

9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

Original Policy Date: June 30, 2015 Effective Date: May 1, 2021

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Policy Statement

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

NOTE: Refer to [Appendix A](#) to see the policy statement changes (if any) from the previous version.

Policy Guidelines**Coding**

The following CPT code is specific to computerized imaging of the anterior eye segment:

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

Effective July 1, 2020, there are new category III CPT codes for optical coherence tomography:

- **0604T:** Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment
- **0605T:** Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days
- **0606T:** Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days

Description

Optical coherence tomography is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. Optical coherence tomography of the anterior segment is being evaluated as a noninvasive diagnostic and screening tool for detecting angle-closure glaucoma, for presurgical evaluation, surgical guidance, and for assessing complications following surgical procedures. It is also being studied as a tool to evaluate the pathologic processes of dry eye syndrome, tumors, uveitis, and infections.

Related Policies

- Aqueous Shunts and Stents for Glaucoma
- Endothelial Keratoplasty
- Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

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

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

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

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

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

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

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

| Device | Manufacturer | Date Cleared | 510(k) No. | Product Code | Product Indication |
|---|--------------------------------|--------------|------------|--------------|---|
| 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 |

| Device | Manufacturer | Date Cleared | 510(k) No. | Product Indication Code | Product Indication |
|--|-----------------------|--------------|------------|-------------------------|---|
| 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

Background

Optical Coherence Tomography

Optical coherence tomography is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. Optical coherence tomography creates an image of light reflected from the ocular structures. In this technique, a reflected light beam interacts with a reference light beam. The coherent (positive) interference between the 2 beams (reflected and reference) is measured by an interferometer, allowing construction of an image of the ocular structures. This method allows cross-sectional imaging at a resolution of 6 to 25 μm .

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

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

Other Diagnostic Tools

Optical coherence tomography of the anterior eye segment is being evaluated as a noninvasive diagnostic and screening tool with a number of potential applications. One proposed use of anterior segment optical coherence tomography is to determine whether there is a narrowing of the anterior chamber angle, which could lead to angle-closure glaucoma. Another general area of potential use is as a presurgical and postsurgical evaluation tool for anterior chamber procedures. This could include assessment of corneal thickness and opacity, calculation of intraocular lens power, guiding surgery, imaging intracorneal ring segments, and assessing complications following surgical procedures such as blockage of glaucoma tubes or detachment of Descemet membrane following endothelial keratoplasty (see Blue Shield of California Medical Policy: 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 ($\gg 50$ 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 (see Blue Shield of California Medical Policy: Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma on imaging of the optic nerve with posterior segment optical coherence tomography, 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.

Literature Review

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

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

Angle-Closure Glaucoma

Clinical Context and Test Purpose

One potential use of anterior segment optical coherence tomography 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 question addressed in this evidence review is: Does anterior segment optical coherence tomography of the anterior chamber improve health outcomes compared with alternative methods in those with glaucoma?

The following PICO was 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 optical coherence tomography of the anterior eye segment.

Optical coherence tomography of the anterior eye segment is most likely to be administered in an outpatient facility by an ophthalmologist.

Comparators

Alternative tests are gonioscopy or ultrasound biomicroscopy, which are the most 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.

Gonioscopy and ultrasound biomicroscopy are most likely to be administered in an outpatient facility by an ophthalmologist.

Outcomes

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

1. The study population represents the population of interest. Eligibility and selection are described.
2. The test is compared with a credible reference standard.
3. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
4. 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.
5. Studies should also report reclassification of diagnostic or risk category.

Review of Evidence

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

A number of studies have compared optical coherence tomography with gonioscopy for the detection of primary angle closure. 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.³ The patients, recruited from glaucoma clinics, had been diagnosed with primary angle-closure, primary open-angle glaucoma, ocular hypertension, and cataracts; some had previously been treated with iridotomy. Images were assessed by 2 glaucoma experts, and the results were compared with an independently obtained reference standard (gonioscopy). Data were reported from 342 eyes of 200 individuals. A closed-angle was identified in 152 eyes with gonioscopy and in 228 eyes with 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 used differed between methods.

