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| **Subject: Optical Coherence Tomography of the Anterior Eye Segment** | **Original Effective Date:** Q4 2020 |
| **Policy Number: MCP-388** | **Revision Date(s):** |
| **Review Date:** | |
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# Contents



## DISCLAIMER

*This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.*

## RECOMMENDATION

**Optical coherence tomography (OCT) of the anterior eye segment is considered investigational and not medically necessary for all indications** due to insufficient evidence demonstrating improvement in health outcomes in comparison to the current clinical standard for evaluating of the anterior segment of the eye, gonioscopy and/or ultrasound biomicroscopy. The lack of clinical validity of OCT includes evidence of additional eyes identified as having narrow angles by OCT compared with available alternative treatments (i.e., gonioscopy, ultrasonography, or slit-lamp biomicroscopy) which are more likely to progress to primary angle closure glaucoma. There are also no clinical guidelines recommending anterior segment OCT at this time.

There is insufficient evidence for other potential indications (e.g., cataract surgery, endothelial keratoplasty, anterior uveitis) to determine the effectiveness and utility of OCT also. The current literature consists mainly of small, nonrandomized trials or case series which utilize OCT for a variety of indications, including plaque observation (Takezawa et al. 2017), preparation for eye surgery (Venincasa et al. 2017), clarification of diagnoses in pediatric patients (Cauduro et al. 2012), prediction of primary failure following endothelial keratoplasty (Shih et al. 2009; Moutsouris et al. 2011, Steven et al. 2013) and detection of inflammatory reaction in uveitis (Agarwal et al. 2009). **Larger, randomized, trials of longer duration and follow-up are recommended to evaluate whether additional conditions detected by OCT also results in improved health outcomes**

**NOTE:** This policy addresses the the anterior eye segment (does not include the posterior segment).

## DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

**Optical Coherence Tomography** (OCT) is a non-invasive imaging technology used to obtain high resolution cross-sectional images of the retina and measurements of the anterior segment ocular structures which includes the cornea, anterior chamber, iris and the central portion of the lens. The layers within the retina can be differentiated and retinal thickness can be measured to aid in the early detection and diagnosis of retinal diseases and conditions. OCT for the anterior eye segment (OCT-AS), a non-contact imaging technology, can be used to assess anterior chamber biometry, corneal thickness and opacity, lens thickness, and angle configuration; to visualize pathological processes; to evaluate postsurgical anatomy and post-traumatic eyes; and to image phakic intraocular lenses and intracorneal ring segments' (Doors et al.). The clinical applications of OCT-AS in the pre-operative, intra-operative and post-operative setting has been utilized. OCT-AS imaging applications is being further evaluated as a diagnostic and screening tool for ocular surface evaluation, corneal evaluation impacting surgical outcomes, angle assessment for glaucoma diagnosis, aqueous outflow assessment and vascular supply of the anterior chamber anatomy and in other conditions such as angle-closure glaucoma uveitis, tumors, dry eye syndrome, and infections (Szalai et al., 2017).

**Gonioscopy** is the current clinical standard for evaluating of the anterior segment of the eye. An UpToDate review on "Angle-closure glaucoma" (Weizer, 2015) states that 'Gonioscopy is the gold-standard method of diagnosing angle-closure …. High definition anterior segment optical coherence tomography is being used as a modality to image the drainage angle and detect eyes at risk for angle-closure. Findings suggest that eyes prone to developing angle-closure do not merely differ anatomically from normal eyes, but may also respond differently to light stimuli.' **Current literature is limited but there is some evidence that the high-resolution images from OCT-AS are superior to results from slit-lamp examination or gonioscopy for some indications; however the evidence remains insufficient to determine the improvement on health outcomes.**

Regulatory Status

510(k) clearance from the FDA has been issued to several OCT-AS devices (may not be an all-inclusive list):

