Medical Policy

BlueCross BlueShield of Kansas
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Title: Optical Coherence Tomography (OCT) of the Anterior Eye Segment

Professional
Original Effective Date: January 1, 2011
Revision Date(s): March 28, 2011; July 13, 2012; April 26, 2013; April 14, 2015; April 11, 2018; December 3, 2018; April 24, 2019
Current Effective Date: December 3, 2018

Institutional
Original Effective Date: January 1, 2011
Revision Date(s): March 28, 2011; July 13, 2012; April 26, 2013; April 14, 2015; April 18, 2018; December 3, 2018; April 24, 2019
Current Effective Date: December 3, 2018

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are being evaluated for angle-closure glaucoma	Interventions of interest are: • Anterior segment optical coherence tomography	Comparators of interest are: • Gonioscopy • Ultrasound biomicroscopy	Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events
Individuals: • Who are being evaluated for anterior eye surgery or postsurgical complications	Interventions of interest are: • Anterior segment optical coherence tomography	Comparators of interest are: • Gonioscopy • Slit-lamp biomicroscopy • Scheimpflug imaging • Ultrasound biomicroscopy	Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events

Populations	Interventions	Comparators	Outcomes
Individuals: • With anterior eye segment disease or pathology	Interventions of interest are: • Anterior segment optical coherence tomography	Comparators of interest are: • Clinical evaluation • Slit-lamp biomicroscopy • Ultrasound biomicroscopy	Relevant outcomes include: • Test accuracy • Symptoms • Change in disease status • Morbid events

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 pre-surgical and postsurgical anterior chamber 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.

OBJECTIVE

The objective of this policy is to evaluate whether optical coherence tomography of the anterior eye segment improves health outcomes compared with existing technologies in patients with angle-closure glaucoma, undergoing anterior eye surgery or experiencing postsurgical complications, or anterior eye segment disease or pathology.

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, 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 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 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. 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.[1] 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. 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 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

Device	Manufacturer	Date Cleared	510(k) No.	Indication
Propper Insight Binocular Indirect Ophthalmosope	Propper Manufacturing Co Inc.	9/17/2014	K141638	Anterior segment optical 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 tomogra

POLICY

A. Scanning computerized ophthalmic (eg, OCT) imaging may be **medically necessary** when used to examine the anterior segment structures of the eye for the following conditions:

   1. Narrow angle, suspected narrow angle, and mixed narrow and open angle glaucoma

   2. Iris mass

   3. Presence of corneal edema or opacity that precludes visualization or study of the anterior chamber

B. Scanning computerized ophthalmic (eg, OCT) imaging of the anterior eye segment is considered **experimental / investigational** for all other indications.

Policy Guidelines

1. Both gonioscopy and anterior segment OCT should not be billed concurrently at the same visit with the same diagnosis.

RATIONALE

A search of the MEDLINE database was initially performed in December 2007 and updated periodically using the MEDLINE database. The most recent literature review was performed through January 6, 2019.

Evidence reviews assess whether a medical test is clinically useful. A useful test provides information to make a clinical management decision that improves the net health outcome. That is, the balance of benefits and harms is better when the test is used to manage the condition than when another test or no test is used to manage the condition.

The first step in assessing a medical test is to formulate the clinical context and purpose of the test. The test must be technically reliable, clinically valid, and clinically useful for that purpose. Evidence reviews assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these reviews, and credible information on technical reliability is available from other sources.

Angle-Closure Glaucoma

Clinical Context and Test Purpose

One potential use of anterior segment (AS) optical coherence tomography (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 AS OCT of the AC improve health outcomes compared with alternative methods in those with glaucoma?

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 as part of a diagnostic or screening test.

Interventions

The test being considered is 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 the diagnostic accuracy of AS OCT compared with 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 or angle-closure glaucoma. One longitudinal study (Baskaran et al, 2015) reported on 4-year follow-up after AS OCT.[2,] 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.

Simplifying Test Terms

There are 3 core characteristics for assessing a medical test. Whether imaging, laboratory, or other, all medical tests must be:

- Technically reliable
- Clinically valid
- Clinically useful.

Because different specialties may use different terms for the same concept, we are highlighting the core characteristics. The core characteristics also apply to different uses of tests, such as diagnosis, prognosis, and monitoring treatment.

Diagnostic tests detect presence or absence of a condition. Surveillance and treatment monitoring are essentially diagnostic tests over a time frame. Surveillance to see whether a condition develops or progresses is a type of detection. Treatment monitoring is also a type of detection because the purpose is to see if treatment is associated with the disappearance, regression, or progression of the condition.

