MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Optical Coherence Tomography for Ophthalmologic Applications**
Policy Number	**9.01.10**
Category	**Technology Assessment**
Original Effective Date	**09/16/04**
Committee Approval 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, 04/16/20, 04/15/21, 04/21/22, 04/20/23**
Current Effective Date	**04/20/23**
Archived Date	**N/A**
Archive Review Date	**N/A**
Product Disclaimer	• *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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based upon our criteria and assessment of the 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, is considered **medically appropriate** for the following indications:

   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 the peer-reviewed literature, imaging of the *anterior segment* of the eye using OCT has not been medically proven effective and, therefore, is considered **investigational**.

III. Based upon our criteria and the lack of peer-reviewed literature, the use of remote, patient-initiated image capture and transmission via the optical coherence tomography (OCT) device has not been medically proven to be effective and, therefore, is considered **investigational**.

Refer to Corporate Medical Policy #9.01.06 Ophthalmologic Techniques for the Diagnosis of Glaucoma

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

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 the high resolution of the imaging, 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.

The anterior segment is the front third of the eye and includes the structures in front of the vitreous humor: 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 in measuring the effectiveness of therapy, determining the need for ongoing therapy, and determining 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 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 glaucoma 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 performed more easily, e.g., the testing does not always require dilated pupils, and ambient light level may be (is)

less critical. In addition, while serial stereophotographs of the optic nerves are considered by many to be 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 than 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 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 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: (1) lighting is known to affect angle closure, and the lighting conditions were different for the two methods (gonioscopy requires some light); (2) placement of the gonioscopy lens on the globe may have caused distortion of the anterior segment; and (3) 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.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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
0604T **(E/I)**	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment
0605T **(E/I)**	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days
0606T **(E/I)**	Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days

HCPCS Codes

Code	Description
No specific codes	

ICD10 Codes

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)

Code	Description
H30.891-H30.899	Other chorioretinal inflammations (code range)
H30.90-H30.93	Unspecified chorioretinal inflammation (code range)
H31.001-H31.009	Unspecified chorioretinal scars (code range)
H31.101-H31.9	Choroidal degeneration and disorders (code range)
H32	Chorioretinal disorders in diseases classified elsewhere
H33.001-H33.8	Retinal detachments and retinal breaks (code range)
H34.00-H34.9	Retinal vascular occlusions (code range)
H35.00-H35.9	Background retinopathy and retinal vascular changes (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-H400.49	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)
H40.1210-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)
H40.151-H40.159	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)

Code	Description
H40.30X0-H40.33X4	Glaucoma secondary to eye trauma (code range)
H40.40X0-H40.43X4	Glaucoma secondary to eye inflammation (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
H43.00-H43.399	Disorders of vitreous body (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

Based upon our review, 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-details.aspx?LCDId=34380&ver=41&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD&PolicyType=Both&s=41&KeyWord=computerized+ophthalmic+diagnostic+imaging&KeyWordLookUp=Title&KeyWordSearchType=Exact&kq=true&bc=MAAAABAAAAAA&