Optical Coherence Tomography (OCT) of the Anterior Eye Segment

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for anterior eye segment optical imaging. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

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

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<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>
</tr>
<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>
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</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>
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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.

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 technical performance, diagnostic accuracy (sensitivity, specificity, predictive value), and effect on health outcomes. Technically, OCT has the ability to create high-resolution images of the AS. 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 1 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 health 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 anterior segment disease or pathology (eg, dry eye syndrome, tumors, uveitis, infections) is limited, and does not support
improvements in imaging compared to alternative diagnostic techniques. The evidence is insufficient to determine the effects of the technology on health outcomes.

**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 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 OCT, 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 OCT and AC Cornea OCT 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 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 μm, allowing imaging and measurement of corneal layers.

**Applications of OCT**

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 (AS) OCT 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 pre- and postsurgical evaluation tool for of 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 evidence review 9.03.22). 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 (UBM) due to higher resolution; in addition, AS OCT does not require probe placement under topical anesthesia.

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. 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 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 allows sufficient drainage of aqueous humor, whereas a narrow angle may impede the drainage system and leave the patient susceptible to an increase in IOP and angle-closure glaucoma.

A comprehensive ophthalmologic examination for glaucoma includes assessment of the optic nerve and retinal nerve fiber layer (see separate policy on imaging of the optic nerve with posterior segment OCT), 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 (IOP), is sufficient for a definitive diagnosis of glaucoma.

Alternative methods of evaluating the AC are slit-lamp biomicroscopy or UBM. 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. 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 2-dimensional image of the ocular structures. It has a resolution of 100 μm but only moderately high intraobserver and low interobserver reproducibility. UBM (≈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.

Regulatory Status
Multiple optical coherence tomography (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, Toronto, ON) is not cleared for marketing in the United States.

**Rationale**
This evidence review was originally created in December 2007 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through January 25, 2017. Literature searches have found numerous studies that use optical coherence tomography (OCT) to evaluate the anatomy of the anterior segment (AS) of the eye and report qualitative and quantitative imaging and detection capabilities.

Assessment of a diagnostic technology typically focuses on 3 categories of evidence: (1) its technical performance (test-retest reliability or interrater reliability); (2) diagnostic accuracy (sensitivity, specificity, and positive and negative predictive value) in relevant populations of patients; and (3) demonstration that the diagnostic information can be used to improve patient outcomes. In addition, subsequent use of a technology outside of the investigational setting may also be evaluated.

**Angle-closure glaucoma**

**Clinical Context and Test Purpose**
One potential use of AS OCT is to determine whether there is a narrowing of the anterior chamber (AC) angle, which could lead to angle-closure glaucoma. There are 2 scenarios where this might occur: (1) for the diagnosis of angle-closure glaucoma and (2) as a screening method for future angle-closure glaucoma.

The question addressed in this evidence review is: Does OCT of the AC improve health outcomes compared to alternative methods?

The following PICOTS was used to select literature is relevant to the review.

**Patients**
The population of interest is individuals being evaluated for angle-closure glaucoma for diagnosis or screening.

**Interventions**
OCT of the anterior eye segment.

**Comparators**
Alternative tests are gonioscopy or ultrasound biomicroscopy (UBM), which are the commonly used. OCT is proposed to be an improvement over gonioscopy and UBM because OCT has higher resolution and does not require a probe placed under topical anesthesia.
Outcomes
The outcomes of interest are technical performance, including intraobserver and interobserver reliability, diagnostic accuracy compared to other methods, and the effect of the test on health outcomes, including prediction of angle-closure glaucoma, change in glaucoma status, and prevention of glaucoma.

Timing
The appropriate duration of follow-up is the time interval needed to detect the development of an increase in intraocular pressure (IOP) or angle-closure glaucoma. One longitudinal study (Baskaran et al, 2015) reported used a 4-year follow-up after AS OCT. In this study, 17% of participants developed gonioscopic angle closure by 4 years. Longer follow-up would be needed to evaluate the true-positive and false-positive rates.

Setting
This procedure is most likely to be administered in an outpatient facility by an ophthalmologist.

Technical Performance
Maram et al (2014) assessed the reproducibility of angle metrics using the Visante OCT. The ACAC angle from 20 eyes of 20 healthy subjects (open angle) were measured (1) by masked expert graders on 2 occasions, 1 week apart, to assess intraobserver reliability, and (2) by 2 independent reviewers to assess interobserver reliability. Intraobserver reproducibility was high (intraclass correlation coefficients [ICC], ≥0.93), while the interobserver reproducibility was modest (ICC, 0.49-0.82) for measurement of the angle-opening distance, trabecular iris space area, and scleral spur angle. The percent error ranged from 9.29% for the scleral spur angle to 21.18% for the trabecular iris space area.