- Visante OCT™ (Carl Zeiss Meditec, USA; FDA product code: MXK)) and the Slit-Lamp OCT (SL-OCT, Heidelberg Engineering, Germany; FDA product code: MXK): The first commercial OCT systems specifically designed for anterior segment imaging, FDA-approved in 2005 and 2006 respectively
- RTVue-CAM (Optovue) (FDA product code: HLI);

- Microscope-integrated OCT devices for intraoperative use include: ReScan 700 (Zeiss) and iOCT® system (Haag-Streit)
- Portable devices for intraoperative use include: Envisu™ (Bioptigen) and iVue® (Optovue)
- Ultrahigh resolution OCT devices include: SOCT Copernicus HR (Optopol Technologies)
- Commercially available laser systems, such as the LenSx® (Alcon), Catalys® (OptiMedica), and VICTUS® (Technolas Perfect Vision), include OCT to provide image guidance for laser cataract surgery. FDA product code: OOE.
- Custom-built devices are also utilized and do not require FDA approval.

**Anterior-segment OCT systems are categorized by wavelength of light sources; dedicated systems using 1310 nm (Zeiss Visante, Heidelberg SL-OCT, Tomey CASIA, etc.) and systems converted from a retinal scanner using 830 nm (Optovue RTvue, Optovue iVue, Zeiss Cirrus, Heidelberg Spectralis, etc.) (Reference: Lim SH 2015)*

**Although FDA-approved, clinical studies are still required to establish clinical utility beyond the current standard of care of gonioscopy and ultrasound. OCT-AS devices have the potential for use as a screening tool for detection of occludable angles.**

## SUMMARY OF MEDICAL EVIDENCE

**Glaucoma** is characterized by degeneration of the optic nerve and classified as open angle or angle closure from assessment of the anterior segment anatomy, particularly that of the anterior chamber angle (AC angle). Visualization of the AC angle is critical in the diagnosis of glaucoma, especially angle-closure variants since it is characterized by narrowing or closure of the anterior chamber angle which leads to increased intraocular pressure (IOP) and damage to the optic nerve. The width of the anterior angle affects the drainage of aqueous humor which may be blocked by anatomic narrowing of the angle in primary angle-closure glaucoma. Secondary angle-closure is caused by a variety of processes that either push or pull the anterior chamber angle closed, including fibrosis and scarring, drug reactions, neovascularization, or mass. **Gonioscopy is the clinical standard for the diagnosis of narrow angles (Weizer 2020). Slit-lamp biomicroscopy and ultrasound biomicroscopy are alternative methods of evaluating the the anterior chamber; however, the chamber angle can only be examined with specialized lenses, the most common of these being the gonioscopic mirror.** Other techniques for imaging the anterior eye segment include ultrasonography and OCT.

Angle-closure Glaucoma

There is insufficient evidence in the form of high-quality peer-reviewed medical literature to establish the efficacy or effects on health care outcomes using OCT. Several studies have compared OCT and established techniques to measure the anterior segment ocular structure (Dada, 2007; Li, 2007; Pavlin, 2009; Sakata, 2008; Zhao, 2007); however, none have established the superiority of OCT. There are retrospective case series, prospective studies, and observational studies comparing the diagnostic performance of OCT with gonioscopy, ultrasound biomicroscopy (UBM), and slit-lamp biomicroscopy. However, these studies present major methodological limitations, such as small sample size and the heterogeneity of study subjects and lack of longer-term studies and follow-up. Furthermore, existing studies do not show direct evidence of the clinical utility of OCT for diagnosing narrow angle glaucoma available compared to current standards of care. This includes whether it is more accurate in diagnosing clinically significant closed angles than alternatives. This is also true for other disorders of the

anterior chamber OCT is being investigated for potential indications. The clinical place of OCT in comparison to gonioscopy, ultrasonography, or slit-lamp biomicroscopy as demonstrated by improvement in the identification of any additional eyes with narrow angles (which is more likely to progress to primary angle closure glaucoma) is also inconclusive.