Narayanaswamy et al (2010) conducted a community-based cross-sectional study of glaucoma screening.⁴ The study population consisted of individuals 50 years or older who underwent anterior segment optical coherence tomography 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.⁵ 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 | Treatment 1 | Treatment 2 | Follow-Up |
|---|--|-----------|-------|---|-------------|-------------|-----------|
| Nolan et al (2007) ³ | Prospective, observational case series | Singapore | NR | Patients with suspected or confirmed primary angle closure (n=200 patients, 342 eyes) | AS-OCT | Gonioscopy | NR |
| Narayanaswamy et al (2010) ⁴ | Cross-sectional | Singapore | NR | Patients age 50 yrs 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 et al (2007)³ | | | | |
| AS-OCT | 142 (71%) patients 228 (66.7%) eyes | 55.40% | | |
| Gonioscopy | 99 (49.5%) patients 152 (44.4%) eyes | | | |
| Narayanaswamy et al (2010)⁴ | | | 0.9 | 0.91 |
| 95% CI | | | 0.89 to 0.92 | 0.90 to 0.93 |

AUC: area under the receiver operating characteristic curve; AOD750: angle opening distance at 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 anterior chamber angle by anterior segment optical coherence tomography with ultrasound biomicroscopy in patients with suspected primary angle-closure, primary angle-closure, or primary angle-closure glaucoma.⁶ In this study, 55 eyes of 33 consecutive patients presenting with the 3 angle-closure conditions were examined with 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 anterior segment optical coherence tomography 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, 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 anterior segment optical coherence tomography 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 anterior segment optical coherence tomography 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 anterior segment optical coherence tomography of the anterior chamber to improved health outcomes compared with alternative methods in individuals with glaucoma.

Section Summary: Angle-Closure Glaucoma

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 anterior segment optical coherence tomography.

When compared with gonioscopy, anterior segment optical coherence tomography 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 anterior segment optical coherence tomography. Longitudinal studies are needed to determine whether eyes classified as closed by anterior segment optical coherence tomography, 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 optical coherence tomography 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 question addressed in this evidence review is: Does anterior segment optical coherence tomography of the anterior chamber improve outcomes compared with alternative methods of assessing the anterior chamber for those who will or have had eye surgery?

The following PICO was 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 optical coherence tomography of the anterior eye segment.

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

Comparators

Alternative tests are clinical evaluation, slit-lamp biomicroscopy, Scheimpflug imaging, or ultrasound biomicroscopy. These alternative tests are most likely to be administered in an outpatient facility by an ophthalmologist.

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.

1. The study population represents the population of interest. Eligibility and selection are described.
2. The test is compared with a credible reference standard.
3. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
4. 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.
5. Studies should also report reclassification of diagnostic or risk category.

Review of Evidence**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).⁷ 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 anterior segment optical coherence tomography, Scheimpflug imaging, and slit-lamp biomicroscopy in 120 eyes of 110 patients after Descemet membrane endothelial keratoplasty.⁸ 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).

Other Indications

Venincasa et al (2017) reported on combining grayscale and color images captured using anterior segment optical coherence tomography to prepare for eye surgery.⁹ Viewing an image in different colors provides different perspectives. The authors of this retrospective study determined that while grayscale is good for mapping extraocular muscle structures, the addition of color can improve the accuracy in finding the ideal point of insertion. Accuracy was measured as being within 1.00 mm of the intraoperative caliper measurement. One hundred thirty-nine anterior segment optical coherence tomography images were collected from 74 patients. When using grayscale and color imaging, anterior segment optical coherence tomography 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, 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.¹⁰ 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 as well as postoperative assessment of intraocular stability of phakic lens and optic changes related to intraocular lens or ocular media opacities. Anterior segment optical coherence tomography is also being studied for imaging of intraocular stents and shunts and for imaging of graft detachment. However, it is unclear whether these imaging capabilities would improve health outcomes.

