

MEDICAL POLICY

| MEDICAL POLICY DETAILS | |
|------------------------|--|
| Medical Policy Title | OPTICAL COHERENCE TOMOGRAPHY FOR OPHTHALMOLOGIC APPLICATIONS |
| Policy Number | 9.01.10 |
| Category | Technology Assessment |
| Effective Date | 09/16/04 |
| Revised Date | 06/16/05, 04/20/06, 03/15/07, 05/14/08, 05/28/09, 05/27/10, 05/19/11, 05/24/12, 05/23/13, 05/22/14, 05/28/15, 04/21/16, 4/20/17, 04/19/18, 04/18/19 |
| Product Disclaimer | <ul style="list-style-type: none"> • If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply. • If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit. • If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit. |

POLICY STATEMENT

- I. Based upon our criteria and assessment of peer-reviewed literature, imaging of the *posterior segment* of the eye using optical coherence tomography (OCT) has been medically proven to be effective and therefore, **medically appropriate** for the following:
 - A. In the evaluation of patients with retinal diseases. Retinal diseases include, but are not limited to macular edema, macular holes, choroidal lesions and retinal inflammatory diseases; or
 - B. As a method for detecting glaucoma damage to the retinal nerve fiber layer (RNFL):
 1. In glaucoma suspects; or
 2. For routine monitoring for progression of the disease in known glaucoma patients.
- II. Based upon our criteria and assessment of peer-reviewed literature, imaging of the *anterior segment* of the eye using OCT has not been medically proven effective and is considered **investigational**.

Refer to Corporate Medical Policy #9.01.06 regarding *Ophthalmologic Techniques for the Diagnosis of Glaucoma (Scanning Laser Polarimetry and Ophthalmoscopy)*

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

OCT is a noninvasive, non-contact diagnostic imaging technique that provides high resolution, cross sectional images of the retina in vivo. OCT is analogous to ultrasonic pulse echo imaging, except that light rather than sound is used to measure the distance between reflective surfaces. This technique allows visualization of tissue morphologic characteristics at depths significantly greater than the penetration depth offered by conventional bright-field and confocal microscopy. As a result of this high resolution, the clinical utility of OCT has been investigated for imaging of both the anterior and posterior segments of the eye.

OCT imaging of the posterior segment is utilized for a broad range of retinal/macular conditions as well as providing measurements of the RNFL thickness. The RNFL is the innermost layer of the retina and consists of ganglion cell axons, which are the target cells in glaucoma. Axonal loss in glaucoma causes visual field loss, which, however, is only detected when a considerable amount of the nerve fiber layer has been lost. It has been proposed that RNFL defects can precede optic disc and visual field damage by several years and may be the earliest sign of glaucomatous damage.

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The anterior segment is the front third of the eye and includes the structures in front of the vitreous humour: the cornea, iris, ciliary body and lens. Within the anterior segment are two fluid-filled spaces, the anterior and posterior chambers. While gonioscopy is currently the standard method for clinically assessing the anterior chamber angle, imaging of the anterior segment by OCT has also been utilized in determining the width of the anterior chamber angle, an important measurement in the diagnosis of angle-closure glaucoma. Use of OCT imaging of the anterior segment has also been investigated in the measurement of other anterior segment structures including anterior chamber depth, and anterior chamber diameters. It has been utilized in the measurement of corneal thickness to help qualify patients for vision correction/refractive surgery; for the measurement of corneal flap thickness and residual stromal thickness following a refractive procedure; and in the pre and post-operative evaluation of patients undergoing cataract extraction and intraocular lens insertion.

Two separate OCT devices are utilized for imaging the posterior and anterior segments of the eye. OCT imaging of the posterior segment uses a 0.8 micron wavelength light source which is specifically designed for evaluating the optic nerve head, retinal thickness and RNFL; anterior segment imaging utilizes a 1.3 micron wavelength light that penetrates the sclera, allowing for cross sectional imaging of the anterior chamber and ciliary body. The light, however, is typically blocked by pigment, preventing exploration behind the iris.

RATIONALE

Posterior segment

Several OCT devices for viewing the posterior segment of the eye have received FDA approval. Examples include, but are not limited to, the OCT3, Stratus OCT™ and Cirrus™ HD-OCT. These devices are intended for use as a diagnostic device to aid in the detection and management of ocular diseases, including but not limited to macular edema, central serous retinopathy, diabetic retinopathy age-related macular degeneration and glaucoma.