Optical Coherence Tomography vs. Gonioscopy

There are studies comparing OCT with gonioscopy for the detection of primary angle closure; however the prospective and retrospective case series do not validate whether early detection of angle closure will improve health outcomes in individuals who do not have symptoms of angle closure. The evidence is inconclusive, insufficient to determine the effects of the technology on health outcomes. Randomized trials with longer duration and follow-up are recommended to evaluate whether additional conditions detected by OCT also results in improved health outcomes

Nolan et al., in a prospective observational case series, evaluated anterior segment optical coherence technology (AS-OCT) to detect primary angle closure when compared with gonioscopy in Asian subjects. The study included 203 Asian patients recruited from glaucoma clinics. The patients were diagnosed with primary angle closure, primary open-angle glaucoma, ocular hypertension, and cataracts; some had previously been treated with iridotomy. Two glaucoma experts assessed the images and the compared the results to an independently obtained reference standard (gonioscopy). Data was obtained from 342 eyes of 200 individuals. A closed angle was identified in 152 eyes with gonioscopy and 228 eyes with OCT; agreement was obtained between the 2 methods in 143 eyes. Although these results suggest AS OCT is highly sensitive in detecting angle closure when compared with gonioscopy. However, it is unclear how many of these cases are true positives or false positives.

Pekmezci et al. (2009) retrospectively analyzed the accuracy of AS-OCT for detecting occludable angles and compare the results of high- and low-resolution images with gonioscopy. The researchers reviewed OCT and gonioscopy records from a glaucoma clinic for 303 eyes of 155 patients. The subjects looked at prepositioned targets to prevent image distortion with low- and high-resolution OCT. At the time of the study, the parameters analyzed could not be measured by commercially available software so the images were converted to a format that could be analyzed by ultrasound biomicroscopy software. The blinded analysis found sensitivity and specificity between 70% and 80% in comparison with gonioscopy, depending on the angle opening distances and the cut-off value. The authors concluded that AS-OCT appears to be a promising screening tool for narrow angle however notes that ‘a truer measure of occludable angles is whether an eye develops angle-closure glaucoma in the future’ and long-term follow-up of patients examined by these two methods would be useful.

Optical Coherence Tomography vs. Ultrasound Biomicroscopy (UBM)

Bianciotto et al. (2011) performed a retrospective, noninterventional case series analysis of 200 eyes of 200 patients with anterior segment tumors. The tumors were evaluated with ultrasound biomicroscopy (OPKO Instrumentation/OTI) and Visante AS-OCT (Carl Zeiss Meditec). The researches compared the image resolution for the 2 techniques and noted that ultrasound biomicroscopy (UBM) had better overall tumor visualization with study results showing high overall image quality in 80% of UBM images and 68% of AS-OCT images. Visualization of tumor margins was considered adequate in 95% of UBM images and 40% of AS-OCT scans. Althought AS-OCT is a useful tool for evaluation of superficial, nonpigmented lesions of the eye (such as

conjunctival tumors), its disadvantage is poor resolution withshadowing in cases of large or pigmented lesions. UBM appears to have a the advantage of the better ability to penetrate through the lesion into the eye, providing better images of the posterior margin as well as the entire tumor configuration compared with AS-OCT. The study concluded that ultrasound biomicroscopy offered better visualization of anterior segment tumors than did anterior segment optical coherence tomography.

Mansouri et al. (2010) completed a prospective, non-randomized cross-sectional observational study of ultrasound biomicroscopy (UBM) to AS-OCT measurements in suspected primary angle closure, primary angle closure, or primary angle-closure glaucoma. The ability to visualize and measure the anterior chamber (AC) angle for the assessment of individuals with glaucoma is important. A total of 33 participants (55 eyes) were studied by AS-OCT followed by UBM. Measurement of the trabecular-iris angle (TIA) was made in all four quadrants. The mean of the four angle measurements was slightly higher in the AS-OCT group (19.72 vs 17.43° with UBM). and shows poor agreement between the two methods for measurements. The authors noted that the 'comparative study shows that AS-OCT measurements are significantly correlated with UBM measurements but show poor agreement with each other.' It was concluded that AS-OCT is not a replacement for UBM, which remains the gold standard for the quantitative measurement of angle parameters.

