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.

RELATED PROTOCOLS
Aqueous Shunts and Stents for Glaucoma
Corneal Topography/Computer-Assisted Corneal Topography/Photokeratoscopy
Endothelial Keratoplasty

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Individuals: • Who are being evaluated for angle-closure glaucoma</td>
<td>Interventions of interest are: • Anterior segment optical coherence tomography</td>
<td>Comparators of interest are: • Gonioscopy • Ultrasound biomicroscopy</td>
<td>Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events</td>
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<tr>
<td>Individuals: • Who are being evaluated for anterior eye surgery or post-surgical complications</td>
<td>Interventions of interest are: • Anterior segment optical coherence tomography</td>
<td>Comparators of interest are: • Gonioscopy • Slit-lamp biomicroscopy • Scheimpflug imaging • Ultrasound biomicroscopy</td>
<td>Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events</td>
</tr>
<tr>
<td>Individuals: • With anterior eye segment disease or pathology</td>
<td>Interventions of interest are: • Anterior segment optical coherence tomography</td>
<td>Comparators of interest are: • Clinical evaluation • Slit-lamp biomicroscopy • Ultrasound biomicroscopy</td>
<td>Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events</td>
</tr>
</tbody>
</table>

DESCRIPTION
Optical coherence tomography is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. Optical coherence tomography of the anterior segment 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 anterior segment optical coherence tomography, 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 anterior segment optical coherence tomography detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of optical coherence tomography 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 anterior segment optical coherence tomography 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 anterior segment optical coherence tomography 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 anterior segment optical coherence tomography are at higher risk for 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 that the technology results in an improvement in the net health outcome.

For individuals who are being evaluated for anterior eye surgery or postsurgical complications who receive anterior segment optical coherence tomography, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Use of anterior segment optical coherence tomography has been reported for presurgical evaluation, surgical guidance, and monitoring for postsurgical complications. There is some evidence that the high-resolution images provided by anterior segment optical coherence tomography 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 that the technology results in an improvement in the net health outcome.

For individuals who have anterior eye segment disease or pathology who receive anterior segment optical coherence tomography, 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 anterior segment optical coherence tomography for anterior segment 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 that the technology results in an improvement in the net health outcome.

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 is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. Optical coherence tomography 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 μm.

The Stratus optical coherence tomography, which uses a 0.8-μm 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 optical coherence tomography and anterior chamber Cornea optical coherence tomography use a 1.3-μm 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 angle and ciliary body. The light is, however, typically blocked by pigment, preventing exploration behind the iris. Ultrahigh-resolution optical coherence tomography can achieve a spatial resolution of 1.3 μm, allowing imaging and measurement of corneal layers.

An early application of optical coherence tomography 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

Optical coherence tomography 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 optical coherence tomography is to determine whether there is a narrowing of the anterior chamber angle, which could lead to angle-closure glaucoma. Another general area of potential use is as a presurgical and postsurgical evaluation tool for anterior chamber 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 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 anterior segment optical coherence tomography provides better images than slit-lamp biomicroscopy/
gonioscopy and ultrasound biomicroscopy due to higher resolution; in addition, anterior segment optical coherence tomography does not require probe placement under topical anesthesia.

Alternative methods of evaluating the anterior chamber are slit-lamp biomicroscopy or ultrasound biomicroscopy. Slit-lamp biomicroscopy is typically used to evaluate the anterior chamber; however, the chamber angle can only be examined with specialized lenses, the most common being the gonioscopic mirror. In this procedure, a goniolens 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 to 20 MHz) to build 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 μm but only moderately high intraobserver and low interobserver reproducibility. Ultrasound biomicroscopy (>50 MHz) has a resolution of 30 to 50 μm. 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 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 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. 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 optical coherence tomography 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; FDA product code: HLI); the RTVue® (Optovue; FDA product code: OBO) and the Slitlamp optical coherence tomography (SL-OCT; Heidelberg Engineering; FDA product code: MXK).

The microscope-integrated optical coherence tomography devices for intraoperative use include the ReScan 700 (Zeiss; FDA product code: OBO) and the iOCT® system (Haag-Streit).

Portable devices for intraoperative use include the Bioptigen Envisu™ (Bioptigen; FDA product code: HLI) and the Optovue iVue® (Optovue; FDA product code: OBO). Ultrahigh-resolution optical coherence tomography devices include the SOCT Copernicus HR (Optopol Technologies; FDA product code OBO).

Commercially available laser systems, such as the LenSx® (Alcon), Catalys® (OptiMedica), and VICTUS® (Technolas Perfect Vision), include optical coherence tomography 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 anterior chamber Cornea optical coherence tomography (Ophthalmic Technologies) is not cleared for marketing in the United States.
Table 1. Ocular Imaging Devices Cleared by the U.S. Food and Drug Administration

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
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<td>Xephilio OCT-A1</td>
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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.