Diagnostic Accuracy

OCT vs Gonioscopy
A number of studies have compared OCT with gonioscopy for the detection of primary angle closure. For example, Nolan et al (2007) assessed the ability of a Visante OCT prototype to detect primary angle closure in 203 Asian patients. 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 were compared with 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 in 228 eyes with OCT; agreement was obtained between the 2 methods in 143 eyes. Although these results suggested low specificity for OCT, gonioscopy is not considered a criterion standard. The authors suggested 3 possible reasons for the increase in identification of closed angles with OCT: lighting is known to affect angle closure, and the lighting conditions differed for the 2 methods (gonioscopy requires some light); placement of the gonioscopy lens on the globe may have caused distortion of the AS; and landmarks used differed between methods.
Narayanaswamy et al (2010) conducted a community-based cross-sectional study of glaucoma screening. The study population consisted of individuals 50 years or older who underwent AS OCT by a single ophthalmologist and gonioscopy by an ophthalmologist masked to the OCT findings. Individuals were excluded if they had a disease or pathology that could influence the quality of angle imaging by OCT. The angle opening distance (AOD) was calculated at 250, 500, and 750 μm from the scleral spur. Of 2047 individuals examined, 573 (28%) were excluded due to inability to locate the scleral spur, poor image quality, or software delineation errors. Of the remaining 1465 participants, only 315 (21.5%) had narrow angles on gonioscopy. 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 examined the sensitivity and specificity of the Visante OCT using different cutoff values for the AOD measured at 250, 500, and 750 μm from the scleral spur. OCT and gonioscopy records were available for 303 eyes of 155 patients seen at a glaucoma clinic. Blinded analysis showed sensitivity and specificity between 70% and 80% (vs gonioscopy), depending on the AOD and the cutoff value. Correlation coefficients between the qualitative gonioscopy grade and quantitative OCT measurement ranged from 0.75 (AOD=250 μm) to 0.88 (AOD=750 μm). As noted by these investigators, “a truer measure of occludable angles is whether an eye develops angle-closure glaucoma in the future.”

**OCT vs UBM**

Mansouri et al (2010) compared the measurement accuracy of the AC angle by AS OCT and UBM in patients with suspected primary angle closure, primary angle closure, or primary angle-closure glaucoma. In this study, 55 eyes of 33 consecutive patients presenting with the 3 angle closure conditions were examined with OCT and then UBM. The trabecular-iris angle was measured in all 4 quadrants. AOD was measured at 500 μm from the scleral spur. In this comparative study, OCT measurements correlated significantly with UBM measurements but showed poor agreement with each other. The authors did not believe that AS OCT could replace UBM as a tool for assessing quantitatively the AC angle.

**Effect on Health Outcomes**

The clinical utility of OCT is closely related to its ability to accurately diagnose or prevent angle-closure glaucoma, because treatment is generally initiated after confirmation of the diagnosis. Therefore, if OCT is more accurate in diagnosing clinically significant closed angles than alternatives, it can be considered to have clinical utility above that of the alternative tests.

A key question is whether the increase in cases of angle closure identified by AS OCT compared to the current standard of gonioscopy represents true cases of the disease. In 2015, Baskaran et al reported on a comparative cohort study assessing the ability of OCT to predict incident gonioscopic angle closure. A total of 2052 mostly Chinese participants attending a community health center underwent
gonioscopy and AS OCT by examiners masked to the other test. Of the 342 participants evaluable for follow-up at 4 years, 65 had open angles on both tests at baseline (control group) and 277 had open angles on gonioscopy but closed angles determined by OCT at baseline (experimental group). At 4-year follow-up, 48 (17.3%) of the 277 patients in the experimental group had gonioscopic angle closure compared to none of the control group. The incidences of increased IOP and angle-closure glaucoma were not reported.

**Section Summary: Angle-Closure Glaucoma**
A reproducibility study of angle metrics (ie, angle-opening, trabecular-iris space area, scleral spur angle) found high intraobserver reproducibility but modest interobserver reproducibility. In a comparative study, the primary landmark used to measure the AC angle (the scleral spur) could not be identified in a substantial number of eyes with AS OCT.

When compared with gonioscopy, AS OCT measurement of the AC angle detects more narrow angles than gonioscopy. It is not known if these additional cases will lead to angle-closure glaucoma or if early detection will improve health outcomes.

