI Institute. Algorithms for Automated Detection of Diabetic Retinopathy. Published: 10/28/2010. Available at URL address: <http://www.ecri.org>.
11. EyeTel Imaging, Inc. accessed December 2010. Available at URL address: <http://www.eyetel-imaging.com/digiscope.asp>
12. Fleming AD, Goatman KA, Philip S, Prescott GJ, Sharp PF, Olson JA. Automated grading for diabetic retinopathy: a large-scale audit using arbitration by clinical experts. *Br J Ophthalmol*. 2010 Dec;94(12):1606-10. Epub 2010 Sep 21.
13. Fonda SJ, Bursell SE, Lewis DG, et al. The relationship of a diabetes telehealth eye care program to standard eye care and change in diabetes health outcomes. *Telemed J E Health* 2007;13:635-44.
14. Fransen S, Leonard-Martin T, Feuer W, Hildebrand PL. Clinical evaluation of patients with diabetic retinopathy, accuracy of the Inoveon Diabetic Retinopathy-3DT System. *Ophthalmology*. 2002;109:595–601.
15. Goebel W, Kretzchmar-Gross T. Retinal thickness in diabetic retinopathy: a study using optical coherence tomography (OCT). *Retina*. 2002 Dec;22(6):759-67.
16. Goebel W, Franke R. Retinal thickness in diabetic retinopathy: comparison of optical coherence tomography, the retinal thickness analyzer, and fundus photography. *Retina*. 2006 Jan;26(1):49-57.

17. Gómez-Ulla F, Fernandez MI, Gonzalez F, Rey P, Rodriguez M, Rodriguez-Cid MJ, et al. Digital retinal images and teleophthalmology for detecting and grading diabetic retinopathy. *Diabetes Care*. 2002 Aug;25(8):1384-9.
18. Inoveon Corporation. INOVEON™ System. Accessed December 2010. Available at URL address: <http://www.inoveon.com/index.html>
19. Joslin Vision Network (JVN). Accessed December 2010. Available at URL address: <http://www.joslin.org/3072.asp>
20. Kang SW, Park CY, Ham DI. The correlation between fluorescein angiographic and optical coherence tomographic features in clinically significant diabetic macular edema. *Am J Ophthalmol*. 2004 Feb;137(2):313-22.
21. Larsen N, Godt J, Grunkin M, Lund-Andersen H, Larsen M. Automated detection of diabetic retinopathy in a fundus photographic screening population. *Invest Ophthalmol Vis Sci*. 2003 Feb;44(2):767-71.
22. Leese GP, Ellis JD, Morris AD, Ellingford A. Does direct ophthalmoscopy improve retinal screening for diabetic eye disease by retinal photography? *Diabet Med* 2002;19:867-9.
23. Liesenfeld B, Kohner E, Piehlmeier W, Kluthe S, Aldington S, Porta M, et al. A telemedical approach to the screening of diabetic retinopathy: digital fundus photography. *Diabetes Care*. 2000 Mar;23(3):345-8.
24. Lopez-Bastida J, Cabrera-Lopez F, Serrano-Aguilar P. Sensitivity and specificity of digital retinal imaging for screening diabetic retinopathy. *Diabet Med*. 2007 Apr;24(4):403-7.
25. Massin P, Aubert JP, Eschwege E, Erginay A, Bourovitch JC, BenMehidi A, et al. Evaluation of a screening program for diabetic retinopathy in a primary care setting Dodia (Dépistage ophtalmologique du diabète) study. *Diabetes Metab*. 2005 Apr;31(2):153-62.
26. McDonald HR, Williams GA, Scott IU, Haller JA, American Academy of Ophthalmology, Ophthalmic Technology Assessment Committee Retina Panel, et al. Laser scanning imaging for macular disease: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2007 Jun;114(6):1221-8.
27. Neubauer AS, Welge-Lüssen UC, Thiel MJ, Alge C, Priglinger SG, Hirneiss C, et al. Tele-screening for diabetic retinopathy with the retinal thickness analyzer. *Diabetes Care*. 2003 Oct;26(10):2890-7.
28. Perumalsamy N, Prasad NM, Sathya S, Ramasamy K. Software for reading and grading diabetic retinopathy: Aravind Diabetic Retinopathy Screening 3.0. *Diabetes Care*. 2007 Sep;30(9):2302-6.
29. Philip S, Fleming AD, Goatman KA, Fonseca S, McNamee P, Scotland GS, et al. The efficacy of automated "disease/no disease" grading for diabetic retinopathy in a systematic screening programme. *Br J Ophthalmol*. 2007 Nov;91(11):1512-7. Epub 2007 May 15.
30. Rodbard HW, Blonde L, Braithwaite SS, Brett EM, Cobin RH, AACE Diabetes Mellitus Clinical Practice Guidelines Task Force, et al. American Association of Clinical Endocrinologists medical guidelines for clinical practice for the management of diabetes mellitus. *Endocr Pract*. 2007 May-Jun;13 Suppl 1:1-68. Accessed December 2010. Available at URL address: <http://www.aace.com/pub/guidelines/>
31. Rudnisky CJ, Hinz BJ, Tennant MT, et al. High-resolution stereoscopic digital fundus photography versus contact lens biomicroscopy for the detection of clinically significant macular edema. *Ophthalmology* 2002;109:267-74.
32. Rudnisky CJ, Tennant MT, Weis E, Ting A, Hinz BJ, Greve MD. Web-based grading of compressed stereoscopic digital photography versus standard slide film photography for the diagnosis of diabetic retinopathy. *Ophthalmology*. 2007 Sep;114(9):1748-54.