Prognostic tests predict the risk of developing a condition in the future. Tests to predict response to therapy are also prognostic. Response to therapy is a type of condition and can be either a beneficial response or adverse response. The term predictive test is often used to refer to response to therapy. To simplify terms, we use prognostic to refer both to predicting a future condition or to predicting a response to therapy.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

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.[3,] 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.[4,] 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.[5,] 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."

Table 2. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants	Treatment1	Treatment2	Follow Up
Nolan (2007)	Prospective, observational case series	Singapore	NR	Patients with suspected or confirmed primary angle closure (n=200 patient, 342 eyes)	AS-OCT	Gonioscopy	NR
Narayanaswamy (2010)	Cross-sectional	Singapore	NR	Patients age 50 years with phakic eyes (n=1465)	AS-OCT	Gonioscopy	NR

NR: not reported; AS-OCT: anterior segment optical coherence technology.

Table 3. Summary of Key Nonrandomized Study Results

Study	Detection of Angle Closure 1 Quadrants	Specificity with Gonioscopy as the Reference Standard.	AUC for AOD750 in the Nasal Quadrant	AUC for AOD750 in the Temporal Quadrant
Nolan (2007)				
AS-OCT	142 (71%) patients	55.40%		
	228 (66.7%) eyes			
Gonioscopy	99 (49.5%) patients			
	152 (44.4%) eyes			
Narayanaswamy (2010)			0.9	0.91
95% CI			0.89-0.92	0.90-0.93

AUC: area under the receiver operating characteristic curve; AOD750: angle opening distance at 750 µm.

OCT vs UBM

Mansouri et al (2010) compared the measurement accuracy of the AC angle by AS OCT with UBM in patients with suspected primary angle-closure, primary angle-closure, or primary angle-closure glaucoma.[6,] 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 concluded that AS OCT could replace UBM as a tool for assessing quantitatively the AC angle.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

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 with the current standard of gonioscopy represents true cases of the disease. Baskaran et al (2015) reported on a comparative cohort study assessing the ability of OCT to predict incident gonioscopic angle closure.[2,] 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 with none of the control group. The incidences of increased intraocular pressure and angle-closure glaucoma were not reported.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. A chain of evidence cannot be constructed to link use of AS OCT of the AC to improved health outcomes compared with alternative methods in individuals with glaucoma.

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 whether these additional cases will lead to angle-closure glaucoma or if early detection will improve health outcomes

Results from a 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 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 AS OCT of the AC improve outcomes compared with alternative methods of assessing the AC for those who will or have had eye surgery?

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

The test being considered is 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 with 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.

Technically Reliable

Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid

A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Aqueous Tube Shunts
One potential application of OCT is visualization for surgical placement of aqueous tube shunts or stents. Jiang et al (2012) 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).[7,] 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 scar tissue 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. Moutsouris et al (2011) 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.[8,] 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 Descemet membrane endothelial keratoplasty 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).

Other Indications
Venincasa et al (2017) reported on combining grayscale and color images captured using AS OCT for of preparing for eye surgery.[9,] Viewing an image in different colors provides different perspectives. The authors of this retrospective study determined that while grayscale is good for mapping extraocular muscle structures, the addition of color can improve the accuracy in finding the ideal point of insertion. Accuracy was measured as being within 1.00 mm of the intraoperative caliper measurement. One hundred thirty-nine AS OCT images were collected from 74 patients. When using grayscale and color imaging, AS OCT accuracy increased from 77% to 87%. Accuracy was lower (ie, falling outside the 1.00-mm range) when applying this practice to reoperations. The authors concluded that, especially for first time surgeries, use of combination imaging could be clinically useful.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

There is literature review on the risk-benefit of OCT laser-assisted cataract surgery vs traditional phacoemulsification.[10,] OCT has found increasing roles in both preoperative surgical planning and postoperative evaluation and management for cataract surgery. However, additional studies are required to establish how OCT should be used to manage cataract surgery.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility.

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, current literature is very limited and there is no clear link between AS OCT and improvements in health outcomes.

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

The question addressed in this evidence review is: Does AS OCT of the AC improve outcomes compared with alternative methods of assessing anterior eye segment diseases or pathology?

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

Patients
The population of interest is individuals being evaluated for AS disease or pathology.

Interventions
The test being considered is OCT of the anterior eye segment.

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

Outcomes
The outcomes of interests are 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.

Technically Reliable
Assessment of technical reliability focuses on specific tests and operators and requires review of unpublished and often proprietary information. Review of specific tests, operators, and unpublished data are outside the scope of this evidence review and alternative sources exist. This evidence review focuses on the clinical validity and clinical utility.

Clinically Valid
A test must detect the presence or absence of a condition, the risk of developing a condition in the future, or treatment response (beneficial or adverse).

Neoplastic Disease
Several retrospective studies have compared OCT with UBM for assessing AS tumors. Bianciotto et al (2011) retrospectively analyzed 200 consecutive patients who underwent both AS OCT and UBM for AS tumors.[11,] When comparing the image resolution of 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 with UBM in patients who had 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.

