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Optical Coherence Tomography of the Anterior Eye Segment

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

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Coverage

Scanning computerized ophthalmic imaging (e.g., optical coherence tomography) of the anterior eye segment **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Optical Coherence Tomography
Optical coherence tomography is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. Optical coherence tomography creates an image of light reflected from the ocular structures. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the 2 beams (reflected and

reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 to 25 µm.

The Stratus optical coherence tomography, which uses a 0.8-µm wavelength light source, was designed to evaluate the optic nerve head, retinal nerve fiber layer, and retinal thickness in the posterior segment. The Zeiss Visante optical coherence tomography and anterior chamber Cornea optical coherence tomography use a 1.3-µm wavelength light source designed specifically for imaging the anterior eye segment. Light of this wavelength penetrates the sclera, permitting high-resolution cross-sectional imaging of the anterior chamber angle and ciliary body. The light is, however, typically blocked by pigment, preventing exploration behind the iris. Ultrahigh-resolution optical coherence tomography can achieve a spatial resolution of 1.3 µm, allowing imaging and measurement of corneal layers.

An early application of optical coherence tomography technology was the evaluation of the cornea before and after refractive surgery. Because this noninvasive procedure can be conducted by a technician, it has been proposed that this device may provide a rapid diagnostic and screening tool for detecting angle-closure glaucoma.

Other Diagnostic Tools

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

Alternative methods of evaluating the anterior chamber are slit-lamp biomicroscopy or ultrasound biomicroscopy. Slit-lamp biomicroscopy is typically used to evaluate the anterior chamber; however, the chamber angle can only be examined with specialized lenses, the most common being the gonioscopic mirror. In this procedure, a 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 a picture of the front of the eye. An ultrasound scan along the optical axis assesses corneal thickness, anterior chamber depth, lens thickness, and axial length. Ultrasound scanning across the eye creates a 2-dimensional image of the ocular structures. It has a resolution of 100 µm but only moderately high intraobserver and low interobserver

reproducibility. Ultrasound biomicroscopy (>50 MHz) has a resolution of 30 to 50 µm. As with slit-lamp biomicroscopy with a gonioscopic mirror, this technique requires placement of a probe under topical anesthesia.

Classification and Assessment of Glaucoma
Glaucoma is characterized by degeneration of the optic nerve.

The classification of glaucoma as open-angle or angle-closure relies on assessment of the anterior segment anatomy, particularly that of the anterior chamber angle. Angle-closure glaucoma is characterized by obstruction of aqueous fluid drainage through the trabecular meshwork (the primary fluid egress site) from the eye's anterior chamber. The width of the angle is a factor affecting the drainage of aqueous humor. A wide unobstructed iridocorneal angle permits sufficient drainage of aqueous humor, whereas a narrow-angle may impede the drainage system and leave the patient susceptible to an increase in intraocular pressure and angle-closure glaucoma.

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

Regulatory Status
Multiple optical coherence tomography systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process (Table 1). Examples of approved systems are the Visante™ OCT (Carl Zeiss Meditec; FDA product code: HLI); the RTVue® (Optovue; FDA product code: OBO) and the Slitlamp optical coherence tomography (SL-OCT; Heidelberg Engineering; FDA product code: MXK).

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

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

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

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

The anterior chamber Cornea optical coherence tomography (Ophthalmic Technologies) is not cleared for marketing in the United States.

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

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.	11/09/2022	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	11/5/2021	K211817	OBO	Anterior segment optical coherence tomography
Pentacam AXL Wave	Oculus Optikgeräte GmbH	10/21/2020	K201724	MXK	Anterior segment optical coherence tomography
Xephilio OCT-A1	Canon	7/24/2019	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	1/20/2016	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 Ophthalmoscope	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 Inc.	3/26/2014	K131939	HLI	Anterior segment optical coherence tomography
IVUE 500	Optovue, Inc.	3/19/2014	K133892	HLI	Anterior segment optical coherence tomography

Rationale

Medical policies 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. Medical policies assess the evidence on whether a test is clinically valid and clinically useful. Technical reliability is outside the scope of these policies 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 optical coherence tomography (AS-OCT) is to determine whether there is a narrowing of the anterior chamber 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 following PICO was used to select literature to inform this policy.

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 optical coherence tomography of the anterior eye segment.

Comparators

Alternative tests are gonioscopy or ultrasound biomicroscopy, which are the commonly used. Optical coherence tomography is proposed to be an improvement over gonioscopy and ultrasound biomicroscopy because optical coherence tomography 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 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.

