

Medical Policy



Title: **Optical Coherence Tomography (OCT) of the Anterior Eye Segment**

Professional

Original Effective Date: January 1, 2011
Revision Date(s): March 28, 2011;
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Institutional

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DESCRIPTION

Optical coherence tomography (OCT) is a high resolution method of imaging the ocular structures. OCT for the anterior eye segment is being evaluated as a non-invasive diagnostic and screening tool for the detection of angle closure glaucoma, to assess corneal thickness and opacity, evaluate pre-surgical and postsurgical anterior chamber anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures, and to image intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

Background

The classification of glaucoma (primary open angle or angle closure) relies heavily on knowledge of the anterior segment anatomy, particularly that of the anterior chamber angle. Angle closure glaucoma is characterized by obstruction of aqueous fluid drainage through the trabecular meshwork (the primary fluid egress site) from the eye's anterior chamber. The width of the angle is one factor affecting the drainage of aqueous humor. A wide unobstructed iridocorneal angle allows sufficient drainage of aqueous humor, whereas a narrow angle may impede the drainage system and leave the patient susceptible to angle closure glaucoma. The treatment for this condition is a peripheral iridotomy (laser) or peripheral iridectomy (surgery). Slit lamp biomicroscopy is used to evaluate the anterior chamber; however, the chamber angle can only be examined with specialized lenses, the most common of these being the gonioscopic mirror. In this procedure, a gonio lens is applied to the surface of the cornea, after administration of topical anesthesia, and the image is magnified with the slit lamp. Gonioscopy is the standard method for clinically assessing the anterior chamber angle. Other techniques for imaging the anterior eye segment include ultrasonography and optical coherence tomography (OCT). (1)

Ultrasonography uses high-frequency mechanical pulses (10 to 20 MHz) to build up a picture of the front of the eye. An ultrasound scan along the optical axis assesses corneal thickness, anterior chamber depth, lens thickness, and axial length. Ultrasound scanning across the eye creates a 2-dimensional image of the ocular structures. It has a resolution of 100 microns but only moderately high intra-observer and low inter-observer reproducibility. Ultrasound biomicroscopy (approximately 50 MHz) has a resolution of 30 to 50 microns. As with gonioscopy, this technique requires placement of a probe under topical anesthesia.

OCT is a non-invasive method that creates an image of light reflected from the ocular structures. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the 2 beams (reflected and reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 to 25 microns. The Stratus OCT™ (Carl Zeiss Meditec), which uses a 0.8-micron wavelength light source, was designed for evaluating the optic nerve head, retinal nerve fiber layer, and retinal thickness (see policy No. 9.03.06). The Zeiss Visante OCT™ and AC Cornea OCT (Ophthalmic Technologies) use a 1.3-micron wavelength light source designed specifically for imaging the anterior eye segment. Light of this wavelength penetrates the sclera, allowing high-resolution cross-sectional imaging of the anterior chamber angle and ciliary body. The light is, however, typically blocked by pigment, preventing exploration behind the iris. Ultrahigh resolution OCT can achieve a spatial resolution of 1.3 microns, allowing imaging and measurement of corneal layers.

An early application of OCT technology was the evaluation of the cornea before and after refractive surgery. Since this is a non-invasive procedure that can be conducted by a technician, it has been proposed that this device may provide a rapid diagnostic and screening tool for the detection of angle closure glaucoma. In addition, the non-contact method eliminates patient discomfort and inadvertent compression of the globe. Also being investigated is the possibility that the 0.8-micron wavelength Stratus OCT, which is already available in a number of eye departments, may provide sufficient detail for routine clinical assessment of the anterior chamber angle in glaucoma patients. Add-on lens are also available for imaging the anterior segment with OCT devices designed for posterior segment imaging.

