

# 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> 05/21
<b>Preauthorization</b>	No	<b>Review Dates:</b> 07/11, 07/12, 07/13, 05/14, 05/15, 05/16, 05/17, 05/18, 05/19, 05/20	

***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.*

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"><li>Who are being evaluated for angle-closure glaucoma</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>Anterior segment optical coherence tomography</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>Gonioscopy</li><li>Ultrasound biomicroscopy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>Test accuracy</li><li>Symptoms</li><li>Change in disease status</li><li>Morbid events</li></ul>
Individuals: <ul style="list-style-type: none"><li>Who are being evaluated for anterior eye surgery or post-surgical complications</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>Anterior segment optical coherence tomography</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>Gonioscopy</li><li>Slit-lamp biomicroscopy</li><li>Scheimpflug imaging</li><li>Ultrasound biomicroscopy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>Test accuracy</li><li>Symptoms</li><li>Change in disease status</li><li>Morbid events</li></ul>
Individuals: <ul style="list-style-type: none"><li>With anterior eye segment disease or pathology</li></ul>	Interventions of interest are: <ul style="list-style-type: none"><li>Anterior segment optical coherence tomography</li></ul>	Comparators of interest are: <ul style="list-style-type: none"><li>Clinical evaluation</li><li>Slit-lamp biomicroscopy</li><li>Ultrasound biomicroscopy</li></ul>	Relevant outcomes include: <ul style="list-style-type: none"><li>Test accuracy</li><li>Symptoms</li><li>Change in disease status</li><li>Morbid events</li></ul>

### DESCRIPTION

Optical coherence tomography (OCT) is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. OCT of the anterior segment (AS) is being evaluated as a noninvasive diagnostic and screening tool for detecting angle-closure glaucoma, for presurgical evaluation, surgical guidance, and for assessing complications following surgical procedures. It is also being studied as a tool to evaluate the pathologic processes of dry eye syndrome, tumors, uveitis, and infections.

### SUMMARY OF EVIDENCE

For individuals who are being evaluated for angle-closure glaucoma who receive AS OCT, the evidence includes case series and cohort studies. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Current literature consists primarily of assessments of qualitative and quantitative imaging and

detection capabilities. Ideally, a diagnostic test should be evaluated based on its diagnostic accuracy and clinical utility. Studies have shown that 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 clinical follow-up and validation studies, it is not clear to what degree these additional cases are true positives or false positives and, therefore, the specificity and predictive values cannot be determined. The evaluation of diagnostic performance depends, therefore, on evidence that the additional eyes identified with narrow angle by AS OCT are at higher risk for primary angle-closure glaucoma. Results from a study with mid-term follow-up have shown that some patients identified with angle closure on AS OCT will develop angle closure on gonioscopy after several years, but that there may also be a large number of false-positive results. Longer term studies are needed to determine whether eyes classified as closed angle by AS OCT are at higher risk of developing primary angle-closure glaucoma. It is also not known whether early detection of angle closure will improve outcomes in individuals who do not have symptoms of angle closure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who are being evaluated for anterior eye surgery or postsurgical complications who receive AS OCT, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Use of AS OCT has been reported for presurgical evaluation, surgical guidance, and monitoring for postsurgical complications. There is some evidence that the high-resolution images provided by AS OCT are superior to results from slit-lamp examination or gonioscopy for some indications. However, current literature is very limited. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have anterior eye segment disease or pathology who receive AS OCT, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. The evidence related to the use of AS OCT for AS disease or pathology (e.g., dry eye syndrome, tumors, uveitis, infections) is limited, and does not support improvements in imaging compared with alternative diagnostic techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

## **POLICY**

Scanning computerized ophthalmic (e.g., optical coherence tomography) 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

### OPTICAL COHERENCE TOMOGRAPHY

Optical coherence tomography (OCT) is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. OCT 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 6  $\mu\text{m}$  to 25  $\mu\text{m}$ .

The Stratus OCT, which uses a 0.8- $\mu\text{m}$  wavelength light source, was designed to evaluate the optic nerve head, retinal nerve fiber layer, and retinal thickness in the posterior segment. The Zeiss Visante OCT and AC Cornea OCT use a 1.3- $\mu\text{m}$  wavelength light source designed specifically for imaging the anterior eye segment. Light of this wavelength penetrates the sclera, permitting high-resolution cross-sectional imaging of the anterior chamber (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  $\mu\text{m}$ , 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 noninvasive procedure can be conducted by a technician, it has been proposed that this device may provide a rapid diagnostic and screening tool for detecting angle-closure glaucoma.

### OTHER DIAGNOSTIC TOOLS

OCT of the anterior eye segment is being evaluated as a noninvasive diagnostic and screening tool with a number of potential applications. One proposed use of anterior segment OCT is to determine whether there is a narrowing of the AC angle, which could lead to angle-closure glaucoma. Another general area of potential use is as a pre- and postsurgical evaluation tool for of AC procedures. This could include assessment of corneal thickness and opacity, calculation of intraocular lens power, guiding surgery, imaging intracorneal ring segments, and assessing complications following surgical procedures such as blockage of glaucoma tubes or detachment of Descemet membrane following endothelial keratoplasty (see the Endothelial Keratoplasty Protocol). A third general category of use is to image pathologic processes such as dry eye syndrome, tumors, noninfectious uveitis, and infections. It is proposed that AS OCT provides better images than slit-lamp biomicroscopy/gonioscopy and ultrasound biomicroscopy due to higher resolution; in addition, AS OCT does not require probe placement under topical anesthesia.