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 characteristic [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 AS-OCT 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 AS-OCT 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 AS-OCT positivity threshold. The sensitivity of AS-OCT 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 AS-OCT, all used a case-control study design with a high risk of bias. Overall, the authors concluded that AS-OCT 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 optical coherence tomography with gonioscopy for the detection of primary angle closure, some of which are described in Tables 2 and 3. For example, Nolan et al. (2007) assessed the ability of a Visante optical coherence tomography prototype 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 optical coherence tomography; agreement was obtained between the 2 methods in 143 eyes. Although these results suggested low specificity for optical coherence tomography, gonioscopy is not considered a criterion standard. The authors suggested 3 possible reasons for the increase in identification of closed angles with optical coherence tomography: 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 anterior segment; and landmarks that were 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 AS-OCT by a single ophthalmologist and gonioscopy by an ophthalmologist masked to the optical coherence tomography findings. Individuals were excluded if they had a disease or pathology that could influence the quality of angle imaging by optical coherence tomography. Angle opening distance was calculated at 250, 500, and 750 µm from the scleral spur. Of 2,047 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 optical coherence tomography using different cutoff values for the angle opening distance measured at 250, 500, and 750 µm from the scleral spur. (6) Optical coherence tomography 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 angle opening distance and the cutoff value. Correlation coefficients between the qualitative gonioscopy grade and quantitative optical coherence tomography measurement ranged from 0.75 (angle opening distance, 250 µm) to 0.88 (angle opening distance, 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	TX 1	TX 2	F/U
Nolan et al. (2007) (4)	Prospective observational case series	SG	NR	Patients with suspected or confirmed primary angle closure (N=200	AS-OCT	Gonioscopy	NR

				patients, 342 eyes)			
Narayanaswamy et al. (2010) (5)	Cross-sectional	SG	NR	Patients aged 50 years with phakic eyes (N=1465)	AS-OCT	Gonioscopy	NR

AS-OCT: anterior segment optical coherence technology; F/U: Follow up; NR: not reported; SG: Singapore; TX: Treatment.

Table 3. Summary of Key Nonrandomized Study Results

Study	Detection of Angle Closure 1 Quadrants	Specificity with Gonioscopy as the Reference Standard	AUROC for AOD750 in the Nasal Quadrant	AUROC for AOD750 in the Temporal Quadrant
Nolan et al. (2007) (4)				
AS-OCT	142 (71%) patients	55.40%		
	228 (66.7%) eyes			
Gonioscopy	99 (49.5%) patients			
	152 (44.4%) eyes			
Narayanaswamy et al. (2010) (5)				
			0.9	0.91
95% CI			0.89 to 0.92	0.90 to 0.93

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

Optical Coherence Tomography Versus Ultrasound Biomicroscopy

Mansouri et al. (2010) compared the measurement accuracy of the anterior chamber angle by AS-OCT with ultrasound biomicroscopy 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 optical coherence tomography and then ultrasound biomicroscopy. The trabecular-iris angle was measured in all 4 quadrants. Angle opening distance was measured at 500 µm from the scleral spur. In this comparative study, optical coherence tomography measurements correlated significantly with ultrasound biomicroscopy measurements but showed poor agreement with each other. The authors concluded that AS-OCT could replace ultrasound biomicroscopy as a tool for assessing quantitatively the anterior chamber 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 (RCTs).

The clinical utility of optical coherence tomography 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 optical coherence tomography 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 optical coherence tomography to predict incident gonioscopic angle closure. (2) A total of 2,052 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 optical coherence tomography 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 anterior chamber 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 AS-OCT against gonioscopy in detecting eyes with angle closure. Results revealed that AS-OCT 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 anterior chamber 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 anterior chamber 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 optical coherence tomography 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 anterior chamber surgical procedures. This could include a wide range of uses, such as the calculation of intraocular lens power, guiding surgery of the anterior segment, 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 following PICO was used to select literature to inform this policy.

Populations

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

Interventions

The test being considered is optical coherence tomography of the anterior eye segment.

Comparators

Alternative tests are clinical evaluation, slit-lamp biomicroscopy, Scheimpflug imaging, or ultrasound biomicroscopy.

Outcomes

The outcomes of interest are the diagnostic accuracy of optical coherence tomography in visualizing the anterior segment 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

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., ROC, 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).

Aqueous Tube Shunts

One potential application of optical coherence tomography 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 optical coherence tomography, slit-lamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes). (8) High-resolution optical coherence tomography demonstrated shunt position and patency in all 23 eyes. Compared with slit-lamp, 4 eyes had new findings identified by optical coherence tomography. For all 16 eyes in which tube entrance could be clearly visualized by optical coherence tomography, 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 optical coherence tomography 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 optical coherence tomography 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 optical coherence tomography discriminated between a “flat” graft detachment and delayed corneal clearance. Thus, of the 42 eyes, optical coherence tomography 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 AS-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 RCTs.

There is literature on the risk-benefit of optical coherence tomography laser-assisted cataract surgery versus traditional phacoemulsification. (13) Optical coherence tomography 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 optical coherence tomography 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 optical coherence tomography 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 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. Anterior segment optical coherence tomography has been studied in the diagnosis of some of these.

The following PICO was used to select literature to inform this policy.

