Medical Policy

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(See policy history boxes for previous effective dates)

Title: Optical Coherence Tomography Imaging, Anterior Eye

Description/Background

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.

OPTICAL COHERENCE TOMOGRAPHY
Optical coherence tomography (OCT) is a noninvasive high-resolution imaging method that can be used to visualize ocular structures. OCT creates an image of light reflected from the ocular structures. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the two beams (reflected and reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 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 of 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 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 non-invasive 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 presurgical and postsurgical evaluation tool for 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 anterior chamber are slit-lamp biomicroscopy or UBM. Slit lamp biomicroscopy is typically used to evaluate the anterior chamber (AC); however, the chamber angle can only be examined with specialized lenses, the most common of these being the gonioscopic mirror. In this procedure, a gonio lens is applied to the surface of the cornea, which may result in distortion of the globe. Ultrasonography may also be used for imaging the anterior eye segment.(1) Ultrasonography uses high-frequency mechanical pulses (10 to 20 MHz) to build up 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 two-dimensional image of the ocular structures. It has a resolution of 100 microns but only moderately high intra-observer and low inter-observer reproducibility. Ultrasound biomicroscopy (approximately 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 (see evidence review 9.03.06 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, 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; FDA product code: HLI); the RTVue® (Optovue; FDA product code: OBO); 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; FDA product code: OBO).

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 Anterior Chamber 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.	Product Code	Indication
3D optical coherence tomography 3D OCT-1 (type: Maestro2)	Topcon Corporation	10/30/2023	K231222	OBO, HKI	Anterior segment optical coherence tomography
SOLIX	Optovue, Inc.	11/9/2022	K222166	OBO, HKI, HLI	Anterior segment optical coherence tomography
Tomey Cornea/Anterior Segment OCT CASIA2	Tomey Corporation	4/27/2022	K213265	OBO	Anterior segment optical coherence tomography
Anterion	Heidelberg Engineering GmbH	11/5/21	K211817	OBO	Anterior segment optical coherence tomography
Pentacam AXL Wave	Oculus Optikgerate GmbH	10/21/20	K201724	MXK	Anterior segment optical coherence tomography
Xephilio OCT-A1	Canon	7/24/19	K182942	OBO, HLI	Anterior segment optical coherence tomography
Avanti	Optovue Inc.	6/8/2018	K180660	OBO	Anterior segment optical coherence tomography
iVue	Optovue Inc.	6/9/2017	K163475	OBO	Anterior segment optical coherence tomography
VX130 Ophthalmic Diagnostic Device	LUNEAU SAS	4/24/2017	K162067	HKX	Anterior segment optical coherence tomography
LSFG-NAVI	Softcare Co. Ltd	5/12/2016	K153239	HKI	Anterior segment optical coherence tomography
RTVue XR OCT Avanti with AngioVue Software	Optovue Inc.	2/11/2016	K153080	HLI	Anterior segment optical coherence tomography

Pentacam AXL	Oculus Optikgerate GMBH	1/20/16	K152311	MXK	Anterior segment optical coherence tomography
EnFocus 2300 EnFocus 4400	Bioptigen Inc.	12/2/2015	K150722	HLI	Anterior segment optical coherence tomography
Argos	Santec Corporation	10/2/2015	K150754	MXK	Anterior segment optical coherence tomography
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	HLI	Anterior segment optical coherence tomography
Propper Insight Binocular Indirect Opthalmosope	Propper manufacturing Co. Inc.	9/17/2014	K141638	HLI	Anterior segment optical coherence tomography
Centervue Macular Integrity Assessment	Centervue Spa	4/23/2014	K133758	HLI	Anterior segment optical coherence tomography
Amico DH-W35 Ophthalmoscope Series	Amico Diagnostic Incorporated	3/26/2014	K131939	HLI	Anterior segment optical coherence tomography
IVUE 500	Optovue Inc.	3/19/2014	K133892	HLI	Anterior segment optical coherence tomography

Medical Policy Statement

Optical coherence tomography (OCT) imaging of the anterior segment of the eye is considered experimental/ investigational. The clinical evidence is insufficient to support the use of OCT as a primary diagnostic tool, and clinical literature does not indicate that OCT elicits better clinical outcomes or is as effective as current practice standards.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

92132

Rationale

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 two 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 following PICOs were used to select literature to inform this review.

Populations

The relevant 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.

Beneficial outcomes include accurate diagnosis of angle-closure glaucoma and change in glaucoma status leading to proper treatment or prevention of glaucoma. Harmful outcomes would include optical coherence tomography's inability to detect angle-closure glaucoma or glaucoma status, resulting in improper treatment or no treatment.

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 reported on four-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.