Clinically Useful
A test is clinically useful if the use of the results informs management decisions that improve the net health outcome of care. The net health outcome can be improved if patients receive correct therapy, or more effective therapy, or avoid unnecessary therapy, or avoid unnecessary testing.

Direct Evidence
Direct evidence of clinical utility is provided by studies that have compared health outcomes for patients managed with and without the test. Because these are intervention studies, the preferred evidence would be from randomized controlled trials.

The criterion standard for the diagnosis of ocular surface tumors such as ocular surface squamous neoplasia is histologic examination of tissue specimens from excisional biopsy.[14,] In a review, Thomas et al (2014) noted that noninvasive methods of diagnosing ocular surface squamous neoplasia would be increasingly important as treatment moves toward medical therapy, although future studies would have to evaluate the diagnostic accuracy for this indication.[15,] Additional studies are needed to further evaluate AS OCT for AS disease or pathology and to demonstrate the clinical utility of using OCT for these indications.

Chain of Evidence
Indirect evidence on clinical utility rests on clinical validity. If the evidence is insufficient to demonstrate test performance, no inferences can be made about clinical utility. A chain of evidence cannot be constructed to link use of AS OCT of the AC to improved health outcomes compared with alternative methods in individuals with AS disease or pathology.

Section Summary: Anterior Segment Disease or Pathology
The evidence on use of AS OCT for AS disease or pathology, such as dry eye syndrome, tumors, uveitis, and infections, is limited. The evidence to date does not support an improvement using imaging compared with UBM.

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 (eg, 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.

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 this technique is investigational. Some reviewers commented that this technique 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 published a preferred practice pattern on primary angle closure.[16] The Academy stated that gonioscopy of both eyes should be performed on all patients in whom angle closure is suspected and that 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 OCT. It was noted that AS OCT is limited to evaluating the iridocorneal angle.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

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

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01746537	A prospective, observational, case series investigating the feasibility of utilizing OCT scans of the anterior chamber of eyes with uveitis	1500	Jun 2018 (ongoing)
NCT02542644	Assessment of Corneal Graft Attachment in Patients With Fuchs Endothelial Corneal Dystrophy Following Descemet's Membrane Endothelial Keratoplasty Using Ultra-high Resolution Optical Coherence Tomography	80	Dec 2020

NCT: national clinical trial.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

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

ICD-10 Diagnoses

C79.89	Secondary malignant neoplasm of other specified sites
D48.7	Neoplasm of uncertain behavior or other specified sites
H17.11	Central corneal opacity, right eye
H17.12	Central corneal opacity, left eye
H17.13	Central corneal opacity, bilateral
H17.811	Minor opacity of cornea, right eye
H17.812	Minor opacity of cornea, left eye
H17.813	Minor opacity of cornea, bilateral
H17.821	Peripheral opacity of cornea, right eye
H17.822	Peripheral opacity of cornea, left eye
H17.823	Peripheral opacity of cornea, bilateral
H17.89	Other corneal scars and opacities
H18.011	Anterior corneal pigmentations, right eye
H18.012	Anterior corneal pigmentations, right eye
H18.013	Anterior corneal pigmentations, bilateral
H18.20	Unspecified corneal edema
H18.211	Corneal edema secondary to contact lens, right eye
H18.212	Corneal edema secondary to contact lens, left eye
H18.213	Corneal edema secondary to contact lens, bilateral
H18.221	Idiopathic corneal edema, right eye
H18.222	Idiopathic corneal edema, right eye
H18.223	Idiopathic corneal edema, bilateral
H18.231	Secondary corneal edema, right eye
H18.232	Secondary corneal edema, left eye
H18.233	Secondary corneal edema, bilateral
H18.30	Unspecified corneal membrane change
H21.231	Degeneration of iris (pigmentary), right eye
H21.232	Degeneration of iris (pigmentary), left eye
H21.233	Degeneration of iris (pigmentary), bilateral
H21.301	Idiopathic cysts of iris, ciliary body or anterior chamber, right eye
H21.302	Idiopathic cysts of iris, ciliary body or anterior chamber, left eye
H21.303	Idiopathic cysts of iris, ciliary body or anterior chamber, bilateral
H21.311	Exudative cysts of iris or anterior chamber, right eye
H21.312	Exudative cysts of iris or anterior chamber, left eye
H21.313	Exudative cysts of iris or anterior chamber, bilateral
H21.321	Implantation cysts of iris, ciliary body or anterior chamber, right eye