In addition to the evaluation of anterior chamber angle, OCT is being evaluated to assess corneal thickness and opacity, evaluate pre-surgical and postsurgical anterior chamber anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures (e.g., blockage of glaucoma tubes, detachment of Descemet membrane, disrupted keratoprosthesis-cornea interface), and to image intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

Regulatory Status

The Visante OCT received marketing clearance through the U.S Food and Drug Administration (FDA) 510(k) process in 2005, listing the Stratus OCT and Orbscan™ II as predicate devices. 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 Slit-Lamp OCT (SL-OCT, Heidelberg Engineering) received marketing clearance through the FDA's 510(k) process in 2006. The SL-OCT is intended as an aid for the quantitative analysis of structures and the diagnosis and assessment of structural changes in the anterior segment of the eye. “The SL-OCT examination system is not intended for the analysis of the cross-sectional images to obtain quantitative measured values. Neither the obtained measured values nor the qualitative evaluation of the images should be used as the sole basis for therapy-related decisions.”

The RTVue (Optovue) is a commercially available Fourier-domain OCT system with a resolution of 5 microns that received marketing clearance from the FDA in 2010. Although indicated for posterior segment imaging, a lens is available to allow imaging of the anterior segment.

Three commercially available laser systems, the LenSx (Alcon), Catalys (Optimedica), and VICTUS (Technolas Perfect Vision), include OCT to provide image guidance for laser cataract surgery.

POLICY

Scanning computerized ophthalmic (e.g., OCT) imaging of the anterior eye segment is considered **experimental / investigational**.

RATIONALE

A search of the MEDLINE database was initially performed in December 2007, focusing on the use of anterior imaging with optical coherence tomography (OCT) to diagnose or manage closed angle glaucoma. The literature search identified a number of technical reviews, however, clinical research at the time this policy was created appeared to be at an early stage of development. The evidence for this policy has been periodically updated, with the most recent search of the MEDLINE database performed through January 15, 2013. Recent literature searches have found numerous studies that use OCT to evaluate the anatomy of the anterior segment and report qualitative and quantitative imaging and detection capabilities. Although these studies provide evidence for the technical performance of OCT, assessment of a diagnostic technology typically focuses on 3 parameters: 1) technical performance; 2) diagnostic performance (sensitivity, specificity, and positive and negative predictive value) in appropriate populations of patients; and 3) demonstration that the diagnostic information can be used to improve patient outcomes. This policy focuses specifically on evidence for diagnostic performance of the technology and the effect on health outcomes (clinical utility).

Diagnostic Performance

Optical Coherence Tomography versus Gonioscopy

Several studies have compared OCT with gonioscopy for the detection of primary angle closure. For example, Nolan and colleagues assessed the ability of a prototype of the Visante OCT to detect primary angle closure in 203 Asian patients. (2) 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 2 glaucoma experts, and the results 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 2 methods in 143 eyes. Although these results suggest low specificity for OCT, it is noted that gonioscopy is not considered to be a gold standard. The authors suggest 3 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 2 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 2 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.

Narayanaswamy et al. conducted a community-based cross-sectional study of glaucoma screening. (3) The study population consisted of individuals 50 years or older who underwent anterior segment OCT by a single ophthalmologist and gonioscopy by an ophthalmologist who was masked to the OCT findings. Individuals were excluded if they had a history of intraocular surgery, any evidence of aphakia/pseudophakia, or penetrating trauma in the eye; previous anterior segment laser treatment; a history of glaucoma; or corneal disorders such as corneal endothelial dystrophy, corneal opacity, or pterygium, all of which could influence the quality of

angle imaging by OCT. The angle opening distance (AOD) was calculated at 250, 500, and 750 microns from the scleral spur. Of 2,047 individuals examined, 28% were excluded due to inability to locate the scleral spur (n=515), poor image quality (n=28), or software delineation errors (n=39). Of the remaining 1,465 participants, 315 (21.5%) had narrow angles on gonioscopy, defined as having a narrow angle if the posterior pigmented trabecular meshwork was not visible for at least 180 degrees on nonindentation gonioscopy with the eye in the primary position. Out of those who had an acceptable image, the area under the receiver operating characteristic curve was highest at 750 microns from the scleral spur in the nasal (0.90) and temporal (0.91) quadrants. A noted limitation of this quantitative technique for screening of angle closure glaucoma was the inability to define the scleral spur in 25% of the study population.