Study Selection Criteria

Below are selection criteria for studies to assess whether a test is clinically valid.

- The study population represents the population of interest. Eligibility and selection are described.
- The test is compared with a credible reference standard.

- If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
- Studies should report sensitivity, specificity, and predictive values. Studies that completely report true- and false positive results are ideal. Studies reporting other measures (e.g., receiver operating characteristics [ROC], area under the receiver operating characteristic curve [AUROC], c-statistic, likelihood ratios) may be included but are less informative.
- Studies should also report reclassification of diagnostic or risk category.

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).

Ocular Coherence Tomography Versus Gonioscopy

Systematic Reviews
Desmond et al (2021) performed a systematic review and meta-analysis of literature that compared the accuracy of anterior segment optical coherence tomography against gonioscopy in detecting eyes with angle closure.(3) A literature search was performed in April 2020 resulting in the inclusion of 23 studies (N=5663). Only studies that provided enough data to determine the sensitivity and specificity of anterior segment optical coherence tomography and assessed the ability to detect an eye with angle closure were included. Eighteen studies were conducted in Asia, 3 in the United States, and 2 in the United Kingdom. There was substantial variation in the assessed parameters and methodology among the studies including the use of different optical coherence tomography devices, gonioscopy diagnostic criteria, and anterior segment optical coherence tomography positivity threshold. The sensitivity of anterior segment optical coherence tomography ranged from 46% to 100% (median, 87%) with a specificity ranging from 55.3% to 100% (median, 84%). Of the 4 studies with the best diagnostic accuracy for anterior segment optical coherence tomography, all used a case-control study design with a high risk of bias. Overall, the authors concluded that anterior segment optical coherence tomography demonstrates "good sensitivity for detecting angle closure"; however, it is not yet "able to replace gonioscopy" and further studies are required to better determine its utility.

Nonrandomized Studies
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 prototype of the Visante OCT to detect primary angle closure in 203 Asian patients.(4) 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.(5) The study population consisted of individuals 50 years or older who underwent anterior segment 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.

Pekmezci et al (2009) examined the sensitivity and specificity of the Visante OCT using different cut-off values for the AOD measured at 250, 500, and 750 µm from the scleral spur.(6) 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% (in comparison with gonioscopy), depending on the AOD and the cut-off value. Correlation coefficients between the qualitative gonioscopy grade and quantitative OCT measurement ranged from 0.75 (AOD 250) to 0.88 (AOD 750). 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	Treatment 1	Treatment 2	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

AUROC: area under the receiver operating characteristic curve: AOD750: angle opening distance at the 750 µm. AS-OCT: anterior segment optical coherence technology; CI: confidence interval.

Optical Coherence Tomography Versus Ultrasound Biomicroscopy

Mansouri et al (2010) compared the measurement accuracy of the AC angle by AS OCT with ultrasound biomicroscopy (UBM) in patients with suspected primary angle-closure, primary angle-closure, or primary angle-closure glaucoma.(7) 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 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 anterior segment 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 four 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 four-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 anterior segment OCT of the AC to improved health outcomes compared with alternative methods in individuals with glaucoma.

Section Summary: Angle-Closure Glaucoma
A systematic review and meta-analysis compared the accuracy of anterior segment optical coherence tomography against gonioscopy in detecting eyes with angle closure. Results revealed that anterior segment optical coherence tomography demonstrated good sensitivity for detecting angle closure but insufficient to replace gonioscopy as a standard of care.

A reproducibility study of angle metrics (i.e., 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 anterior segment OCT.

When compared with gonioscopy, anterior segment 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 anterior segment OCT. Longitudinal studies are needed to determine whether eyes classified as closed by anterior segment 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 anterior segment 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 anterior segment, to image intracorneal ring segments, and assessing complications following surgical procedures such as blockage of glaucoma tubes or detachment of Descemet membrane after endothelial keratoplasty.

The following PICOs were used to select literature to inform this review.

Populations

The relevant population of interest is individuals who are 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, Scheimpflug imaging, or ultra biomicroscopy.

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. Harmful outcomes would include optical coherence tomography's inability to detect angle-closure glaucoma or to properly guide surgery, resulting in surgical errors, complications, and possible infection.

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

Study Selection Criteria
Selection criteria for studies to assess whether a test is clinically valid are described in the first indication.

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 for the visualization of aqueous tube shunts or stents. In 2012, Jiang et al reported 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).(8) High-resolution OCT demonstrated shunt position and patency in all 23 eyes. Compared with slit lamp, four 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. 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.(9) 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).