The evidence from clinical studies has demonstrated that OCT can provide additional information as good as or superior to currently available techniques. Imaging of the posterior segment of the eye using OCT provides qualitative information about retinal disorders as well as quantitative measurements of retinal anatomy. OCT has been found to be a valuable tool for the evaluation and treatment of patients with retinal diseases. OCT has been found to be useful to measure the effectiveness of therapy, determining the need for ongoing therapy, or the safety of cessation of that therapy.

Numerous articles continue to describe findings from patients with known and suspected glaucoma using scanning laser techniques such as OCT. Studies note that abnormalities may be detected on these examinations before functional changes are noted. These techniques have become incorporated into glaucoma care and are viewed as an additional piece of information that may be useful in the clinical management of these patients. There is data to demonstrate that this testing is equivalent to expert assessment of optic disc photography for both detecting glaucoma and showing disease progression. There are also favorable aspects of this testing. For example, in contrast to other glaucoma testing, these tests can be done more easily, e.g. this testing does not always need to be done with dilated pupils and ambient light level may be (is) less critical. In addition, while serial stereo-photographs of the optic nerves are considered by many as the gold standard, these are not always practical, especially for general ophthalmologists. This testing also requires less cooperation from the patient, which can be helpful in some older patients. In summary, the use of a scanning laser technique such as OCT has become one additional test that may be utilized in the diagnosis and management of patients with glaucoma. These results are often considered along with other findings to make diagnostic and therapeutic decisions about glaucoma care.

Anterior segment

The Visante OCT received marketing clearance through the FDA 510(k) process in 2005. The 510(k) summary describes the Visante OCT as “a non-contact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the anterior segment, such as corneal and LASIK flap thickness”. The SL-OCT (Heidelberg Engineering) is also another dedicated anterior segment OCT.

WP Nolan, et al. (2007) assessed the ability of a prototype of the Visante OCT to detect primary angle closure in 203 Asian patients. The patients, recruited from glaucoma clinics, had been diagnosed with primary angle closure, primary open-angle glaucoma, ocular hypertension, and cataracts; some had previously been treated with iridotomy. Images were

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assessed by two glaucoma experts, and the results were compared to an independently obtained reference standard (gonioscopy). Data were reported from 342 eyes of 200 individuals. A closed angle was identified in 152 eyes with gonioscopy and 228 eyes with OCT, agreement was obtained between the two methods in 143 eyes. The authors suggest three possible reasons for the increase in identification of closed angles with OCT: lighting is known to affect angle closure, and the lighting conditions were different for the two methods (gonioscopy requires some light); placement of the gonioscopy lens on the globe may have caused distortion of the anterior segment; and landmarks are not the same with the two methods. The authors noted that longitudinal studies will be required to determine whether eyes classified as closed by OCT but not by gonioscopy are at risk of developing primary angle-closure glaucoma.

Another prospective observational study by M Kalev-Landoy and colleagues (2007) evaluated imaging of the anterior angle chamber with the Stratus OCT, which had been developed for retinal imaging. Ten eyes with normal open angles and 16 eyes with narrow or closed angles or plateau iris configuration as determined by gonioscopy were assessed. The OCT image was rated for quality, for ability to demonstrate the anterior chamber angle, and for ability to visualize the iris configuration; patients were classified as having open angles, narrow angles, closed angles, or plateau iris configuration. Ultrasound biomicroscopy was performed for comparison if plateau iris configuration was diagnosed. The investigators reported that the Stratus OCT provided high-resolution images of iris configuration and narrow or closed angles, and imaging of the angle was found to be adequate in cases of acute angle-closure glaucoma where the cornea was too cloudy to enable a clear gonioscopic view. Open angles and plateau iris configurations could not be visualized with the 0.8-micron wavelength Stratus OCT.

Ideally, a diagnostic test would be evaluated based on its technical performance, diagnostic performance (sensitivity and specificity), and clinical validity. Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Technically, the Visante OCT has the ability to create high-resolution images of the anterior eye segment. Studies indicate that the Visante OCT detects more eyes with narrow or closed angles than gonioscopy, showing high sensitivity and low specificity in comparison with the reference standard. However, if the reference standard is flawed (e.g., does not detect all cases), the information provided by sensitivity and specificity is limited. Evaluation of the diagnostic performance of the Visante OCT depends, therefore, on demonstration of an improvement in clinical outcomes. Although the resolution of the images and the ease of use might be considered advantageous, evidence is insufficient to determine whether use of OCT can improve detection and management of patients at risk of developing primary angle-closure glaucoma. Given the number of questions regarding the impact of this new technology on health outcomes, this procedure is considered investigational.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member’s subscriber contract.*
- ***CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.***
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

| Code | Description |
|-------------|--|
| 92132 (E/I) | Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral |
| 92133 | Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral, optic nerve |
| 92134 | Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral, retina |