A 2009 publication also examined the sensitivity and specificity of the Visante OCT when using different cut-off values for the AOD measured at 250, 500, and 750 microns from the scleral spur. (4) OCT and gonioscopy records were available for 303 eyes of 155 patients seen at a glaucoma clinic. The patients were asked to look at prepositioned targets to prevent image distortion with low- and high-resolution OCT. The parameters analyzed could not be measured by commercially available software at the time of the study, so the images were converted to a format that could be analyzed by ultrasound biomicroscopy software. Blinded analysis showed sensitivity and specificity between 70% and 80% (in comparison with gonioscopy), depending on the AOD and the cut-off value. Correlation coefficients between the qualitative gonioscopy grade and quantitative OCT measurement ranged from 0.75 (AOD 250) to 0.88 (AOD 750). As noted by these investigators, "a truer measure of occludable angles is whether an eye develops angle-closure glaucoma in the future." Long-term follow-up of patients examined with these 2 methods would be informative.

A prospective observational study (n=26) evaluated imaging of the anterior angle chamber with the Stratus OCT, which had been developed for retinal imaging. (5) 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, in which 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.

Optical Coherence Tomography versus Ultrasound

Garcia and Rosen evaluated the diagnostic performance of AC Cornea OCT (Ophthalmic Technologies Inc., Toronto, Ontario, Canada) by comparing image results with ultrasound biomicroscopy (UBM) in patients with conditions of the anterior segment. (6) The patients were recruited from various specialty clinics, and imaging with OCT and ultrasound was performed sequentially after obtaining informed consent. Eighty eyes with pathologic conditions involving the anterior ocular segment were included in the study; 6 cases were reported in detail to demonstrate the imaging capabilities of OCT and UBM. Comparison of OCT and UBM images shows that while the AC Cornea OCT has high resolution for the cornea, conjunctiva, iris, and anterior angle, ultrasound biomicroscopic images are also clear for these areas. In addition,

ultrasound biomicroscopy was found to be superior at detecting cataracts, anterior tumors, ciliary bodies, haptics, and posterior chamber intraocular lenses. OCT was found to be superior at detecting a glaucoma tube and a metallic foreign body in the cornea when imaging was performed in the coronal plane.

Mansouri and colleagues published a study that compared the accuracy in measurement of the anterior chamber (AC) angle by anterior segment OCT and UBM in European patients with suspected primary angle closure (PACS), primary angle closure (PAC), or primary angle-closure glaucoma (PACG). (7) In this study, 55 eyes of 33 consecutive patients presenting with PACS, PAC, or PACG were examined with OCT, followed by UBM. The trabecular-iris angle (TIA) was measured in all 4 quadrants. The angle-opening distance (AOD) was measured at 500 microns from the scleral spur. In this comparative study, the authors concluded that OCT measurements were significantly correlated with UBM measurements but showed poor agreement with each other. The authors do not believe that anterior segment OCT can replace UBM for the quantitative assessment of the anterior chamber angle.

Bianciotto et al. reported a retrospective analysis of 200 consecutive patients who underwent both anterior segment OCT and UBM for anterior segment tumors. (8) When comparing the image resolution for the 2 techniques, UBM was found to have better overall tumor visualization.