Posterior Capsular Dehiscence
Dhanaseelan et al (2023) reported on the role of AS-OCT in assessing preoperative posterior capsular dehiscence in patients undergoing planned cataract surgery in a retrospective, single-center study.(10) One hundred patients who underwent cataract surgery were included. Of those 100, AS-OCT preoperatively identified 14 (14%) to have preoperative posterior capsular defect. Intraoperatively, posterior capsular rupture was observed in 13 patients and cortex drop was noted in 1 among those 13. Out of the 13 posterior capsular rupture cases, 12 were identified by AS-OCT to have preoperative posterior capsular dehiscence. The sensitivity of AS-OCT for detection of posterior capsule dehiscence was 92.3% and specificity was 97.7%. The positive predictive value (PPV) and negative predictive value (NPV) were 85.7% and 98.8%, respectively. Another study by Sarkar and Das (2023) conducted a similar,

observational study undergoing planned cataract surgery.(11) Forty-four eyes were included; out of those, AS-OCT found that 9 (20.5%) had preoperative posterior capsular dehiscence. Of those 9 eyes, 7 (77.8%) had intraoperative posterior capsule rupture and 2 (22.2%) did not. The sensitivity, specificity, PPV, and NPV for AS-OCT detecting dehiscence were 94.4%, 87.5%, 97.1%, and 77.8%, respectively. The authors calculated that the diagnostic accuracy of AS-OCT was 95.45%. The small sample sizes and the lack of a comparator limit the conclusions that can be drawn from these studies.

Other Indications

Venincasa et al (2017) reported on combining grayscale and color images captured using anterior segment OCT to prepare for eye surgery.(12) 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 (i.e., 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 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 on the risk-benefit of OCT laser-assisted cataract surgery vs traditional phacoemulsification.(13) 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.

Anterior segment OCT is also being studied for preoperative evaluation of intraocular lens power postoperative assessment of intraocular stability of phakic lens and optic changes related to intraocular lens or ocular media opacities 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 anterior segment 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 anterior segment 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 anterior segment 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. Anterior segment OCT has been studied in the diagnosis of some of these.

The following PICOs were used to select literature to inform this review.

Populations
The relevant population of interest is individuals being evaluated for anterior segment 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 ultrasound biomicroscopy.

Outcomes
The outcomes of interest are diagnostic accuracy and the effect of the test on health outcomes including symptoms and functional outcomes.

Beneficial outcomes would include correct diagnosis and treatment. Harmful outcomes would include optical coherence tomography's inability to accurately detect pathology, leading to incorrect or no treatment.

The duration of follow-up is short-term, for diagnosis and treatment.

Study Selection Criteria
Selection criteria for studies to assess whether a test is clinically valid are discussed in the first indication.

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 anterior segment tumors. Bianciotto et al (2011) retrospectively analyzed 200 consecutive patients who underwent both anterior segment OCT and UBM for anterior segment tumors.(14) When comparing the image resolution of the two techniques, UBM had better overall tumor visualization.

Uveitis of the Anterior Segment

In a study from India, Agarwal et al (2009) evaluated the anterior chamber inflammatory reaction by anterior segment high-speed anterior segment OCT.(15) This prospective, nonrandomized, observational case series of 62 eyes of 45 patients. Of 62 eyes, grade IV aqueous flare was detected by OCT imaging in seven eyes and clinically in five eyes. The authors concluded that anterior segment 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 anterior chamber Cornea OCT by comparing image results with UBM in patients with conditions of the anterior segment.(16) 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 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.(17) 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.(18) 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.

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 anterior segment OCT of the AC to improved health outcomes compared with alternative methods in individuals with anterior segment disease or pathology.

Section Summary: Anterior Segment Disease or Pathology

The evidence on use of anterior segment 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 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 a systematic review, 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 OCT detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of OCT may be 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 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 anterior segment 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 anterior segment 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 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 OCT, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Use of anterior segment 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 anterior segment 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 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 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 anterior segment OCT 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.

Supplemental Information

CLINICAL INPUT RECEIVED THROUGH 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.

2011 Input

In response to requests, Blue Cross Blue Shield Association received input 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

American Academy of Ophthalmology

The American Academy of Ophthalmology (2020) published a preferred practice pattern on primary angle closure disease.(19) The Academy stated that gonioscopy of both eyes should be performed on all patients in whom primary angle closure disease is suspected to evaluate the angle anatomy, including the presence of iridotrabecular contact and/or peripheral anterior synechiae, and plateau iris configuration. Anterior segment imaging may be a useful adjunct to gonioscopy and is particularly helpful when the ability to perform gonioscopy is precluded by corneal disease or poor patient cooperation. Although anterior segment optical coherence tomography can be very useful, it has limitations in evaluating the angle. Neither the posterior aspect of the iris nor the ciliary body are well imaged with anterior segment optical coherence tomography, reducing the utility of this approach in evaluating plateau iris configuration or ciliary body abnormalities. Isolated peripheral anterior synechiae or small tufts of neovascularization may be missed if not in the plane imaged by anterior segment optical coherence tomography.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this review are listed in Table 4.

