Molina Clinical Policy
Optical Coherence Tomography of the Anterior Eye Segment: Policy No. 388

Last Approval: 6/14/2023
Next Review Due By: June 2024

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment, and clinical recommendations for the Member. 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 (e.g., 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 MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

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 (Jacobs 2022; Weizer 2021). Visualization of the anterior chamber 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 (Jacobs 2022). 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 2021). Slit lamp biomicroscopy and ultrasound biomicroscopy are alternative methods of evaluating 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 optical coherence tomography (OCT) and ultrasonography (Jacobs 2022; Weizer 2021).

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 (AS) ocular structure. 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, 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.

OCT is a non-invasive imaging technology used to obtain high resolution cross-sectional images of the retina and measurements of the AS 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 (AS-OCT), a non-contact imaging technology, can be used to assess anterior chamber biometry, corneal thickness and opacity, lens thickness, and angle configuration It can also be used to visualize pathological processes, to evaluate postsurgical anatomy and post-traumatic eyes, and to image phakic intraocular lenses and intracorneal ring segments' (). The clinical applications of AS-OCT in the pre-operative, intra-operative and post-operative setting has been utilized. AS-OCT 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.

Gonioscopy is the current clinical standard for evaluating the AS of the eye. An UpToDate review on "Angle-closure glaucoma" (Weizer 2021) 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 AS-OCT 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 AS-OCT devices (may not be an all-inclusive list; refer to the FDA 510(k) Premarket Notification database for information on specific AS-OCT devices):

- Visante OCT™ (Carl Zeiss Meditec, USA; FDA product code: HLI); RTVue® (Optovue; FDA product code: OBO) and the Slit lamp OCT (SL-OCT, Heidelberg Engineering, Germany; FDA product code: MXK).
- The microscope-integrated OCT 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: Envisu™ (Bioptigen FDA product code: HLI) and iVue® (Optovue; FDA product code: OBO)
- Ultrahigh resolution OCT devices include: SOCT Copernicus HR (Optopol Technologies; FDA product code OBO)
- Commercially available laser systems, such as the LenSx® (Alcon), Catalys® (OptiMedica), and VICTUS® (Technolas Perfect Vision), include OCT to provide image guidance for laser cataract surgery. FDA product code: OOE.
- Custom-built devices are also utilized and do not require FDA approval.

*AS-OCT systems are categorized by wavelength of light sources, including 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.).

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

COVERAGE POLICY

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 AS 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 AS-OCT at this time.

EXCEPTION: OCT may be authorized for members who have met all criteria and received authorization for Vabysmo (faricimab-svoa) for the treatment of neovascular (wet) age-related macular degeneration (nAMD) or diabetic macular edema. For additional information, please refer to Vabysmo (faricimab-svoa) Policy Number: C8633-A.

There is insufficient evidence for other potential indications (e.g., cataract surgery, endothelial keratoplasty, anterior uveitis). The current literature consists mainly of small, nonrandomized trials or case series which utilize OCT for a variety of indications, including plaque observation, preparation for eye surgery , clarification of diagnoses in pediatric patients , prediction of primary failure following endothelial keratoplasty and detection of inflammatory reaction in uveitis. Larger, randomized, trials of longer duration and follow-up are recommended to evaluate whether additional

conditions detected by OCT also result in improved health outcomes.

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

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

OCT 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 and 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

Desmond et al. (2021) completed a systematic review and meta-analysis to compare the diagnostic efficacy of AS-OCT to gonioscopy in the detection of angle closure. Inclusion criteria included studies measuring the diagnostic accuracy of AS-OCT with enough information to determine the specificity and sensitivity of AS-OCT. The review and meta-analysis included 23 studies with a total of 5663 patients. Notably, 7 of the included studies were performed by the same researchers with the same group of patients. However, each of the studies measured different parameters, negating the need to exclude the studies. The patients included in these 7 studies were only counted once. The results of the meta-analysis showed a sensitivity range from 46-100% with a median of 87%. The specificity ranged from 55.3-100% with a median of 84%. There were 4 studies included that provided the best diagnostic accuracy for AS-OCT. However, these studies had a considerable risk of bias. AS-OCT was noted to have good sensitivity for detecting angle closure. However, Desmond et al. noted that additional studies were needed to determine the ability of AS-OCT to replace gonioscopy.

AS Imaging During Minimally Invasive Glaucoma Surgery

Kan et al. (2022) completed a systematic review to examine the role of perioperative AS imaging in minimally invasive glaucoma surgery. A total of 21 studies were reviewed. AS imaging methods evaluated included AS-OCT, ultrasound microscopy, aqueous angiography, and in vivo confocal microscopy. Of the studies reviewed, 19 used AS imaging postoperatively, 3 studies used AS imaging intraoperatively, and 1 study used AS imaging preoperatively. Only 2 studies assessed the intraoperative application of AS-OCT. It was noted that AS-OCT was beneficial in negating the need for intraoperative gonioscopy as it allowed for “real time imaging during removal of the trabecular network.” However, the anterior chamber angle anatomy was difficult to visualize using AS-OCT “due to shadowing artifact from the more superficial layers.” AS-OCT and ultrasound microscopy were both noted to be beneficial at objectively evaluating the effects of trabectome surgery on the anatomy of the angle. AS-OCT was also noted to be comparable to ultrasound microscopy in the detection of cyclodialysis cleft.