OCT Compared with Slit-Lamp Biomicroscopy

Jiang et al. (2012) assessed a cross-sectional, observational study of the visualization of aqueous tube shunts by high-resolution OCT, slitlamp biomicroscopy, and gonioscopy in 18 consecutive patients (23 eyes). High resolution OCT demonstrated the shunt position and patency in all 23 eyes. In comparison to the slit-lamp, 4 eyes had new findings identified by OCT. For all 16 eyes in which the tube entrance could be clearly visualized by OCT, growth of fibrous scar tissue could be seen between the tube and the corneal endothelium. This was not identified in the patient records (retrospectively analyzed) of the slitlamp examination. The investigators noted that 'There were several limitations to our study. The first was its small sample size. Despite the many types of AC shunts implanted clinically, only one kind of aqueous shunt was studied here. As this was a cross-sectional study and corneal endothelial density was not recorded, the relationship between the endothelial density and the OCT findings was not evaluated. Thus, further study with long-term followup and more cases may determine the significance of the OCT findings, including the position of the tube, location of the entrance, and presence of fibrous tissue proliferation.' It was concluded that additional studies are necessary to validate the results of this small obeservational study.

Human Tear Meniscus and Dry Eyes

Qui et al. (2011) in a prospective, randomized, case-control study reported on the use of Fourier-domain anterior segment optical coherence tomography (FD-ASOCT) to screen and diagnose dry eye, specifically human tear meniscus. 'A total of 146 participants with dry eye and 160 control participants were included in the study. Data was collected by a dry eye questionnaire with measurement of the tear menisci using an AS-OCT system, tear film breakup time, corneal fluorescein staining, and Shirmer I test. Correct diagnosis of dry eye measured using the AS-OCT was 68.95% in tear meniscus height, 70.59% in tear meniscus depth, and 70.92% in tear meniscus area which suggests limitations in dry eye diagnosis when using only meniscus measurements.' The researchers concluded that further research will be needed to establish the type of dry eye that is best diagnosed with FD-ASOCT.

Systematic Review and Meta-Analysis

*Evaluation of Corneal and Conjunctival Tumors*

Janssens et al. (2016), in a systematic review, analyzed corneal and conjunctival tumor thickness and internal characteristics and extension in depth and size and shape measured by two noninvasive techniques, anterior segment optical coherence tomography (AS-OCT) and ultrasound biomicroscopy (UBM). The review included corneal or conjunctival tumors by a total of 14 sources retrieved from a comprehensive search of 4 databases (Medline, Embase, Web of Science, and Cochrane Library) of articles published between January 1, 1999 and December 31, 2015. The authors noted that several studies on the quality of AS-OCT and UBM showed that these imaging techniques provided useful information about the internal features, extension, size, and shape of tumors. However, there is insuffient evidence on the advantages and disadvantages of UBM and AS-OCT in certain tumor types. It was concluded that due to their different measuring technique, AS-OCT and UBM have different advantages and disadvantages. The disadvantage of AS-OCT is that did not penetrate deeper than 1 to 3 mm and did not penetrate through pigmented lesions; however, it was noted that for smaller lesions AS-OCT is a more accurate technique that can give detailed images of the remaining healthy cornea, can identify cysts, or might be useful in detecting tumor recurrence. For larger or pigmented lesions UBM can better delineate tumor margins and tumor thickness. **The major limitation of this systematic review was the small sample size of most of the studies and the limited types of tumors examined which made it difficult to extrapolate the findings to all corneal and conjunctival tumors.** There is not limited evidence on the advantages and disadvantages of UBM and AS-OCT in certain tumor types. **The authors concluded that additional comparative studies are required to determine which imaging technique is most suitable for a certain tumor type.**

Clinical Practice Guidelines

No U.S. professional societies have released clinical practice guidelines recommending the use of anterior segment optical coherence tomography (September 2020).