Section Summary: Evaluation for Surgery or Postsurgical Complications

The use of anterior segment optical coherence tomography has been reported for presurgical evaluation, surgical guidance, and monitoring for postsurgical complications. There is some evidence that the high-resolution images provided by anterior segment optical coherence tomography are superior to results from slit-lamp examination or gonioscopy for some

indications. However, current literature is very limited and there is no clear link between anterior segment optical coherence tomography 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 chamber optical coherence tomography has been studied in the diagnosis of some of these.

The question addressed in this evidence review is: Does anterior segment optical coherence tomography of the anterior chamber improve outcomes compared with alternative methods of assessing anterior eye segment diseases or pathology?

The following PICO was 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 optical coherence tomography of the anterior eye segment.

The setting for optical coherence tomography is an outpatient facility with an ophthalmologist.

Comparators

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

The setting for these alternative tests is an outpatient facility with an ophthalmologist.

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.

1. The study population represents the population of interest. Eligibility and selection are described.
2. The test is compared with a credible reference standard.
3. If the test is intended to replace or be an adjunct to an existing test; it should also be compared with that test.
4. 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.
5. Studies should also report reclassification of diagnostic or risk category.

Review of Evidence

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 anterior segment optical coherence tomography and ultrasound biomicroscopy for anterior segment tumors.¹¹ 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 anterior segment optical coherence tomography.¹² 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 anterior segment optical coherence tomography can detect inflammatory reaction in uveitis and in eyes with decreased corneal clarity.

Other Indications

Garcia and Rosen (2008) evaluated the diagnostic performance of the anterior chamber Cornea optical coherence tomography device by comparing image results with ultrasound biomicroscopy in patients who had conditions of the anterior segment.¹³ 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, 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.¹⁴ In a review, Thomas et al (2014) noted that noninvasive methods of diagnosing ocular surface squamous neoplasia would be increasingly important as treatment moves toward medical therapy, although future studies would have to evaluate the diagnostic accuracy for this indication.¹⁵ Additional studies are needed to further evaluate anterior segment optical coherence tomography 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 anterior segment optical coherence tomography 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 anterior segment optical coherence tomography 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, the evidence includes case series and cohort studies. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Ideally, a diagnostic test should be evaluated based on its diagnostic accuracy and clinical utility. Studies have shown that anterior segment optical coherence tomography detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of optical coherence tomography is higher than that of gonioscopy. However, because of clinical follow-up and validation studies, it is not clear to what degree these additional cases are true-positives or false-positives and, therefore, the specificity and predictive values cannot be determined. The evaluation of diagnostic performance depends, therefore, on evidence that the additional eyes identified with narrow-angle by anterior segment optical coherence tomography are at higher risk for primary angle-closure glaucoma. Results from a study with mid-term follow-up have shown that some patients identified with angle-closure on anterior segment optical coherence tomography will develop angle-closure on gonioscopy after several years, but that there may also be a large number of false-positive results. Longer-term studies are needed to determine whether eyes classified as closed-angle by anterior segment optical coherence tomography are at higher risk 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 optical coherence tomography, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Use of anterior segment optical coherence tomography has been reported for presurgical evaluation, surgical guidance, and monitoring for postsurgical complications. There is some evidence that the high-resolution images provided by anterior segment optical coherence tomography are superior to results from slit-lamp examination or gonioscopy for some indications. However, current literature is very limited. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have anterior eye segment disease or pathology who receive anterior segment optical coherence tomography, the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. The evidence related to the use of anterior segment optical coherence tomography for anterior segment disease or pathology (e.g., dry eye syndrome, tumors, uveitis, infections) is limited, and does not support improvements in imaging compared with alternative diagnostic techniques. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate

reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests from Blue Cross Blue Shield Association, input was received from 1 physician specialty society and 3 academic medical centers in 2011. There was general, but not unanimous, agreement that optical coherence tomography is investigational. Some reviewers commented that optical coherence tomography may have applications in specific conditions such as globe perforation, anterior segment (anterior segment; iris) tumors, and in the postoperative care of endothelial keratoplasty cases.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Ophthalmology