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

Interventions
The test being considered is optical coherence tomography of the anterior eye segment.

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

Outcomes
The outcomes of interests 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

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., ROC, 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).

Neoplastic Disease

Several retrospective studies have compared optical coherence tomography with ultrasound biomicroscopy for assessing anterior segment tumors. Bianciotto et al. (2011) retrospectively analyzed 200 consecutive patients who underwent both AS-OCT and ultrasound biomicroscopy for anterior segment tumors. (14) When comparing the image resolution of the 2 techniques, ultrasound biomicroscopy had overall tumor visualization.

Uveitis of the Anterior Segment

In a study from India, Agarwal et al. (2009) evaluated the anterior chamber inflammatory reaction by high-speed AS-OCT. (15) This prospective, nonrandomized, observational case series included 62 eyes of 45 patients. Of 62 eyes, grade 4 aqueous flare was detected by optical coherence tomography 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.

Del-Prado-Sánchez (2024) assessed the effectiveness of AS-OCT in screening for anterior uveitis in children with juvenile idiopathic arthritis in a cross-sectional, non-randomized study in Spain. (16) The study included 300 eyes of 150 children (mean age 11.1 years; 74% female). Anterior uveitis was clinically diagnosed in 16 eyes via slit-lamp examination, while AS-OCT identified 27 suspicious cases, detecting cells in all 27 and retrokeratic precipitates in 5. Sensitivity, specificity, positive predictive value, and negative predictive value were 0.94, 0.96, 0.59, and 0.99, respectively, with a Kappa-Cohen index of 0.71.

Other Indications

Garcia and Rosen (2008) evaluated the diagnostic performance of the anterior chamber cornea optical coherence tomography device by comparing image results with ultrasound biomicroscopy in patients who had conditions of the anterior segment. (17) Patients were recruited from various specialty clinics, and 80 eyes with pathologic conditions involving the

anterior ocular segment were included. Comparison of optical coherence tomography and ultrasound biomicroscopy images showed that, while the anterior chamber cornea optical coherence tomography has high resolution for the cornea, conjunctiva, iris, and anterior angle, ultrasound biomicroscopy images were also clear for these areas. In addition, ultrasound biomicroscopy was found to be superior at detecting cataracts, anterior tumors, ciliary bodies, haptics, and posterior chamber intraocular lenses. Optical coherence tomography 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 RCTs.

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. (18) 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. (19) Additional studies are needed to further evaluate AS-OCT for anterior segment disease or pathology and to demonstrate the clinical utility of using optical coherence tomography 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 anterior chamber 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 AS-OCT for anterior segment disease or pathology, such as dry eye syndrome, tumors, uveitis, and infections, is limited. The evidence to date does not support an improvement using imaging compared with ultrasound biomicroscopy.

Summary of Evidence

For individuals who are being evaluated for angle-closure glaucoma who receive anterior segment optical coherence tomography (AS-OCT), the evidence includes 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 AS-OCT detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of optical coherence tomography 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 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 a 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 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 that the technology results in an improvement in the net health outcome.

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 a AS-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.

Practice Guidelines and Position Statements

American Academy of Ophthalmology

In 2020, the American Academy of Ophthalmology published a preferred practice pattern on primary angle closure disease. (20) 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 AS-OCT 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 AS-OCT, 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 AS-OCT.

Ongoing and Unpublished Clinical Trials

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

Table 4. Summary of Key Trials

NCT Number	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT01746537	Automated Analysis of Anterior Chamber Inflammation by Optical Coherence Tomography	1500	Jun 2026 (recruiting)
NCT00532051	Guiding the Treatment of Anterior Eye Diseases With Optical Coherence Tomography	690	Jul 2026
Unpublished			
NCT03461978	Ultrahigh-resolution Optical Coherence Tomography Imaging of the Anterior Eye Segment Structures - a Pilot Study	60	Oct 2023 (unknown status)
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

NCT: national clinical trial.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	92132
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
06/15/2025	Document updated with literature review. Coverage unchanged. Added new reference 16.
09/15/2024	Document updated with literature review. Coverage unchanged. The following references were added: 10 and 11.
12/01/2023	Reviewed. No changes.
07/15/2022	Document updated with literature review. Coverage unchanged. Added/updated the following references: 3 and 17.
09/01/2021	Reviewed. No changes.
07/15/2020	Document review with literature update. Coverage unchanged. No new references added.
07/15/2019	Reviewed. No changes.

07/15/2018	Document updated with literature review. Coverage unchanged. References 2 and 9 added.
07/15/2017	Reviewed. No changes.
07/01/2016	Document updated with literature review. Coverage unchanged.
04/15/2015	Reviewed. No changes.
05/15/2014	Document updated with literature review. Coverage unchanged. Title changed from Anterior Eye Segment Imaging.
02/15/2011	Document updated with literature review. Rationale updated. Coverage unchanged.
06/01/2008	New Medical Policy.