Results from 1 longitudinal study found that OCT detected more cases of mild angle closure than gonioscopy, and that some of these cases would develop angle closure as measured by gonioscopy. However, the study also indicated a potentially high number of false positives, and it is not known whether clinical outcomes would be improved with early monitoring based on AS OCT. Longitudinal studies are needed to determine whether eyes classified as closed by AS OCT, but not by gonioscopy, are at risk of developing primary angle-closure glaucoma.

**Evaluation for Surgery or PostSurgical Complications**

**Clinical Context and Test Purpose**
Another potential use of AS OCT is for evaluation for AC surgical procedures. This could include a wide range of uses, such as the calculation of intraocular lens power, guiding surgery of the AS, imaging intracorneal ring segments, and assessing complications following surgical procedures such as blockage of glaucoma tubes or detachment of Descemet membrane after endothelial keratoplasty.

The question addressed in this evidence review is: Does OCT of the AC improve outcomes compared to alternative methods of assessing the AC?

The following PICOTS was used to select literature relevant to the review.

**Patients**
The population of interest is individuals who undergoing presurgical evaluation, surgical guidance, or postsurgical complications.

**Interventions**
OCT of the anterior eye segment.
Comparators
Alternative tests are clinical evaluation, slit-lamp biomicroscopy, or UBM.

Outcomes
The outcomes of interest are the diagnostic accuracy of OCT in visualizing the AS compared to alternative techniques, and the effect of the test on health outcomes, including successful outcomes for surgery and postsurgical monitoring.

Timing
The duration of follow-up for these studies is short-term efficacy of the surgical procedure or near postoperative evaluation for surgical complications.

Setting
The setting is a surgical suite or outpatient facility with an ophthalmologist.

Technical Performance
No studies on the technical performance of OCT in the setting of ocular surgery were identified.

Diagnostic Accuracy

Aqueous Tube Shunts
One potential application of OCT is visualization for surgical placement of aqueous tube shunts or stents. In 2012, Jiang et al reported on a cross-sectional, observational study of the visualization of aqueous tube shunts by high-resolution OCT, slit-lamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes). High-resolution OCT demonstrated shunt position and patency in all 23 eyes. Compared with slit-lamp, 4 eyes had new findings identified by OCT. For all 16 eyes in which 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 (retrospectively analyzed) in the patient records of the slit-lamp examination.

Endothelial Keratoplasty
Use of OCT is being reported for intraoperative and postoperative evaluation of graft apposition and detachment in endothelial keratoplasty procedures. In 2011, Moutsouris et al reported on a prospective comparison of AS OCT, Scheimpflug imaging, and slit-lamp biomicroscopy in 120 eyes of 110 patients after Descemet membrane endothelial keratoplasty (DMEK). 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 normal corneal clearance by all 3 imaging techniques. The remaining 42 eyes showed persistent stromal edema within the first month, suggesting (partial) graft detachment. Biomicroscopy detected the presence or absence of a graft detachment in 35 eyes. Scheimpflug imaging did not provide additional information over biomicroscopy. In 15 eyes, only OCT discriminated between a “flat” graft detachment and delayed corneal clearance. Thus, of the 42 eyes, OCT
provided added diagnostic value in 36% of cases. This led to further treatment in some of the additional cases. Specifically, a secondary Descemet stripping automated endothelial keratoplasty 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).

**Effect on Health Outcomes**
There is research on the risk-benefit of OCT laser-assisted cataract surgery versus traditional phacoemulsification. AS OCT is also being studied for preoperative evaluation of intraocular lens power as well as postoperative assessment of intraocular stability of phakic lens and optic changes related to intraocular lens or ocular media opacities. AS OCT is also being studied for imaging of intraocular stents and shunts and for imaging of graft detachment. However, it is unclear whether these imaging capabilities would improve health outcomes.

**Section Summary: Evaluation for Surgery or Postsurgical Complications**
The 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, the literature at this time is very limited and there is no clear link between AS OCT and improvements in health outcomes.

**Anterior Eye Segment Disease or Pathology**

**Clinical Context and Test Purpose**
Anterior eye segment diseases represent a varied group of pathologies. AC OCT has been studied in the diagnosis of some of these.

The following PICOTS was used to select literature relevant to the review.

**Patients**
The population of interest is individuals being evaluated for anterior segment disease or pathology.

**Interventions**
OCT of the anterior eye segment.

**Comparators**
Alternative tests are clinical evaluation, slit-lamp biomicroscopy, or UBM.

**Outcomes**
The outcomes of interests are technical performance, diagnostic accuracy, and the effect of the test on health outcomes, including symptoms and functional outcomes.
**Timing**
The duration of follow-up is short-term for diagnosis and treatment.