Table 4. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03461978	Ultrahigh-resolution Optical Coherence Tomography Imaging of the Anterior Eye Segment Structures - a Pilot Study	60	Oct 2023 (enrolling by invitation)
NCT01746537	Automated Analysis of Anterior Chamber Inflammation by Optical Coherence Tomography	1500	Jun 2023 (recruiting)
NCT00532051	Guiding the Treatment of Anterior Eye Diseases With Optical Coherence Tomography	690	July 2025
Unpublished			
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	12	Mar 2022
	Role of Anterior Segment Optical Coherence	23	Dec 2021

NCT04969640	Tomography in Staging and Evaluation of Treatment Response in Infectious Keratitis

NCT: national clinical trial

Government Regulations

National:

There is no National Coverage Determination on this topic.

Local:

There is a Local Coverage Determination on this topic, "**Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI)**." LCD L34760, Original Effective Date 10/01/15, Revision Effective Date 6/29/23:

Medicare will consider scanning computerized ophthalmic diagnostic imaging (SCODI) medically reasonable and necessary in evaluating retinal disorders, glaucoma and anterior segment disorders as documented in this local coverage determination (LCD).

SCODI includes the following tests:

- **Confocal Laser Scanning Ophthalmoscopy (topography)** uses stereoscopic videographic digitized images to make quantitative topographic measurements of the optic nerve head and surrounding retina.
- **Scanning Laser Polarimetry (nerve fiber analyzer)** measures change in the linear polarization of light (retardation). It uses both a polarimeter (an optical device to measure linear polarization change) and a scanning laser ophthalmoscope, to measure the thickness of the nerve fiber layer of the retina.
- **Optical Coherence Tomography (OCT)** a non-invasive, non-contact imaging technique.

Anterior Segment Disorders

SCODI may be used to examine the structures in the anterior segment structures of the eye. However, it is still seen as experimental/investigational except in the following:

1. Narrow angle, suspected narrow angle, and mixed narrow and open angle glaucoma
2. Determining the proper intraocular lens for a patient who has had prior refractive surgery and now requires cataract extraction
3. Iris tumor
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. Payment will only be made for the cataract codes as long as additional documentation is available in the patient record of their prior refractive procedure. Payment will not be made in addition to A-scan or IOL master.

LCA: **"Independent Diagnostic Testing Facilities – physician supervision and technician requirements (A54953)"**; Original effective date: 4/1/16; Revision effective date: 6/29/23

This article is a list of diagnostic services that may be performed in an Independent Diagnostic Testing Facilities (IDTF) provided they have the appropriate physician supervision and technician requirements. The CPT codes in this document do not imply coverage of the

procedure. All of the procedure codes are subject to Medicare rules and regulations, applicable Local Coverage Decisions (LCD's), and medical necessity.

CPT/HCPCS Codes	Description	Supervising physician Qualification Requirements	Technician Qualification
92132	Cmptr ophth dx img ant segmt	Ophthalmologist or Optometrist	Credentialed by JCAHPO: COMT

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Aqueous Shunts and Stents for Glaucoma
Corneal Hysteresis Measurement for Glaucoma
Home Monitoring Device for Age-Related Macular Degeneration
Ophthalmologic Techniques that Evaluate the Posterior Segment for Glaucoma

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through August 1, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/08	5/19/08	7/1/08	Joint policy established
7/1/09	4/21/09	5/11/09	Routine maintenance
5/1/11	2/15/11	3/3/11	Routine maintenance; deleted code 0187T; added code 92132; added “glaucoma” in diagnosis section; updated references; expanded rationale section
9/1/12	6/12/12	6/19/12	Routine maintenance; added additional references and expanded rationale.
3/1/14	12/10/13	1/6/14	Routine maintenance
9/1/15	6/16/15	7/16/15	Updated Medicare information to reflect coverage of 92132; updated references and rationale
9/1/16	6/21/16	6/21/16	Routine policy maintenance. No change in policy status.
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance
1/1/22	10/19/21		Routine maintenance
1/1/23	10/18/22		Routine maintenance (slp)
1/1/24	10/17/23		Routine maintenance (slp) Vendor managed: N/A
1/1/25	10/15/24		Routine maintenance (slp) Vendor managed: N/A

Next Review Date: 4th Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OPTICAL COHERENCE TOMOGRAPHY IMAGING, ANTERIOR EYE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.