Alternative methods of evaluating the AC are slit-lamp biomicroscopy or ultrasound biomicroscopy. Slit-lamp biomicroscopy is typically used to evaluate the AC; however, the chamber angle can only be examined with specialized lenses, the most common 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.<sup>1</sup> Ultrasonography uses high-frequency mechanical pulses (10-20 MHz) to build 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  $\mu\text{m}$  but only moderately high intraobserver and low interobserver reproducibility. Ultrasound biomicroscopy ( $\approx$ 50 MHz) has a resolution of 30 to 50  $\mu\text{m}$ . As with slit-lamp biomicroscopy with a gonioscopic mirror, this technique requires placement of a probe under topical anesthesia.

### CLASSIFICATION AND ASSESSMENT OF GLAUCOMA

Glaucoma is characterized by degeneration of the optic nerve.

The classification of glaucoma as open angle or angle closure relies on assessment 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 a factor affecting the drainage of aqueous humor. A wide unobstructed iridocorneal angle permits sufficient drainage of aqueous humor, whereas a narrow angle may impede the drainage system and leave the patient susceptible to an increase in intraocular pressure and angle-closure glaucoma.

A comprehensive ophthalmologic examination for glaucoma includes assessment of the optic nerve and retinal nerve fiber layer, evaluation of visual fields, and measurement of ocular pressure. The presence of characteristic changes in the optic nerve or abnormalities in visual field, together with increased intraocular pressure, is sufficient for a definitive diagnosis of glaucoma.

## REGULATORY STATUS

Multiple OCT systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. Examples of approved systems are the Visante™ OCT (Carl Zeiss Meditec); the RTVue® (Optovue) (FDA product code: HLI); and the Slit Lamp OCT (SL-OCT; Heidelberg Engineering) (FDA product code: MXK). The microscope-integrated OCT devices for intraoperative use include the ReScan 700 (Zeiss) and the iOCT® system (Haag-Streit). Portable devices for intraoperative use include the Bioptigen Envisu™ (Bioptigen) and the Optovue iVue® (Optovue). Ultrahigh resolution OCT devices include the SOCT Copernicus HR (Optopol Technologies).

Commercially available laser systems, such as the LenSx® (Alcon), Catalys® (OptiMedica), and VICTUS® (Technolas Perfect Vision), include OCT to provide image guidance for laser cataract surgery. FDA product code: OOE.

Custom-built devices, which do not require FDA approval, are also used.

The AC Cornea OCT (Ophthalmic Technologies) is not cleared for marketing in the United States.

Table 1. Ocular Imaging Devices Cleared by the US Food and Drug Administration

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Avanti	Optovue Inc.	6/8/2018	K180660	Anterior segment optical coherence tomography
iVue	Optovue Inc.	6/9/2017	K163475	Anterior segment optical coherence tomography
VX130 Ophthalmic Diagnostic Device	LUNEAU SAS	4/24/2017	K162067	Anterior segment optical coherence tomography
LSFG-NAVI	Softcare Co. Ltd	5/12/2016	K153239	Anterior segment optical coherence tomography
RTVue XR OCT Avanti with AngioVue Software	OPTOVUE INC.	2/11/2016	K153080	Anterior segment optical coherence tomography
Pentacam AXL	OCULUS OPTIKGERATE GMBH	1/20/2016	K152311	Anterior segment optical coherence tomography
EnFocus 2300 EnFocus 4400	BIOPTIGEN INC.	12/2/2015	K150722	Anterior segment optical coherence tomography
ARGOS	SANTEC CORPORATION	10/2/2015	K150754	Anterior segment optical coherence tomography
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	Anterior segment optical coherence tomography
PROPPER INSIGHT BINOCULAR	PROPPER MANUFACTURING	9/17/2014	K141638	Anterior segment optical

Device	Manufacturer	Date Cleared	510(k) No.	Indication
INDIRECT OPHTHALMOSCOPE	CO.INC.			coherence tomography
CENTERVUE MACULAR INTEGRITY ASSESSMENT	CENTERVUE SPA	4/23/2014	K133758	Anterior segment optical coherence tomography
AMICO DH-W35 OPHTHALMOSCOPE SERIES	AMICO DIAGNOSTIC INCORPORATED	3/26/2014	K131939	Anterior segment optical coherence tomography
IVUE 500	OPTOVUE INC.	3/19/2014	K133892	Anterior segment optical coherence tomography

## RELATED PROTOCOLS

Aqueous Shunts and Stents for Glaucoma

Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy

Endothelial Keratoplasty

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

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18. National Coverage Determination (NCD) for Ocular Photodynamic Therapy (OPT) (80.2.1), Implementation Date 7/16/2013.