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FEP Medical Policy Manual

FEP 9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

Annual Effective Policy Date: July 1, 2024

Original Policy Date: June 2012

Related Policies:

9.03.06 - Ophthalmologic Techniques That Evaluate the Posterior Segment for Glaucoma

Optical Coherence Tomography of the Anterior Eye Segment

Description

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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.

OBJECTIVE

The objective of this evidence review is to evaluate whether optical coherence tomography of the anterior eye segment improves health outcomes compared with existing technologies in individuals with angle-closure glaucoma, undergoing anterior eye surgery or experiencing postsurgical complications, or anterior eye segment disease or pathology.

POLICY STATEMENT

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

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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 (Table 1). 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
3D optical coherence tomography 3D OCT-1 (type: Maestro2)	Topcon Corporation	10/30/2023	K231222	OBO, HKI	Anterior segment optical coherence tomography
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

RATIONALE

Summary of Evidence

For individuals who are being evaluated for angle-closure glaucoma who receive anterior segment optical coherence tomography (AS-OCT), 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 AS-OCT 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 AS-OCT 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 AS-OCT 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 AS-OCT 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 AS-OCT , the evidence includes case series. Relevant outcomes are test accuracy, symptoms, change in disease status, and morbid events. Use of AS-OCT has been reported for presurgical evaluation, surgical guidance, and monitoring for postsurgical complications. There is some evidence that the high-resolution images provided by AS-OCT 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 AS-OCT , 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 AS-OCT for anterior segment disease or pathology (eg, 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

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.[19,] 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.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy.	
June 2013	Replace policy.	Policy updated with literature search, Policy title changed to Optical Coherence Tomography (OCT) of the Anterior Eye Segment; references added and reordered, policy statement unchanged.
June 2014	Replace policy.	Policy updated with literature search, adding reference 13. The policy statement was unchanged.
June 2015	Replace policy.	Policy updated with literature search, adding references 11, 12 and 18,19. No changes were made to the policy statement.
September 2016	Replace policy.	Policy updated with literature review through July 12, 2016; references 11 and 17 added. Policy statement unchanged.
June 2018	Replace policy.	Policy updated with literature review through January 26, 2018;references 9 added. Policy statement unchanged except "not medically necessary€š corrected to "investigational€š due to FDA 501(k) status.
June 2019	Replace policy.	Policy updated with literature review through January 6, 2019; no references added. Policy statement unchanged.
June 2020	Replace policy	Policy updated with literature review through January 13, 2020; no references added. Policy statement unchanged.
June 2021	Replace policy	Policy updated with literature review through January 27, 2021; no references added. Policy statement unchanged.
June 2022	Replace policy	Policy updated with literature review through January 23, 2022; reference added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through January 20, 2023; no references added. Policy statements unchanged.
June 2024	Replace policy	Policy updated with literature review through January 29, 2024; references added. Policy statements unchanged.