

Anterior Segment Optical Coherence Tomography Clinical Coverage Criteria

Overview

Optical Coherence Tomography (OCT) is a non-invasive imaging technique that produces crosssectional images of tissue with high resolution. Therefore it is especially valuable in organs, where traditional microscopic tissue diagnosis by means of biopsy is not available—such as the human eye. OCT allows for visualization and analytics of anterior segment structures of the eye, including the cornea, anterior chamber, iris, and lens.

Policy

This Policy applies to the following Fallon Health products:

- Sealon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
- MassHealth ACO
- ☑ NaviCare HMO SNP (Dual Eligible Medicare Advantage and MassHealth)
- ☑ NaviCare SCO (MassHealth-only)
- ☑ PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)
- Community Care (Commercial/Exchange)

Anterior segment optical coherence tomography requires prior authorization.

Medicare Advantage

Fallon Health complies with CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations for Medicare Advantage members. When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health may create internal coverage criteria under specific circumstances described at § 422.101(b)(6)(i) and (ii).

Medicare statutes and regulations do not have coverage criteria for ambulatory cardiac monitoring. Medicare does not have an NCD for optical coherence tomography. National Government Services, Inc., the Part A/B Medicare Administrative Carrier (MAC) with jurisdiction in the Plan's service area has an LCD Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) L34380 (Medicare Coverage Database search 05/27/2024).

Link: LCD Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) L34380

Note: Anterior segment OCT is not covered for screening.

Coverage criteria for anterior segment optical coherence tomography are fully established by Medicare, therefore the Plan's coverage criteria are not applicable.

MassHealth ACO

Fallon Health follows Medical Necessity Guidelines published by MassHealth when making medical necessity determinations for MassHealth members. In the absence of Medical Necessity

Guidelines published by MassHealth, Fallon Health may create clinical coverage criteria in accordance with the definition of Medical Necessity in 130 CMR 450.204.

MassHealth does not have Guidelines for Medical Necessity Determination for anterior segment optical coherence tomography (MassHealth website search 05/27/2024). Fallon Health does not have clinical coverage criteria for anterior segment optical coherence tomography, therefore, Fallon Health will review requests for anterior segment optical coherence tomography for MassHealth ACO members on an individual case-by-case basis in accordance with the MassHealth definition of Medical Necessity in 130 CMR 450.204.

NaviCare HMO SNP, NaviCare SCO

For plan members enrolled in NaviCare, Fallon Health first follow's CMS's national coverage determinations (NCDs), local coverage determinations (LCDs) of Medicare Contractors with jurisdiction for claims in the Plan's service area, and applicable Medicare statutes and regulations when making medical necessity determinations.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, or if the NaviCare member does not meet coverage criteria in applicable Medicare statutes, regulations, NCDs or LCDs, Fallon Health then follows Medical Necessity Guidelines published by MassHealth when making necessity determinations for NaviCare members.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria

Fallon Health Clinical Coverage Criteria apply to Community Care members. Refer to Policy section above for coverage for Medicare Advantage, MassHealth ACO, NaviCare and PACE plan members.

Fallon Health considers the use of anterior segment OCT experimental/investigational due to lack of scientific literature supporting its definitive use. Fallon Health will review requests for anterior segment optical coherence tomography on an individual case-by-case basis, prior authorization is required. Medical records from the requesting provider are required.

Exclusions

- Any use of anterior segment optical coherence tomography other than outlined above.
- Anterior segment optical coherence tomography performed in relation to a non-covered eye procedure (e.g. refractive surgery).

Evidence Summary

Glaucoma

Glaucoma is a group of eye disorders characterized by progressive deterioration of the optic nerve that can lead to vision loss. Primary glaucoma can be classified into 2 main categories: open-angle glaucoma and angle-closure glaucoma. Primary open-angle glaucoma (POAG) is the most common form in the United States. POAG is a chronic, progressive disease causing loss of the optic nerve rim and retinal nerve fiber layer with associated visual field defects. The anterior chamber is open, and the disease is generally bilateral. Risk factors for POAG include older age, African or Latino/Hispanic ethnicity, elevated intraocular pressure, family history of glaucoma, lower ocular perfusion pressure, type 2 diabetes and think central cornea.

The American Academy of Ophthalmology (AAO, 2020a) describes primary angle closure disease (PACD) along a spectrum: primary angle closure suspect (PACS), primary angle closure (PAC), primary angle closure glaucoma (PACG), and acute angle-closure crisis (AACC), plateau iris configuration, and plateau iris syndrome. Risk factors for PACD include Asian descent, hyperopia, older age, female gender, short axial length, and thick and anteriorly positioned crystalline lens.

