MEDICAL POLICY

POLICY TITLE	OPTICAL COHERENCE TOMOGRAPHY (OCT) OF THE ANTERIOR EYE SEGMENT
POLICY NUMBER	MP 2.085

Effective Date:	11/1/2023

I. POLICY

Scanning computerized ophthalmic (e.g., optical coherence tomography) imaging of the anterior eye segment is considered **not medically necessary**. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:

MP 2.028 Eye Care
MP 2.056 Ophthalmologic Techniques That Evaluate the Posterior Eye Segment for Glaucoma
MP 2.086 Retinal Telescreening for Diabetic Retinopathy

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI below. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at*:* https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies.

III. DESCRIPTION/BACKGROUND

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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.

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.

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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 MP 9.011). 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. Ultrasonography uses high-frequency mechanical pulses (10 to 20 MHz) to build a picture of the front of the eye. An ultrasound scan along the optical axis assesses corneal thickness, anterior chamber depth, lens thickness, and axial length. Ultrasound scanning across the eye creates a 2-dimensional image of the ocular structures. It has a resolution of 100 μm but only moderately high intraobserver and low interobserver reproducibility. Ultrasound biomicroscopy (»50 MHz) has a resolution of 30 to 50 μm. As with slit-lamp biomicroscopy with a gonioscopic mirror, this technique requires placement of a probe under topical anesthesia.

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Per the American Academy of Ophthalmology's Primary Angle-Closure Disease Preferred Practice Pattern, 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 OCT (AS-OCT) can be very useful, it has its 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 AS-OCT in evaluating plateau iris configuration or ciliary body abnormalities. Isolated peripheral anterior synechiae (PAS) or small tufts of neovascularization may be missed if not in the plane imaged by AS-OCT. Patchy pigment throughout the angle (indicative of intermittent iridotrabecular contact) would also not be recorded in AS-OCT. Swept source OCT offers a clear advantage over time domain OCT in this regard. However, even swept source OCT demonstrates only moderate agreement with gonioscopy assessment of angle closure.

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 MP 2.056 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.

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	Indication
SOLIX	Optovue, Inc.	11/9/2022	K222166	OBO, HKI, HLI	Anterior segment optical coherence tomography
Tomey Cornea/Anterior Segment OCT CASIA2	Tomey Corporation	4/27/2022	K213265	OBO	Anterior segment optical coherence tomography
Anterion	Heidelberg Engineering GmbH	11/5/2021	K211817	OBO	Anterior segment optical coherence tomography
Pentacam AXL Wave	Oculus Optikgerate GmbH	10/21/2020	K201724	MXK	Anterior segment optical coherence tomography
Xephilio OCT-A1	Canon	7/24/2019	K182942	OBO, HLI	Anterior segment optical coherence tomography
Avanti	Optovue Inc.	6/8/2018	K180660	OBO	Anterior segment optical coherence tomography
iVue	Optovue Inc.	6/9/2017	K163475	OBO	Anterior segment optical coherence tomography
VX130 Ophthalmic Diagnostic Device	Luneau SAS	4/24/2017	K162067	HKX	Anterior segment optical coherence tomography

LSFG-NAVI	Softcare Co. Ltd	5/12/2016	K153239	HKI	Anterior segment optical coherence tomography
RTVue XR OCT Avanti with AngioVue Software	Optovue Inc.	2/11/2016	K153080	HLI	Anterior segment optical coherence tomography
Pentacam AXL	Oculus Optikgerate GmbH	1/20/2016	K152311	MXK	Anterior segment optical coherence tomography
EnFocus 2300 EnFocus 4400	Bioptigen Inc.	12/2/2015	K150722	HLI	Anterior segment optical coherence tomography
ARGOS	Santec Corporation	10/2/2015	K150754	MXK	Anterior segment optical coherence tomography
OCT-Camera	OptoMedical Technologies GmbH	3/4/2015	K142953	HLI	Anterior segment optical coherence tomography
Propper Insight Binocular Indirect Ophthalmosope	Propper Manufacturing Co. Inc.	9/17/2014	K141638	HLI	Anterior segment optical coherence tomography
CenterVue Macular Integrity Assessment	CenterVue SpA	4/23/2014	K133758	HLI	Anterior segment optical coherence tomography
Amico DH-W35 Ophthalmoscope Series	Amico Diagnostic Inc.	3/26/2014	K131939	HLI	Anterior segment optical coherence tomography
IVUE 500	Optovue Inc.	3/19/2014	K133892	HLI	Anterior segment optical coherence tomography

