

FEP 9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

Effective Date: July 15, 2018

Related Policies:

9.03.06 Ophthalmologic Techniques of Evaluating Glaucoma
9.03.21 Aqueous Shunts and Stents for Glaucoma

Optical Coherence Tomography of the Anterior Eye Segment

Description

Optical coherence tomography (OCT) is a noninvasive, high-resolution imaging method that can be used to visualize ocular structures. OCT of the anterior segment (AS) 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.

FDA REGULATORY STATUS

Multiple OCT 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); the RTVue® (Optovue) (FDA product code: HLI); and the Slit Lamp OCT (SL-OCT; Heidelberg Engineering) (FDA product code: MXK). The microscope-integrated OCT devices for intraoperative use include the ReScan 700 (Zeiss) and the iOCT® system (Haag-Streit). Portable devices for intraoperative use include the Bioptigen Envisu™ (Bioptigen) and the Optovue iVue® (Optovue). Ultrahigh resolution OCT devices include the 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, which do not require FDA approval, are also used.

The AC Cornea OCT (Ophthalmic Technologies) is not cleared for marketing in the United States.

POLICY STATEMENT

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

BENEFIT APPLICATION

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

FEP 9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

RATIONALE

Summary of Evidence

For individuals who are being evaluated for angle-closure glaucoma who receive AS OCT, the evidence includes 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 OCT is 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 the effects of the technology on health outcomes.

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 the effects of the technology on health outcomes.

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 AS 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 the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

In 2015, the American Academy of Ophthalmology published a preferred practice pattern on primary angle closure.¹⁶ The Academy stated 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. AS imaging methods discussed were ultrasound biomicroscopy, Scheimpflug imaging, and AS OCT. It was noted that AS OCT is limited to evaluating the iridocorneal angle.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

FEP 9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

REFERENCES

1. Wolffsohn JS, Peterson RC. Anterior ophthalmic imaging. *Clin Exp Optom*. Jul 2006;89(4):205-214. PMID 16776728
2. Baskaran M, Iyer JV, Narayanaswamy AK, et al. Anterior segment imaging predicts incident gonioscopic angle closure. *Ophthalmology*. Dec 2015;122(12):2380-2384. PMID 26359189
3. Nolan WP, See JL, Chew PT, et al. Detection of primary angle closure using anterior segment optical coherence tomography in Asian eyes. *Ophthalmology*. Jan 2007;114(1):33-39. PMID 17070597
4. Narayanaswamy A, Sakata LM, He MG, et al. Diagnostic performance of anterior chamber angle measurements for detecting eyes with narrow angles: an anterior segment OCT study. *Arch Ophthalmol*. Oct 2010;128(10):1321-1327. PMID 20938002
5. Pekmezci M, Porco TC, Lin SC. Anterior segment optical coherence tomography as a screening tool for the assessment of the anterior segment angle. *Ophthalmic Surg Lasers Imaging*. Jul-Aug 2009;40(4):389-398. PMID 19634744
6. Mansouri K, Sommerhalder J, Shaarawy T. Prospective comparison of ultrasound biomicroscopy and anterior segment optical coherence tomography for evaluation of anterior chamber dimensions in European eyes with primary angle closure. *Eye (Lond)*. Feb 2010;24(2):233-239. PMID 19444291
7. Jiang C, Li Y, Huang D, et al. Study of anterior chamber aqueous tube shunt by fourier-domain optical coherence tomography. *J Ophthalmol*. Jul 2012;2012:189580. PMID 22778909
8. Moutsouris K, Dapena I, Ham L, et al. Optical coherence tomography, scheinplflug imaging, and slit-lamp biomicroscopy in the early detection of graft detachment after descemet membrane endothelial keratoplasty. *Cornea*. Dec 2011;30(12):1369-1375. PMID 21993458
9. Venincasa MJ, Osigian CJ, Cavuoto KM, et al. Combination of anterior segment optical coherence tomography modalities to improve accuracy of rectus muscle insertion location. *J AAPOS*. Jun 2017;21(3):243-246. PMID 28526283
10. Nguyen P, Chopra V. Applications of optical coherence tomography in cataract surgery. *Curr Opin Ophthalmol*. Jan 2013;24(1):47-52. PMID 23197267
11. Bianciotto C, Shields CL, Guzman JM, et al. Assessment of anterior segment tumors with ultrasound biomicroscopy versus anterior segment optical coherence tomography in 200 cases. *Ophthalmology*. Jul 2011;118(7):1297-1302. PMID 21377736
12. Agarwal A, Ashokkumar D, Jacob S, et al. High-speed optical coherence tomography for imaging anterior chamber inflammatory reaction in uveitis: clinical correlation and grading. *Am J Ophthalmol*. Mar 2009;147(3):413-416 e413. PMID 19054493
13. Garcia JP, Jr., Rosen RB. Anterior segment imaging: optical coherence tomography versus ultrasound biomicroscopy. *Ophthalmic Surg Lasers Imaging*. Nov-Dec 2008;39(6):476-484. PMID 19065978
14. Medina CA, Plesec T, Singh AD. Optical coherence tomography imaging of ocular and periocular tumours. *Br J Ophthalmol*. Jul 2014;98(Suppl 2):ii40-46. PMID 24599420
15. Thomas BJ, Galor A, Nanji AA, et al. Ultra high-resolution anterior segment optical coherence tomography in the diagnosis and management of ocular surface squamous neoplasia. *Ocul Surf*. Jan 2014;12(1):46-58. PMID 24439046
16. American Academy of Ophthalmology. Preferred Practice Pattern: Primary angle closure. 2015; [http://www.aaojournal.org/article/S0161-6420\(15\)01271-3/pdf](http://www.aaojournal.org/article/S0161-6420(15)01271-3/pdf). Accessed February 26, 2018.

POLICY HISTORY

Date	Action	Description
June 2012	New Policy	
June 2013	Update 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	Update Policy	Policy updated with literature search, adding reference 13. The policy statement was unchanged.
June 2015	Update Policy	Policy updated with literature search, adding references 11, 12 and 18, 19. No changes were made to the policy statement.
September 2016	Update Policy	Policy updated with literature review through July 12, 2016; references 11 and 17 added. Policy statement unchanged.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.

FEP 9.03.18 Optical Coherence Tomography of the Anterior Eye Segment

June 2018	Update Policy	Policy updated with literature review through January 26, 2018; references 9 added. Policy statement unchanged except “not medically necessary” corrected to “investigational” due to FDA 501k status.
-----------	---------------	--

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.