33. Sánchez-Tocino H, Alvarez-Vidal A, Maldonado MJ, Moreno-Montañés J, García-Layana A. Retinal thickness study with optical coherence tomography in patients with diabetes. *Invest Ophthalmol Vis Sci*. 2002 May;43(5):1588-94.
34. Schiffman R, Jacobsen G, Nussbaum J, Desai U, Carey D, Glasser D, et al. Comparison of a digital retinal imaging system and seven-field stereo color fundus photography to detect diabetic retinopathy. *AQ1. Ophthalmic Surg Lasers Imaging*. 2005 Jan/Feb;36:1.
35. Sharp PF, Olson J, Strachan F, Hipwell J, Ludbrook A, O'Donnell M, et al. The value of digital imaging in diabetic retinopathy. *National Coordinating Centre for Health Technology Assessment. Health Technol Assess*. 2003;7(30):1-119.
36. Srinivasan VJ, Wojtkowski M, Witkin AJ, Duker JS, Ko TH, Carvalho M, et al. High-definition and 3-dimensional imaging of macular pathologies with high-speed ultrahigh-resolution optical coherence tomography. *Ophthalmology*. 2006 Nov;113(11):2054.e1-14.
37. Taylor CR, Merin LM, Salunga AM, Hepworth JT, Crutcher TD, et al. Improving diabetic retinopathy screening ratios using telemedicine-based digital retinal imaging technology: the Vine Hill study. *Diabetes Care*. 2007 Mar;30(3):574-8.
38. Virgili G, Menchini F, Dimastrogiovanni AF, Rapizzi E, Menchini U, Bandello F, et al. Optical coherence tomography versus stereoscopic fundus photography or biomicroscopy for diagnosing diabetic macular edema: a systematic review. *Invest Ophthalmol Vis Sci*. 2007 Nov;48(11):4963-73.
39. Whited JD. Accuracy and reliability of teleophthalmology for diagnosing diabetic retinopathy and macular edema: a review of the literature. *Diabetes Technol Ther*. 2006 Feb;8(1):102-11.
40. Williams GA, Scott IU, Haller JA, Maguire AM, Marcus D, McDonald HR. Single-field fundus photography for diabetic retinopathy screening: a report by the American Academy of Ophthalmology. *Ophthalmology*. 2004 May;111(5):1055-62.

---

## Policy History

<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
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

"CIGNA", "CIGNA HealthCare" and the "Tree of Life" logo are registered service marks of CIGNA Intellectual Property, Inc., licensed for use by CIGNA Corporation and its operating subsidiaries. All products and services are provided by such operating subsidiaries and not by CIGNA Corporation. Such operating subsidiaries include Connecticut General Life Insurance Company, CIGNA Health and Life Insurance Company, CIGNA Behavioral Health, Inc., CIGNA Health Management, Inc., and HMO or service company subsidiaries of CIGNA Health Corporation and CIGNA Dental Health, Inc. In Arizona, HMO plans are offered by CIGNA HealthCare of Arizona, Inc. In California, HMO plans are offered by CIGNA HealthCare of California, Inc. In Connecticut, HMO plans are offered by CIGNA HealthCare of Connecticut, Inc. In North Carolina, HMO plans are offered by CIGNA HealthCare of North Carolina, Inc. In Virginia, HMO plans are offered by CIGNA HealthCare Mid-Atlantic, Inc. All other medical plans in these states are insured or administered by Connecticut General Life Insurance Company or CIGNA Health and Life Insurance Company.