In 2020, the American Academy of Ophthalmology published a preferred practice pattern on primary angle closure disease.¹⁶ 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

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

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 |
|----------------|---|--------------------|-----------------|
| <i>Ongoing</i> | | | |
| NCT03461978 | Ultrahigh-resolution Optical Coherence Tomography Imaging of the Anterior Eye Segment Structures - a Pilot Study | 60 | Mar 2020 |
| NCT01746537 | Automated Analysis of Anterior Chamber Inflammation by Optical Coherence Tomography | 1500 | Jun 2022 |
| NCT02542644 | Assessment of Corneal Graft Attachment in Patients With Fuchs Endothelial Corneal Dystrophy Following Descemet's Membrane Endothelial Keratoplasty Using Ultra-high Resolution Optical Coherence Tomography | 80 | Dec 2020 |

| NCT No. | Trial Name | Planned Enrollment | Completion Date |
|-----------------------------------|--|--------------------|-----------------------|
| Unpublished NCT03626675 | Anterior Segment Changes Before and After Uneventful Combined Phaco-Trabeculectomy by Using Optical Coherence Tomography (OCT) | 60 | Mar 2020 (unknown) |

NCT: national clinical trial.

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15. Thomas BJ, Galor A, Nanji AA, et al. Ultra high-resolution anterior segment optical coherence tomography in the diagnosis and management of ocular surface squamous neoplasia. *Ocul Surf.* Jan 2014; 12(1): 46-58. PMID 24439046

16. American Academy of Ophthalmology. Preferred Practice Pattern: Primary angle closure disease. 2020; <https://www.aao.org/preferred-practice-pattern/primary-angle-closure-disease-ppp>. Accessed January 27, 2021.
17. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 9.03.18 (March 2021).

Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

| Type | Code | Description |
|------|-------|---|
| CPT® | 0604T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; initial device provision, set-up and patient education on use of equipment (Code effective 7/1/2020) |
| | 0605T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; remote surveillance center technical support, data analyses and reports, with a minimum of 8 daily recordings, each 30 days (Code effective 7/1/2020) |
| | 0606T | Optical coherence tomography (OCT) of retina, remote, patient-initiated image capture and transmission to a remote surveillance center unilateral or bilateral; review, interpretation and report by the prescribing physician or other qualified health care professional of remote surveillance center data analyses, each 30 days (Code effective 7/1/2020) |
| | 92132 | Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral |

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

| Effective Date | Action |
|----------------|--|
| 06/30/2015 | BCBSA Medical Policy adoption |
| 10/01/2016 | Policy revision without position change |
| 04/01/2017 | Policy revision without position change |
| 05/01/2018 | Policy revision without position change |
| 05/01/2019 | Policy revision without position change |
| 05/01/2020 | Annual review. No change to policy statement. Literature review updated. |

| Effective Date | Action |
|----------------|--|
| 08/01/2020 | Coding Update |
| 05/01/2021 | Annual review. No change to policy statement. Literature review updated. |

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

| POLICY STATEMENT (No changes) | |
|---|---|
| BEFORE | AFTER |
| Optical Coherence Tomography of the Anterior Eye Segment 9.03.18 Policy Statement: Scanning computerized ophthalmic (e.g., optical coherence tomography) imaging of the anterior eye segment is considered investigational . | Optical Coherence Tomography of the Anterior Eye Segment 9.03.18 Policy Statement: Scanning computerized ophthalmic (e.g., optical coherence tomography) imaging of the anterior eye segment is considered investigational . |