

# Protocol

## Optical Coherence Tomography of the Anterior Eye Segment

(90318)

<b>Medical Benefit</b>		<b>Effective Date:</b> 07/01/14	<b>Next Review Date:</b> 05/15
<b>Preauthorization</b>	No	<b>Review Dates:</b> 07/11, 07/12, 07/13, 05/14	

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but recommended if, despite this Protocol position you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

### 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 noninvasive diagnostic and screening tool for the detection of angle closure glaucoma, to assess corneal thickness and opacity, evaluate presurgical and postsurgical anterior chamber (AC) 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 (AS) anatomy, particularly that of the AC 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 AC. 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 AC; 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 AC angle. Other techniques for imaging the anterior eye segment include ultrasonography and OCT. (1)

Ultrasonography uses high-frequency mechanical pulses (10-20 MHz) to build up a picture of the front of the eye. An ultrasound scan along the optical axis assesses corneal thickness, AC depth, lens thickness, and axial length. Ultrasound scanning across the eye creates a two-dimensional image of the ocular structures. It has a resolution of 100 microns but only moderately high intraobserver and low interobserver 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 an 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 two 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 six 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. 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 AC 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. Because this is a noninvasive 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 noncontact 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 AC angle in glaucoma patients. Add-on lens are also available for imaging the AS with OCT devices designed for posterior segment imaging.

In addition to the evaluation of AC angle, OCT is being evaluated to assess corneal thickness and opacity, evaluate presurgical and postsurgical AC 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 noncontact, high resolution tomographic and biomicroscopic device indicated for the in vivo imaging and measurement of ocular structures in the AS, such as corneal and LASIK flap thickness.”

The Slit-Lamp OCT (SL-OCT, Heidelberg Engineering) received marketing clearance through 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 AS 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 five 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 AS.

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.

The AC Cornea OCT from Canada is not cleared for marketing in the United States.

#### *Related Protocols*

Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

Aqueous Shunts and Stents for Glaucoma

Endothelial Keratoplasty

**Policy (Formerly Corporate Medical Guideline)**

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

**Medicare Advantage**

For Medicare Advantage members anterior segment OCT is considered to be **medically necessary** to:

- Evaluate narrow angle, suspected narrow angle, mixed narrow and open angle glaucoma, and angle recession as all determined by gonioscopy
- Determine the proper intraocular lens for a patient who has had prior refractive surgery and now requires cataract extraction
- Evaluate iris tumor
- Evaluate corneal edema or opacity that precludes visualization or study of the anterior chamber
- Calculate lens power for cataract patients who have undergone prior refractive surgery. (Additional documentation must be in the medical record of the prior refractive procedure; OCT is not eligible in addition to A-scan or IOL master.)
- Evaluate and plan treatment for patients with diseases affecting the cornea, iris, lens and other anterior segment structures.
- Provide additional information during the planning and follow-up for corneal, iris, cataract, glaucoma and other anterior segment surgeries.

For all business if anterior segment OCT is billed in addition to other services, it will be considered incidental to the other service(s).

---

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

**References**

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Wolffsohn JS, Peterson RC. Anterior ophthalmic imaging. Clin Exp Optom 2006; 89(4):205-14.
2. Nolan WP, See JL, Chew PT et al. Detection of primary angle closure using anterior segment optical coherence tomography in Asian eyes. Ophthalmology 2007; 114(1):33-9.
3. Narayanaswamy A, Sakata LM, He MG et al. Diagnostic performance of anterior chamber angle measurements for detecting eyes with narrow angles: an anterior segment OCT study. Arch Ophthalmol 2010; 128(10):1321-7.

4. Pekmezci M, Porco TC, Lin SC. Anterior segment optical coherence tomography as a screening tool for the assessment of the anterior segment angle. *Ophthalmic Surg Lasers Imaging* 2009; 40(4):389-98.
5. Kalev-Landoy M, Day AC, Cordeiro MF et al. Optical coherence tomography in anterior segment imaging. *Acta Ophthalmol Scand* 2007; 85(4):427-30.
6. Garcia JP, Jr., Rosen RB. Anterior segment imaging: optical coherence tomography versus ultrasound biomicroscopy. *Ophthalmic Surg Lasers Imaging* 2008; 39(6):476-84.
7. Mansouri K, Sommerhalder J, Shaarawy T. Prospective comparison of ultrasound biomicroscopy and anterior segment optical coherence tomography for evaluation of anterior chamber dimensions in European eyes with primary angle closure. *Eye (Lond)* 2010; 24(2):233-9.
8. Bianciotto C, Shields CL, Guzman JM et al. Assessment of anterior segment tumors with ultrasound biomicroscopy versus anterior segment optical coherence tomography in 200 cases. *Ophthalmology* 2011; 118(7):1297-302.
9. Jiang C, Li Y, Huang D et al. Study of anterior chamber aqueous tube shunt by fourier-domain optical coherence tomography. *J Ophthalmol* 2012; 2012:189580.
10. Cauduro RS, Ferraz Cdo A, Morales MS et al. Application of anterior segment optical coherence tomography in pediatric ophthalmology. *J Ophthalmol* 2012; 2012:313120.
11. Nguyen P, Chopra V. Applications of optical coherence tomography in cataract surgery. *Curr Opin Ophthalmol* 2013; 24(1):47-52.
12. Moutsouris K, Dapena I, Ham L et al. Optical coherence tomography, scheimpflug imaging, and slit-lamp biomicroscopy in the early detection of graft detachment after descemet membrane endothelial keratoplasty. *Cornea* 2011; 30(12):1369-75.
13. Steven P, Le Blanc C, Velten K et al. Optimizing descemet membrane endothelial keratoplasty using intraoperative optical coherence tomography. *JAMA Ophthalmol* 2013; 131(9):1135-42.
14. Shih CY, Ritterband DC, Palmiero PM et al. The use of postoperative slit-lamp optical coherence tomography to predict primary failure in descemet stripping automated endothelial keratoplasty. *Am J Ophthalmol* 2009; 147(5):796-800, 00 e1.
15. Agarwal A, Ashokkumar D, Jacob S et al. High-speed optical coherence tomography for imaging anterior chamber inflammatory reaction in uveitis: clinical correlation and grading. *Am J Ophthalmol* 2009; 147(3):413-16 e3.
16. National Government Services Local Coverage Determination (LCD): Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (L28488), Revision Effective Date For services performed on or after 3/1/14.