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HCPCS Codes

| Code | Description |
|-------------------|--------------------|
| No specific codes | |

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| Code | Description |
|-------------------|---|
| A18.53 | Tuberculous chorioretinitis |
| E08.311-E08.359 | Diabetes mellitus due to underlying condition with diabetic retinopathy with/without macular edema (code range) |
| E09.311-E09.359 | Drug or chemical induced diabetes mellitus with diabetic retinopathy with/without macular edema (code range) |
| E10.311-E10.359 | Type 1 diabetes mellitus with diabetic retinopathy with/without macular edema (code range) |
| E11.311-E11.359 | Type 2 diabetes mellitus with diabetic retinopathy with/without macular edema (code range) |
| E13.311-E13.359 | Other specified diabetes mellitus with diabetic retinopathy with/without macular edema (code range) |
| G45.3 | Amaurosis fugax |
| H30.001-H30.139 | Chorioretinal inflammation (code range) |
| H30.141-H30.149 | Acute posterior multifocal placoid pigment epitheliopathy (code range) |
| H30.20-H30.23 | Posterior cyclitis (code range) |
| H30.811-H30.819 | Harada's disease (code range) |
| H30.891-H30.899 | Other chorioretinal inflammations (code range) |
| H30.90-H30.93 | Unspecified chorioretinal inflammation (code range) |
| H31.001-H31.099 | Chorioretinal scars (code range) |
| H31.101-H31.9 | Choroidal degeneration (code range) |
| H32 | Chorioretinal disorders in diseases classified elsewhere |
| H33.001-H33.8 | Retinal detachments and breaks (code range) |
| H34.00-H34.9 | Retinal vascular occlusions (code range) |
| H35.00-H35.9 | Other retinal disorders (code range) |
| H36 | Retinal disorders in diseases classified elsewhere |
| H40.001-H40.009 | Preglaucoma, unspecified (code range) |
| H40.011-H40.029 | Open angle with borderline findings (code range) |
| H40.031-H40.039 | Anatomical narrow angle (code range) |
| H40.041-H40.049 | Steroid responder (code range) |
| H40.051-H40.059 | Ocular hypertension (code range) |
| H40.061-H40.069 | Primary angle closure without glaucoma damage (code range) |
| H40.10X0-H40.10X4 | Unspecified open-angle glaucoma (code range) |
| H40.11X4-H40.11X4 | Primary open-angle glaucoma (code range) |
| H40.1210-H40.1294 | Low-tension glaucoma (code range) |
| H40.1310-H40.1394 | Pigmentary glaucoma (code range) |
| H40.1410-H40.1494 | Capsular glaucoma with pseudoexfoliation of lens (code range) |
| H40.1510-H40.1594 | Residual stage of open-angle glaucoma (code range) |
| H40.20X0-H40.20X4 | Unspecified primary angle-closure glaucoma (code range) |
| H40.211-H40.219 | Acute angle-closure glaucoma (code range) |
| H40.2210-H40.2294 | Chronic angle-closure glaucoma (code range) |
| H40.231-H40.239 | Intermittent angle-closure glaucoma (code range) |
| H40.241-H40.249 | Residual stage of angle-closure glaucoma (code range) |
| H40.30X0-H40.33X4 | Glaucoma secondary to eye trauma (code range) |
| H40.40X0-H40.43X4 | Glaucoma secondary to eye trauma (code range) |
| H40.50X0-H40.53X4 | Glaucoma secondary to other eye disorders (code range) |
| H40.60X0-H40.63X4 | Glaucoma secondary to drugs (code range) |
| H40.811-H40.89 | Other glaucoma (code range) |
| H42 | Glaucoma in diseases classified elsewhere |

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| Code | Description |
|----------------|---|
| H43.00-H43.399 | Other vitreous opacities (code range) |
| H43.811-H43.9 | Other disorders of the vitreous body (code range) |
| Q15.0 | Congenital glaucoma |

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*Key Article

KEY WORDS

OCT, anterior segment imaging

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a Local Coverage Determination (LCD) and related Article for scanning computerized ophthalmic diagnostic imaging. Please refer to the following LCD websites for Medicare Members:

<https://www.cms.gov/medicare-coverage-database/details/lcd->

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34380&ContrId=298&ver=35&ContrVer=1&CtrctrSelected=298*1&Ctrctr=298&name=National+Government+Services%2c+Inc.+\(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K\)&s=All&DocType=Active&bc=AggAAAQAAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=34380&ContrId=298&ver=35&ContrVer=1&CtrctrSelected=298*1&Ctrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J+-+K)&s=All&DocType=Active&bc=AggAAAQAAAA&)