- Primary angle-closure suspect (PACS): ≥180 degrees iridotrabecular contact (ITC), normal intraocular pressure (IOP), and no optic nerve damage.
- Primary angle closure (PAC): ≥180 degrees ITC with peripheral anterior synechiae or elevated IOP, but no optic neuropathy.
- Primary angle-closure glaucoma (PACG): ≥180 degrees ITC with PAS, elevated IOP, and optic neuropathy
- Acute angle-closure crisis (AACC): occlude angle with symptomatic high IOP
- Plateau iris configuration: narrow angle due to an anteriorly positioned ciliary body, with deep central anterior chamber
- Plateau iris syndrome: narrow angle due to an anteriorly positioned ciliary body, with deep central anterior chamber, and any ITC persisting after patent peripheral iridotomy.

Dark room dynamic gonioscopy should be performed to diagnose PACD and verify improvement in angle configuration following treatment. Ultrasound biomicroscopy and anterior segment optical coherence tomography can also aid in the diagnosis of PACD, but only dynamic gonioscopy and ultrasound biomicroscopy can diagnose plateau iris. The goal of managing patients with PACD are to reverse or prevent angle-closure and to control IOP to prevent glaucomatous optic nerve damage.

Components of the physical examination that are relevant for the diagnosis and management of PACD are:

- Refractive status hyperopic eyes tend to have shallower anterior chamber angles which places them at risk for angle closure
- Pupil size and reactivity
- Slit lamp exam
 - Conjunctival hyperemia
 - o Central and peripheral anterior chamber depth narrowing
 - o Cornea swelling and corneal diameter
 - Anterior chamber central and peripheral depth, inflammation
 - o Iris abnormalities areas of atrophy, mass, neovascularization, or posterior synechiae
 - Lens changes

 thickness, phacodonesis, subluxation, glaucomflecken (necrosis of anterior lens capsule; may indicate previous attacks)
- Intraocular pressure measurement, preferably with applanation prior to gonioscopy
- Gonioscopy of both eyes with indentation to evaluate for appositional versus synechial angle closure
- Evaluation of fundus and optic nerve dilation is often not advisable in primary angle closure attack until an iridotomy has been performed and/or the acute attack has resolved as dilation can exacerbate the condition. In contrast, dilation may be permissible as the appropriate treatment in certain forms of secondary angle closure. The fundus should be examined for underlying causes leading to the angle closure.

Anterior segment optical coherence tomography (AS-OCT) 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 (AAO, 2020a).

Anterior Segment Optical Coherence Tomography (AS-OCT)

The first commercial OCT systems specifically designed for anterior segment imaging were the Zeiss Visante OCT (Carl Zeiss Meditec, Dublin, CA, USA) and the Slit-Lamp OCT (SL-OCT, Heidelberg Engineering GmbH, Heidelberg, Germany). Both of these devices received clearance by the United States Food and Drug Administration (FDA) in 2005 and 2006, respectively. There are currently several AS-OCT devices available on the market; depending on the device, they use one of the following methods to obtain clinical data: time domain, spectral domain or the more recent swept source domain method. Spectral and swept source domain methods have a higher scan speed and resolution than time domain methods.

AS-OCT can be widely applicable in various anterior segment pathologies, such as conjunctival neoplasia, pterygium, scleritis, keratoconus, corneal dystrophies, and infectious/noninfectious keratitis. In addition, the clinical applications of AS-OCT (including epithelial mapping) include preoperative planning and postoperative monitoring for corneal and refractive surgeries. AS-OCT also has applications in glaucoma due to its ability to image the anterior segment (Chong et al., 2024).

Systematic Reviews

Desmond et al., 2022, performed a systematic review (SR) with meta-analysis of the diagnostic accuracy of anterior segment optical coherence tomography (AS-OCT) compared to gonioscopy in detecting eves with angle closure. A literature search was performed in April 2020 resulting in the inclusion of 23 studies (N=5.663). Only studies that provided enough data to determine the sensitivity and specificity of AS-OCT and assessed the ability to detect an eye with angle closure were included. Eighteen studies were conducted in Asia, three in the United States, and two in the United Kingdom. There was substantial variation in the assessed parameters and methodology among the studies including the use of different optical coherence tomography devices, gonioscopy diagnostic criteria, and AS-OCT positivity threshold. The sensitivity of AS-OCT ranged from 46% to 100% (median, 87%) with a specificity ranging from 55.3% to 100% (median, 84%). Of the four studies with the best diagnostic accuracy for AS-OCT, all used a case-control study design with a high risk of bias. Overall, the authors concluded that AS-OCT demonstrates "good sensitivity for detecting angle closure. It may provide an avenue to address high rates of undiagnosed angle closure, such as found in developing Asian countries. However, AS-OCT is not yet able to replace gonioscopy." More studies are needed to determine the utility of AS-OCT.