Optical Coherence Tomography versus Slitlamp Biomicroscopy

Jiang et al. reported a cross-sectional, observational study of the visualization of aqueous tube shunts by high resolution OCT, slitlamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes). (9) High resolution OCT demonstrated the shunt position and patency in all 23 eyes. Compared to slitlamp, 4 eyes had new findings identified by OCT. For all 16 eyes in which the tube entrance could be clearly visualized by OCT, growth of fibrous scar tissue could be seen between the tube and the corneal endothelium. This was not identified in the patient records (retrospectively analyzed) of the slitlamp examination.

Clinical Utility (Effect on health outcomes)

In addition to the evaluation of anterior chamber angle, OCT is being evaluated to assess corneal thickness and opacity, evaluate pre-surgical and postsurgical anterior chamber anatomy, calculate intraocular lens power, guide laser-assisted cataract surgery, assess complications following surgical procedures (e.g., blockage of glaucoma tubes, detachment of Descemet membrane, disrupted keratoprosthesis-cornea interface), and to image intracorneal ring segments. It is also being studied in relation to pathologic processes such as dry eye syndrome, tumors, uveitis, and infections.

Cauduro et al. provided a retrospective review of 26 eyes of 19 pediatric patients (range, 2 months to 12 years) who presented with a variety of anterior segment pathologies. (10) OCT was used to clarify the clinical diagnosis. No sedation was needed for this non-contact procedure, and only 1 eye of a 2-month old patient required topical anesthesia. The impact of the procedure on patient care was not reported.

Angle-closure Glaucoma

There are no studies that provide direct evidence on the clinical utility of OCT for diagnosing narrow angle glaucoma. The clinical utility of OCT for diagnosing glaucoma is closely related to its ability to accurately diagnose glaucoma, since treatment is generally initiated upon confirmation

of the diagnosis. Therefore, if OCT is more accurate in diagnosing glaucoma than alternatives, it can be considered to have clinical utility above that of the alternative tests. While the available evidence does suggest that OCT is more sensitive than ultrasound or gonioscopy, the specificity and predictive value cannot be determined.

Cataract Surgery

As of 2013, studies that compare the risk-benefit of OCT-laser assisted cataract surgery vs. traditional phacoemulsification are ongoing. (11) Anterior segment OCT is also being reported for preoperative evaluation of intraocular lens power, and postoperative assessment of intraocular stability of phakic lens and optic changes related to intraocular lens or ocular media opacities. (11)

Endothelial Keratoplasty

Shih and colleagues reported on the use of OCT to predict primary failure in Descemet stripping automated endothelial keratoplasty (DSAEK). (12) This study was conducted to determine if central donor lenticule thickness as measured by slit-lamp optical coherence tomography (SL OCT) is predictive of primary donor failure in patients undergoing DSAEK. In this retrospective study, 93 eyes of 84 consecutive patients who underwent DSAEK surgery also underwent postoperative SL OCT. After 2 months of follow-up, 82 (88%) procedures were successful and 11 (12%) procedures were failures. The average donor lenticule thickness in successful DSAEK eyes was 314 +/- 128 microns on postoperative day 1 as compared with failed DSAEK eyes, which averaged 532 +/- 259 microns (P=0.0013). Statistically significant differences in SL OCT thickness measurements were seen between successful and failed DSAEK cases at all examinations after postoperative week 1. The study concluded that corneal thickness measurements made with SL OCT are an important predictor of DSAEK failure in both attached and detached lenticules within the first week of surgery.