OCT Compared with Slit Lamp Biomicroscopy

Singh et al. (2022) completed a cross-sectional, observational study to assess optic disk by disk damage likelihood scale (DDLS) staging using slit-lamp biomicroscopy and OCT to diagnose primary open-angle glaucoma in patients. A total of 106 patients underwent slit lamp fundoscopy. A +78 D lens and high-definition OCT were compared using vertical cup disk ratios (VCRD). The mean VCRD for slit lamp biomicroscopy was 0.76±0.09 with a range from 0.1-0.77. Mean VCRD for OCT was 0.81± 0.09 with a range from 0.07-0.81. DDLS staging was obtained using parameters from both slit lamp biomicroscopy and OCT. Researchers noted a positive correlation “between DDLS staging by biomicroscopy and best corrected visual acuity, VCDR of slit-lamp biomicroscopy, and VCDR of high-definition OCT.” There was also a strong positive correlation between DDLS staging using biomicroscopy and OCT.

National and Specialty Organizations

No professional societies have released clinical practice guidelines recommending the use of AS-OCT.

The **American Academy of Ophthalmology (AAO)** published a preferred practice pattern on primary angle closure disease in 2022 (AAO 2022). The AAO 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. AS 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 particularly 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.

The AAO preferred practice pattern Summary Benchmarks for Glaucoma (2022) continues to 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.

SUPPLEMENTAL INFORMATION

Gonioscopy: Performed during the ophthalmology exam to evaluate the internal drainage system (anterior chamber angle) to determine the form of glaucoma present (Jacobs 2022).

Angle-closure glaucoma: Glaucoma associated with a physically obstructed anterior chamber angle, which may be chronic or acute. Symptoms of acute angle closure are severe ocular pain and redness, decreased vision, colored halos around lights, headache, nausea, and vomiting. IOP is also elevated (Weizer 2021).

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 bilateral (Weizer 2021).

Primary Angle Closure Glaucoma: A significant cause of blindness worldwide that is 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 (Weizer 2021)

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

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology) Codes

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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

06/14/2023	Policy reviewed, no changes to coverage criteria. Grammatical edits to Disclaimer section and Documentation Requirements disclaimer. Updated Overview, Summary of Medical Evidence, and References sections. Code descriptions updated for codes 0604T, 0605T, and 0606T.
06/08/2022	Policy revised to address coverage of OCT for members authorized to receive Vabysmo (faricimab-svoa) therapy as outlined in Policy Number: C8633-A
12/08/2021	Policy reviewed. No changes in coverage criteria. Updated references; notable updates include the AAO preferred practice pattern guidelines issued in 2020 on primary angle closure disease noting the limitations of the AS-OCT in evaluating angle closure disease.
12/09/2020	New Policy. IRO (Independent Review Organization) Peer Review. 9/25/2020. Practicing physician board-certified in Ophthalmology.

REFERENCES

1. American Academy of Ophthalmology (AAO). Preferred practice pattern: Glaucoma summary benchmarks. Published December 2022. Accessed June 1, 2023. https://www.aao.org/education/summary-benchmark-detail/glaucoma-summary-benchmarks-2020.
2. American Academy of Ophthalmology (AAO). Preferred practice pattern: Primary angle closure. Published November 2020. Accessed June 1, 2023. https://www.aao.org/education/preferred-practice-pattern/primary-angle-closure-disease-ppp.
3. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) (search: optical coherence tomography; scanning computerized ophthalmic diagnostic imaging). Accessed May 31, 2023. https://www.cms.gov/medicare-coverage-database/search.aspx.
4. Desmond T, Tran V, Maharaj M, Carnt N, White A. Diagnostic accuracy of AS-OCT vs gonioscopy for detecting angle closure: a systematic review and meta-analysis. Graefes Arch Clin Exp Ophthalmol. 2022 Jan;260(1):1-23. doi: 10.1007/s00417-021-05271-4. Epub 2021 Jul 5. Erratum in: Graefes Arch Clin Exp Ophthalmol. 2021 Sep 28; PMID: 34223989; PMCID: PMC8255337.
5. Jacobs DS. Open-angle glaucoma: Treatment. Updated September 20, 2022. Accessed May 31, 2023. www.uptodate.com.
6. Kan JT, Betzler BK, Lim SY, Ang BCH. Anterior segment imaging in minimally invasive glaucoma surgery - A systematic review. Acta Ophthalmol. 2022 May;100(3):e617-e634. doi: 10.1111/aos.14962. Epub 2021 Jul 11. PMID: 34250742.
7. Singh K, Bhushan P, Mishra D, Kaur K, Gurnani B, Singh A, Pandey S. Assessment of optic disk by disk damage likelihood scale staging using slit-lamp biomicroscopy and optical coherence tomography in diagnosing primary open-angle glaucoma. Indian J Ophthalmol. 2022 Dec;70(12):4152-4157. doi: 10.4103/ijo.IJO_1113_22. PMID: 36453304; PMCID: PMC9940587.
8. United States Food and Drug Administration (FDA). 510(k) premarket notification. Accessed May 31, 2023. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm.
9. Weizer JS. Angle-closure glaucoma. Updated August 3, 2021. Accessed May 31, 2023. www.uptodate.com.