Jindal et al., 2020 conducted a Cochrane systematic review with meta-analysis to determine the diagnostic accuracy of non-contact tests including AS-OCT for the detection of an occludable angle. This review is an update of "Non-contact methods for the detection of people at risk of primary angle closure glaucoma" in volume 2018, CD012947. A total of 47 studies involving 26,151 participants and analyzing data from 23,440 were included. Most studies were conducted in Asia (36, 76.6%). Fifty-seven per cent of included studies evaluated AS-OCT (27 studies analyzing 15,580 participants). For comparisons of sensitivity and specificity between tests, the authors used limbal anterior chamber depth (van Herick test) <25%, as the reference category. Summary estimates were calculated for commonly reported parameters and thresholds for each test. AS-OCT (subjective opinion of occludability) was evaluated across 13 studies (9,242 eyes) and found to have a sensitivity of 0.85 (95% CI 0.76, 0.91) and specificity 0.71 (95% CI 0.62, 0.78) (moderate-certainty). Comparisons of sensitivity and specificity between index tests and limbal anterior chamber depth (LACD) (\leq 25%) as the reference found AS-OCT had a statistically significant lower specificity (p=0.0003).

Smith et al., 2013, conducted a systematic review of the published literature pertaining to the association between anterior segment imaging and gonioscopy and to determine whether such imaging aids in the diagnosis of primary angle closure. The panel reviewed the full text of these articles and identified 79 studies meeting the inclusion criteria. Gonioscopy has been consistently considered for a long time the gold standard of anterior chamber angle evaluation, although it is a time-consuming examination, requiring a long learning curve and good ocular surface conditions.

Quantitative and qualitative parameters defined from ultrasound biomicroscopy, anterior segment optical coherence tomography. Scheimpflug photography, and the scanning peripheral anterior chamber (SPAC) depth analyzer demonstrate a strong association with the results of gonioscopy. There is substantial variability in the type of information obtained from each imaging method. Imaging of structures posterior to the iris is possible only with ultrasound biomicroscopy. Direct imaging of the anterior chamber angle is possible using ultrasound biomicroscopy and AS-OCT. Noncontact imaging using AS-OCT, Scheimpflug photography, or SPAC makes these methods more attractive for large-scale primary angle closure screening than contact imaging using ultrasound biomicroscopy. Although there is evidence suggesting that anterior segment imaging provides useful information in the evaluation of primary angle closure, none of these imaging methods provides sufficient information about the anterior chamber angle anatomy to be considered a substitute for gonioscopy. There is currently no consensus on which threshold values to use for any of the quantitative parameters mentioned to identify an occludable angle. Longitudinal studies are needed to validate the diagnostic significance of the parameters measured by these instruments for prospectively identifying individuals at risk for primary angle closure (Smith et al., 2013).

Clinical Practice Guidelines

American Academy of Ophthalmology

The American Academy of Ophthalmology Preferred Practice Patterns Committee published Primary Angle-Closure Disease Preferred Practice Pattern in 2020. 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 and that anterior segment imaging may be a useful adjunct to gonioscopy.

Anterior segment optical coherence tomography 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. Anterior segment optical coherence tomography can be used to characterize the angle qualitatively and quantitatively. Quantitative characteristics, available from software included with the anterior segment optical coherence tomography machines, include angle opening depth, trabecular-iris space area and angle recess area, iridotrabecular contact index, lens vault, and iris volume.

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. Patchy pigment throughout the angle (indicative of intermittent iridotrabecular contact) would also not be recorded in anterior segment optical coherence tomography.

Ultrasound biomicroscopy provides better characterization of the posterior iris and ciliary body compared with anterior segment optical coherence tomography. Although ultrasound biomicroscopy is more operator dependent and time consuming than anterior segment optical coherence tomography, ultrasound biomicroscopy is a better imaging modality than anterior segment optical coherence tomography for identifying plateau iris configuration or characterizing the position of the ciliary body.

Summary of Evidence (Rationale for Determination)

Current recommended practice patterns by the American Academy of Ophthalmology endorse gonioscopy as the preferred means of performing evaluation of the anterior chamber angle. Although there remains insufficient evidence to endorse AS-OCT as a substitute for gonioscopy, AS-OCT is a recommended option in cases where angle closure is suspected, and the angle anatomy is not conducive to gonioscopic assessment. It is currently unclear how AS-OCT fits into clinical practice for detecting angle closure.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Procedure codes may be subject to National Correct Coding Initiative (NCCI) edits and other edits.

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

References

- National Government Services, Inc. Local Coverage Determination (LCD): Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (L34380) Original Effective Date: For services performed on or after 10/01/2015. Revision Effective Date: For services performed on or after 09/19/2019.
- National Government Services, Inc. Local Coverage Article Billing and Coding: Scanning Computerized Ophthalmic Diagnostic Imaging (SCODI) (A56537). Original Effective Date: 08/01/2019. Revision Effective Date: 10/01/2020.
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Policy history

Origination date: Approval(s):	02/01/2017 Technology Assessment Committee: 01/25/2017 (new policy), 01/24/2018 (updated references), 01/23/2019 (updated references), 01/22/2020 (updated references), 06/22/2021 (annual review, updated references; 06/15/2021 added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section), 05/28/2024 (annual review, update Medicare and MassHealth information under Policy section, added Summary of Evidence and Apalvaia of Evidences, updated Deferences)
	Analysis of Evidence, updated References).

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.