American Academy of Ophthalmology (AAO)

The AAO published a Preferred Practice Pattern® on primary angle closure (2015) with the recommendation that gonioscopy of both eyes should be performed on all patients in whom angle closure is suspected and that AS imaging should be considered when angle anatomy is difficult to assess on gonioscopy. The guideline stated that there is good evidence demonstrating general agreement between findings on gonioscopy and anterior segment imaging, including ultrasound biomicroscopy and anterior segment optical coherence tomography (AS-OCT). AS imaging methods discussed were ultrasound biomicroscopy, Scheimpflug imaging, and AS OCT. However, AS-OCT is limited to evaluating the iridocorneal angle. AS-OCT is one technology that may prove useful in evaluating secondary causes of angle closure and elucidating plateau iris.

The AAO Preferred Practice Pattern® Summary Benchmarks for Glaucoma (2018) recommend gonioscopy as a key element in the initial evaluation of primary open-angle glaucoma, as a follow-up if there is suspicion of angle closure, anterior-chamber shallowing or anterior-chamber angle abnormalities, in the initial evaluation and follow-up of primary open-angle glaucoma suspect, and in the initial evaluation of primary angle closure. OCT is not mentioned.

## DEFINITIONS

Gonioscopy: Performed during the ophthalmology exam to evaluate the internal drainage system (anterior chamber angle) to determine the form of glaucoma present

Angle-closure glaucoma: Glaucoma associated with a physically obstructed anterior chamber angle, which may be chronic or, rarely, acute. Symptoms of acute angle closure are severe ocular pain and redness, decreased vision, colored halos around lights, headache, nausea, and vomiting. Intraocular pressure (IOP) is elevated.
Angle-closure glaucoma: Glaucoma associated with a physically obstructed anterior chamber angle, which may be chronic or, rarely, acute. Symptoms of acute angle closure are severe ocular pain and redness, decreased vision, colored halos around lights, headache, nausea, and vomiting. Intraocular pressure (IOP) is elevated.

Primary angle closure (PAC): Defined by the AAO as appositional or synechial closure of the anterior chamber angle which can lead to aqueous outflow obstruction and raised IOP, in the absence of glaucomatous optic neuropathy. Multiple mechanisms are identified for PAC, including pupillary block, a main element in the pathogenesis of most instances of PAC); the relative position and thickness of the ciliary body; the location of the iris insertion into the ciliary body, and the volume of the iris. Primary angle closure is generally bilateral.

Primary Angle Closure Glaucoma: A significant cause of blindness worldwide; present in 26% of the glaucoma population but responsible for half the cases of glaucoma-related blindness. The predominant mechanism of angle-closure glaucoma is pupillary block, with anterior lens movement as a strong contributing factor, often due to age, cataractous changes or posterior segment changes (Wright, C., et al. 2016)

Ultrasound biomicroscopy (UBM): A non-invasive high-frequency ultrasound imaging technique that utilizes 50 MHz high-frequency sound waves to produce a imaging of the anterior segment (AS) of the eye.

**CODING INFORMATION** THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

| CPT | Description |
|---|---|
| 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 |

| ICD-10 | Description: [For dates of service on or after 10/01/2015] |
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*Please reference CMS Database for applicable reviews to locate current NCDs/LCDs

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**Professional Society Guidelines and Other Publications**

American Academy of Ophthalmology (AAO). For additional information visit the AAO website: http://www.aao.org/ppp.

- Preferred Practice Pattern Cataract in the Adult Eye. 2016.
- Preferred Practice Pattern Primary Angle Closure. 2015.
- Preferred Practice Pattern Refractive Errors & Refractive Surgery. 2017.
- Preferred Practice Pattern Summary Benchmarks Glaucoma. 2018.

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9/25/2020: New Policy. Peer Review: Policy reviewed by AMR practicing physician board-certified in Ophthalmology. Date: 9/25/2020