**Setting**
The setting is an outpatient facility with an ophthalmologist.

**Technical Performance**
No studies specific to the technical performance of OCT in the anterior segment diseases reviewed in this section were identified.

**Diagnostic Accuracy**

**Neoplastic Disease**
Several retrospective studies have compared OCT with UBM for AS tumors. Bianciotto et al (2011) retrospectively analyzed 200 consecutive patients who underwent both AS OCT and UBM for AS tumors.\(^{11}\) When comparing image resolution for the 2 techniques, UBM had overall tumor visualization.

**Uveitis of the AS**
In a study from India, Agarwal et al (2009) evaluated the AC inflammatory reaction by high-speed AS OCT.\(^{12}\) This prospective, nonrandomized, observational case series included 62 eyes of 45 patients. Of 62 eyes, grade 4 aqueous flare was detected by OCT imaging in 7 eyes and clinically in 5 eyes. The authors concluded that AS OCT can detect inflammatory reaction in uveitis and in eyes with decreased corneal clarity.

**Other Indications**
Garcia and Rosen (2008) evaluated the diagnostic performance of the AC Cornea OCT device by comparing image results to UBM in patients with conditions of the AS.\(^{13}\) Patients were recruited from various specialty clinics, and 80 eyes with pathologic conditions involving the anterior ocular segment were included. Comparison of OCT and UBM images showed that, while the AC Cornea OCT has high resolution for the cornea, conjunctiva, iris, and anterior angle, UBM images were also clear for these areas. In addition, UBM 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.

**Effect on Health Outcomes**
The criterion standard for the diagnosis of ocular surface tumors such as ocular surface squamous neoplasia (OSSN) is histologic examination of tissue specimens from excisional biopsy.\(^{14}\) In a 2014 review, Thomas et al noted that noninvasive methods of diagnosing OSSN would be increasingly important as treatment moves toward medical therapy, although future studies would have to evaluate the technical performance and diagnostic accuracy for this indication.\(^{15}\) Additional studies are needed to further evaluate AS OCT for anterior segment disease or pathology and to demonstrate the clinical utility of using OCT for these indications.
Section Summary: Anterior Segment Disease or Pathology
The evidence on use of AS OCT for anterior segment disease or pathology, such as dry eye syndrome, tumors, uveitis, and infections, is limited. The evidence to date does not support an improvement in imaging compared to UBM.

Summary of Evidence
For individuals who are being evaluated for angle-closure glaucoma who receive anterior segment optical coherence tomography (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 technical performance, diagnostic accuracy (sensitivity, specificity, predictive value), and effect on health outcomes. Technically, OCT has the ability to create high-resolution images of the AS. 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 1 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 health 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.

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evidence is insufficient to determine the effects of the technology on health outcomes.

**Supplemental Information**

**Clinical Input From 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 optical coherence tomography (OCT) is investigational. Some reviewers commented that OCT may have application in specific conditions such as globe perforation, anterior segment (iris) tumors, and in the postoperative care of endothelial keratoplasty cases.

**Practice Guidelines and Position Statements**
In 2015, the American Academy of Ophthalmology (AAO) published a preferred practice pattern on primary angle closure.16 AAO stated that gonioscopy of both eyes should be performed on all patients in whom angle closure is suspected and that anterior segment (AS) imaging should be considered when angle anatomy is difficult to assess on gonioscopy. AS imaging methods discussed were ultrasound biomicroscopy, Scheimpflug imaging, and AS optical coherence tomography (OCT). It was noted that AS OCT is limited to evaluating the iridocorneal angle.

**U.S. Preventive Services Task Force Recommendations**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

**Ongoing and Unpublished Clinical Trials**
Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
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<tr>
<td><strong>Ongoing</strong></td>
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<tr>
<td>NCT01746537</td>
<td>A prospective, observational, case series investigating the feasibility of utilizing OCT scans of the anterior chamber of eyes with uveitis</td>
<td>1500</td>
<td>Jun 2018</td>
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<tr>
<td>NCT02542644</td>
<td>Assessment of Corneal Graft Attachment in Patients With Fuchs Endothelial Corneal Dystrophy Following</td>
<td>80</td>
<td>Sep 2018</td>
</tr>
</tbody>
</table>
Descemet's Membrane Endothelial Keratoplasty
Using Ultra-high Resolution Optical Coherence Tomography

NCT: national clinical trial.

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

Billing Coding/Physician Documentation Information

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

H40.20- Primary angle-closure glaucoma code range
State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.