This Protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following Protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. 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 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.

Summary of Evidence

Ideally, a diagnostic test would be evaluated based on its technical performance, diagnostic accuracy (sensitivity, specificity, predictive value), and effect on health outcomes. Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Technically, anterior segment (AS) optical coherence tomography (OCT) has the ability to create high-resolution images of the AS. In addition, studies indicate that the AS OCT detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of OCT is higher than that of gonioscopy. However, because of the lack of a true criterion 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 AS, such as cataracts, anterior tumors, iris, ciliary bodies, haptics, and posterior chamber intraocular lenses.

Evaluation of the clinical utility of AS 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., to aid in diagnosis of AS pathology or guide surgical procedures), evidence is currently limited.

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

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
• 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.

Background

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 AC anatomy, calculate intraocular lens power, guide 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.

OCT is a noninvasive 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 μm. The Stratus OCT™ (Carl Zeiss Meditec), which uses a 0.8-μm 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-μm 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 μm, 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. The classification of glaucoma (primary open angle or angle closure) relies heavily on knowledge of the 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 typically 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, which may result in distortion of the globe. Ultrasonography may also be used for imaging the anterior eye segment. Ultrasonography uses high-frequency mechanical pulses (10-20 MHz) to build up a picture of the front of the eye. An ultrasound (US) scan along the optical axis assesses corneal thickness, AC depth, lens thickness, and axial length. US scanning across the eye creates a two-dimensional image of the ocular structures. It has a resolution of 100 μm but only moderately high intraobserver and low interobserver reproducibility. US biomicroscopy (= 50 MHz) has a resolution of 30 to 50 μm. As with gonioscopy, this technique requires placement of a probe under topical anesthesia.

**Regulatory Status**

The Visante™ OCT received marketing clearance through the 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 RTVue® (Optovue) is a commercially available Fourier-domain OCT system with a resolution of 5 μm that received marketing clearance from FDA in 2010. Although indicated for posterior segment imaging, a lens is available to allow imaging of the AS. FDA product code: HLI.

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.” FDA product code: MXK.

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. FDA product code: OOE.

Ultrahigh resolution OCT devices include the Bioptigen Envisu (Bioptigen) and the SOCT Copernicus HR (Optopol Technologies). Custom-built devices, which do not require FDA approval, are also used.

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

**Related Protocols**

Aqueous Shunts and Stents for Glaucoma

Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

Endothelial Keratoplasty
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.

8. 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). Feb 2010; 24(2):233-239. PMID 19444291


21. National Government Services, Inc. Local Coverage Determination (LCD): Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (L34380), Revision Effective Date for services performed on or after 10/01/2015.