IV. RATIONALE

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Summary of Evidence

For individuals who are being evaluated for angle-closure glaucoma who receive anterior segment optical coherence tomography, the evidence includes a systematic review, case series, and cohort studies. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Current literature consists primarily of assessments of qualitative and quantitative imaging and detection capabilities. Ideally, a diagnostic test should be evaluated based on its diagnostic accuracy and clinical utility. Studies have shown that anterior segment

optical coherence tomography detects more eyes with narrow or closed angles than gonioscopy, suggesting that the sensitivity of optical coherence tomography may be higher than that of gonioscopy. However, because of clinical follow-up and validation studies, it is not clear to what degree these additional cases are true positives or false positives and, therefore, the specificity and predictive values cannot be determined. The evaluation of diagnostic performance depends, therefore, on evidence that the additional eyes identified with narrow angle by 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

V. DEFINITIONS

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ANTERIOR SEGMENT is the front third of the eye that includes the structures in front of the vitreous humour: the cornea, iris, ciliary body, and lens. Within the anterior segment are two fluid-filled spaces: the anterior chamber between the posterior surface of the cornea (i.e. the corneal endothelium) and the iris and the posterior chamber between the iris and the front face of the vitreous. Aqueous humor fills these spaces within the anterior segment and provides nutrients to the surrounding structures

DIABETIC RETINOPATHY is a disorder of retinal blood vessels characterized by capillary microaneurysms, hemorrhage, exudates, and the formation of new vessels and connective tissue.

INTRAOCULAR PRESSURE refers to the internal pressure of the eye regulated by resistance to the flow of aqueous humor through the fine sieve of the trabecular meshwork.

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not medically necessary and therefore not covered:

Procedure Codes								
92132								

IX. REFERENCES

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20. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 9.03.18, Optical Coherence Tomography of the Anterior Eye Segment. April 2023*

X. POLICY HISTORY

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MP 2.085	**CAC 10/25/11 -New policy**. Adopt BCBSA. This new policy addresses Optical Coherence Tomography (OCT) for evaluation of the anterior segment of the eye which is listed as investigational. OCT for the evaluation of the optic nerve (retinal nerve fiber layer) layer is addressed in MP 2.056.
	CAC 1/29/13 Consensus review. No change to policy statements. References updated. Changed policy title to Optical Coherence Tomography (OCT) of the Anterior Eye Segment (formerly Anterior Eye Segment Optical Imaging. This is consistent with change made by BCBSA. Codes reviewed 12/17/13
	CAC 1/28/14 Consensus review. No change to policy statements. References updated. Rationale added. FEP variation revised to reflect updated title. Codes reviewed.
	CAC 1/27/15 Consensus review. No change to policy statements. References and rationale updated. Codes reviewed.
	11/2/15 Administrative change. LCD number changed from L27529 to L35038 due to Novitas update to ICD-10.
	CAC 1/26/16 Consensus review. No change to the policy statement. References and rationale updated**.**
	CAC 11/29/16 Consensus. No change to policy statement. References and rationale updated. Coding reviewed. Variations updated.
	12/19/17 Consensus review. No changes to the policy statement. Rationale updated.
	11/11/18. Consensus. No change to policy statements. References updated. Rationale condensed.
	8/26/2019. Consensus review. Policy statement unchanged. References updated.

	5/20/2020 Administrative update. New codes 0604T, 0605T, and 0606T added to the policy. Product Variation, Benefit Variation, and Disclaimer updated.
	7/15/20: Consensus review. Background and references updated. No change to policy statement
	6/16/2021 Consensus review. Updated cross references, background, rationale, and references. No changes to coding at this time.
	10/5/2021 Administrative review. Took 0604T-0606T off of policy as they have been placed into MP 2.056. Effective date 3/1/2022.
	05/20/2022 Consensus review. No change to policy statement. FEP language updated. Background and Rationale revised. References added.
	6/14/2023 Minor review. Policy statement changed from INV to NMN. Updated background, cross-references, and references. No changes to coding.

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