H21.322	Implantation cysts of iris, ciliary body or anterior chamber, left eye
H21.323	Implantation cysts of iris, ciliary body or anterior chamber, bilateral
H21.82	Plateau iris syndrome (post-iridectomy) (postprocedural)
H40.011	Open angle with borderline findings, low risk, right eye
H40.012	Open angle with borderline findings, low risk, left eye
H40.013	Open angle with borderline findings, low risk, bilateral
H40.021	Open angle with borderline findings, high risk, right eye
H40.022	Open angle with borderline findings, high risk, left eye
H40.023	Open angle with borderline findings, high risk, bilateral
H40.031	Anatomical narrow angle, right eye
H40.032	Anatomical narrow angle, left eye
H40.033	Anatomical narrow angle, bilateral
H40.10X0	Unspecified open-angle glaucoma, stage unspecified
H40.10X1	Unspecified open-angle glaucoma, mild stage
H40.10X2	Unspecified open-angle glaucoma, moderate stage
H40.10X3	Unspecified open-angle glaucoma, severe stage
H40.1110	Primary open-angle glaucoma, right eye, stage unspecified
H40.1111	Primary open-angle glaucoma, right eye, mild stage
H40.1112	Primary open-angle glaucoma, right eye, moderate stage
H40.1113	Primary open-angle glaucoma, right eye, severe stage
H40.1120	Primary open-angle glaucoma, left eye, stage unspecified
H40.1121	Primary open-angle glaucoma, left eye, mild stage
H40.1122	Primary open-angle glaucoma, left eye, moderate stage
H40.1123	Primary open-angle glaucoma, left eye, severe stage
H40.1130	Primary open-angle glaucoma, bilateral, stage unspecified
H40.1131	Primary open-angle glaucoma, bilateral, mild stage
H40.1132	Primary open-angle glaucoma, bilateral, moderate stage
H40.1133	Primary open-angle glaucoma, bilateral, severe stage
H40.1411	Capsular glaucoma with pseudoexfoliation of lens, right eye, mild stage
H40.1412	Capsular glaucoma with pseudoexfoliation of lens, right eye, moderate stage
H40.1413	Capsular glaucoma with pseudoexfoliation of lens, right eye, severe stage
H40.1414	Capsular glaucoma with pseudoexfoliation of lens, right eye, indeterminate stage
H40.1421	Capsular glaucoma with pseudoexfoliation of lens, left eye, mild stage
H40.1422	Capsular glaucoma with pseudoexfoliation of lens, left eye, moderate stage
H40.1423	Capsular glaucoma with pseudoexfoliation of lens, left eye, severe stage
H40.1424	Capsular glaucoma with pseudoexfoliation of lens, left eye, indeterminate stage
H40.1431	Capsular glaucoma with pseudoexfoliation of lens, bilateral, mild stage
H40.1432	Capsular glaucoma with pseudoexfoliation of lens, bilateral, moderate stage
H40.1433	Capsular glaucoma with pseudoexfoliation of lens, bilateral, severe stage
H40.1434	Capsular glaucoma with pseudoexfoliation of lens, bilateral, indeterminate stage

REVISIONS

03-28-2011	Policy added to the bcbsks.com web site.
07-13-2012	Medical Policy Title has been updated from "Anterior Eye Segment Optical Imaging" to "Optical Coherence Tomography (OCT) of the Anterior Eye Segment"
	Description section updated.
	Rationale section updated.

	Reference section updated.
04-26-2013	Updated Description section.
	Updated Rationale section.
	Updated Reference section.
04-14-2015	Updated Description section.
	Updated Rationale section.
	Updated References section.
04-11-2018	Updated Description section.
	Updated Rationale section.
	Updated References section.
12-03-2018	Policy published to the bcbsks.com website on 11-20-2018 with an effective date of 12-03-2018.
	In Policy section: ▪ Removed previous policy language, "Scanning computerized ophthalmic (eg, optical coherence tomography) imaging of the anterior eye segment is considered experimental / investigational." and replaced with, "A. Scanning computerized ophthalmic (eg, OCT) imaging may be medically necessary when used to examine the anterior segment structures of the eye for the following conditions: 1. Narrow angle, suspected narrow angle, and mixed narrow and open angle glaucoma, 2. Determine the proper intraocular lens for a patient who has had prior refractive surgery and now requires cataract extraction (see Policy Guidelines) 3. Iris mass, 4. Presence of corneal edema or opacity that precludes visualization or study of the anterior chamber, 5. Calculation of lens power for cataract patients who have undergone prior refractive surgery. Additional documentation of prior refractive procedure will be available (see Policy Guidelines). B. Scanning computerized ophthalmic (eg, OCT) imaging of the anterior eye segment is considered experimental / investigational for all other indications. ▪ Added Policy Guidelines.
	Updated Rationale section.
	In Coding section: ▪ Added ICD-10 codes.
	Updated References section.
04-24-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

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