In 2011, Moutsouris et al. reported a prospective comparison of anterior segment OCT, Scheimpflug imaging, and slit-lamp biomicroscopy in 120 eyes of 110 patients after Descemet membrane endothelial keratoplasty (DMEK). (13) All slit-lamp biomicroscopy and OCT examinations were performed by the same experienced technician, and all images were evaluated by 2 masked ophthalmologists. From a total of 120 DMEK eyes, 78 showed a normal corneal clearance by all of the imaging techniques. The remaining 42 eyes showed persistent stromal edema within the first month, suggesting (partial) graft detachment. Biomicroscopy was able to determine the presence or absence of a graft detachment in 35 eyes. Scheimpflug imaging did not give additional information over biomicroscopy. In 15 eyes, only OCT was able to discriminate between a "flat" graft detachment and delayed corneal clearance. Thus, out of the 42 eyes, OCT had an added diagnostic value in 36% of cases. This led to further treatment in some of the additional cases. Specifically, a secondary DSAEK was performed for total graft detachment, while partial graft detachments were rebubbled or observed for corneal clearing. There were no false negatives (graft detachment unrecognized) or false positives (an attached graft recognized as a graft detachment). Additional studies are needed to further evaluate these results and to demonstrate the clinical utility of using OCT in this situation.

Uveitis of the Anterior Segment

In a study from India, Agarwal et al. evaluated the anterior chamber inflammatory reaction by anterior segment high-speed OCT. (14) This was a prospective, nonrandomized, observational case series of 62 eyes of 45 patients. Hyper-reflective spots suggesting the presence of cells in

the anterior chamber from the OCT images were counted manually and by a custom-made automated software package and correlated with clinical grading using Standardization of Uveitis Nomenclature criteria. Of 62 eyes, grade 4 aqueous flare was detected by OCT imaging in 7 eyes and clinically in 5 eyes. The authors concluded that anterior segment (AS)-OCT can be used as an imaging modality in detecting inflammatory reaction in uveitis and also in eyes with decreased corneal clarity. Additional studies are needed to further evaluate these results and to demonstrate the clinical utility of using OCT in this situation.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 1 physician specialty society and 3 academic medical centers while this policy was under review in 2011. There was general, but not unanimous, agreement that this technique is investigational. Some reviewers commented that this technique may have application in specific conditions such as globe perforation, anterior segment (iris) tumors, and in the postoperative care of endothelial keratoplasty cases.

Summary

Ideally, a diagnostic test would be evaluated based on its technical performance, diagnostic performance (sensitivity, specificity, and predictive value), and clinical utility (effect on health outcomes). Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Technically, the anterior segment OCT has the ability to create high-resolution images of the anterior eye segment. In addition, studies indicate that the anterior segment OCT detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of OCT is higher than gonioscopy. However, because of the lack of a true gold standard, it is not clear to what degree these additional cases are true positives versus false-positives, and therefore the specificity and predictive values cannot be determined. Evaluation of the diagnostic performance depends, therefore, on evidence that the additional eyes identified with narrow angle by OCT are more likely to progress to primary angle closure glaucoma. OCT imaging may be less sensitive in comparison with ultrasound biomicroscopy for other pathologic conditions of the anterior segment, such as cataracts, anterior tumors, ciliary bodies, haptics, and posterior chamber intraocular lenses.

Evaluation of the clinical utility of anterior segment OCT depends on demonstration of an improvement in clinical outcomes. For example, outcomes will be improved if OCT detects additional cases of primary angle closure glaucoma, which represent true cases of glaucoma and not false positives, and if these cases are successfully treated for glaucoma. It is not currently possible to determine the frequency of false-positive results with OCT, therefore it cannot be determined whether health outcomes are improved. For other potential indications (e.g., cataract surgery, endothelial keratoplasty, anterior uveitis) evidence is currently limited.

Since the impact on health outcomes of anterior segment OCT for angle closure glaucoma, as well as for other disorders of the anterior chamber, is not known, this procedure is considered investigational.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

92132 Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral

DIAGNOSIS

Experimental / investigational for all diagnosis.

REVISIONS

03-28-2011	Policy added to the bcbsks.com web site.
07-13-2012	Medical Policy Title has been updated from "Anterior Eye Segment Optical Imaging" to "Optical Coherence Tomography (OCT) of the Anterior Eye Segment"
	Description section updated.
	Rationale section updated.
	Reference section updated.
04-26-2013	Updated Description section.
	Updated Rationale section.
	Updated Reference section.

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