

Optical Coherence Tomography (OCT)

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Summary

Optical Coherence Tomography, or "OCT", is a medical imaging test that uses light waves to capture live 3-dimensional images. It is similar in principle to ultrasound (which uses sound echoes, rather than light wave reflections), however OCT provides up to 10 times the resolution. OCT has been used to image different structures of the body, including the eye, the heart, the gastrointestinal (GI) system, the breast, and the upper airway. It does not require any contact with the target surfaces and does not produce any ionizing radiation. In some cases, OCT can be used with other instruments such as an endoscope in the GI system or as an intravascular device in the arteries of the heart. OCT is a relatively novel technology and is rapidly evolving in both technique and clinical utility. This guideline provides the clinical criteria and exclusions for the currently supported clinical applications of Optical Coherence Tomography.

Definitions

"Retinopathy" refers to diseases of the retina that may impair vision, including macular degeneration, diabetic retinopathy, and a number of other conditions. Retinopathy can be "proliferative" or "nonproliferative", depending on the underlying mechanism.

"Macular Degeneration" is an incurable condition that affects the macula, which is the central portion of the retina responsible for fine detail vision. It can be further categorized as "wet" or "dry" depending on

the underlying process, and stratified by stage (early, intermediate, late). Macular degeneration is the leading cause of vision loss.

“Macular Edema” occurs when fluid builds up behind the macula of the eye, leading to swelling and distortion of central vision. Macular edema can occur in a number of diseases, including macular degeneration.

“Optical Coherence Tomography (OCT)” is an imaging technique that uses the reflections of light particles to create live 3-D images. Because OCT is based on light, it has significantly higher resolution than comparable imaging techniques such as ultrasound and MRI. However, given the poor penetration of light into tissue, OCT is limited to relatively superficial surfaces. OCT does not generate ionizing radiation.

- **“Spectral Domain OCT”** is a newer version of OCT technology which can obtain images up to 50 times faster than traditional “time domain” and may be more appropriate in the diagnosis and assessment of certain conditions.
- **“Intravascular OCT”** refers to OCT imaging conducted with specialized, miniature devices from within a blood vessel.

Clinical Indications and Coverage

Oscar considers Optical Coherence Tomography medically necessary when any **ONE** of the following criteria are met:

1. Spectral Domain OCT is indicated when a member is taking **chloroquine, hydroxychloroquine, ezogabine, or vigabatrin** and **ONE** of the following criteria are met:
 - a. Baseline exam within the first year of medication use; **or**
 - b. As a once yearly exam for patients with 1 or more of the following:
 - i. 5 years or more of use; **or**
 - ii. Documentation of elevated risk for developing retinopathy, defined by:
 1. Concurrent macular disease; **or**
 2. Concurrent renal disease; **or**
 3. Concomitant use of tamoxifen; **or**
 4. High-dose chloroquine (>2.3mg/kg) or hydroxychloroquine (>5mg/kg).
2. **Macular edema** when at least **ONE** of the following criteria are met:
 - a. Needed to establish the diagnosis of macular edema; **or**
 - b. When the results may impact the treatment plan (e.g., the need for antiangiogenic treatment).

3. **Neovascular age-related macular degeneration** when at least **ONE** of the following criteria are met:
 - a. Needed to establish the diagnosis when fluorescein angiography is contraindicated or unavailable; **or**,
 - b. When the results may impact the treatment plan (e.g. the need for antiangiogenic treatment).
4. OCT may be indicated to document the appearance of optic nerve head and retina in members who have a diagnosis of at least **ONE** of the following:
 - a. Glaucoma, no more than once per year; **or**
 - b. Posterior vitreous detachment; **or**
 - c. Diabetic retinopathy; **or**
 - d. Macular hole; **or**
 - e. Macular edema; **or**
 - f. Age-related macular degeneration; **or**
 - g. Pseudotumor cerebri.

Coverage Exclusions

Oscar considers Optical Coherence Tomography **experimental and investigational** for the following indications, as the current evidence is insufficient to demonstrate clear clinical benefit:

- Gastrointestinal usage, including but not limited to assessment or diagnosis of:
 - Esophageal mucosal diseases (e.g. Barrett’s esophagus or squamous cell carcinoma)
 - Gastric mucosa
 - Diseases of the colon and small bowel (e.g. inflammatory bowel disorders, polyps)
 - Biliary and pancreatic duct measurements
- Upper airway OCT for obstructive sleep apnea
- Any intraoperative OCT, including OCT for the purpose of lymph node or tumor margin assessment
- Ocular indications other than those defined above, including but not limited to:
 - Anterior segment imaging (e.g. cornea, iris, ciliary body, and lens)
 - *Gonioscopy is the gold-standard for evaluating the anterior segment of the eye, per the American Academy of Ophthalmology.*
 - For primary angle closure (PAC):
 - The American Academy of Ophthalmology (AAO) Preferred Practice Patterns for Primary Angle Closure (2015) state that AS-OCT is “limited to evaluating the iridocorneal angle” and that it “may prove useful in evaluating secondary causes of angle closure”. Gonioscopy is discussed

as the gold standard to be performed in all patients with suspected angle closure.

- Smith et al (2013) - Study conducted on AS-OCT for primary angle closure by the AAO. 79 of the 371 potential studies met their inclusion criteria and were reviewed in full. Authors concluded that while AS-OCT may provide useful anatomic and pathologic information, the evidence is insufficient to consider using AS-OCT as a substitute for gonioscopy, and that further long-term studies are required.
- There have been no large, prospective, randomized clinical trials looking at the clinical effectiveness of AS-OCT for primary angle closure.
 - For assessing the anterior segment anatomy: Dada et al (2007) compared UBM and OCT and found no superiority of OCT in assessing the anterior segment. A study by Li et al (2007) had similar findings.
 - For anterior segment tumors: Pavlin et al (2009) compared UBM and AS-OCT in 18 eyes in a prospective series. They found that UBM was preferable given incomplete penetration by AS-OCT.
 - For lens-to-cornea fit of RGP lenses: Piotrowiak et al (2014) showed AS-OCT was inferior to fluorescein pattern assessment, with lower sensitivity for apical clearance detection.
 - Anterior chamber angle (ACA) measurement - Maram et al (2015) looked at 20 eyes and found low reproducibility among experienced clinicians. Further literature is limited for this indication.
 - Other potential indications for AS-OCT, including but not limited to intraoperative OCT, graft versus host disease (GVHD), anterior segment vascular imaging, and assessment of Haab striae, have inadequate clinical evidence in the currently available literature.
- Routine *screening or diagnosis*, including but not limited to the following:
 - Glaucoma
 - *Coverage rationale*: Bussel et al (2014) summarized the findings of 7 studies on glaucoma screening and monitoring of progression using OCT. They found that “in summary, OCT currently lacks the necessary diagnostic performance for general population glaucoma screening.” While there is some evidence of the ability of OCT to differentiate normal and glaucomatous eyes, the current clinical evidence has not been fully validated.

- Cataracts
 - *Coverage rationale:* OCT is not used for the diagnosis or screening of cataracts. OCT has been used in the pre-operative planning or for monitoring of post-operative complications following cataract surgery; however, the clinical evidence is limited for these indications. Furthermore, the presence of cataracts may impact OCT image quality and retinal thickness measurements (Van Velthoven 2006)
- Keratoconjunctivitis sicca (e.g. dry eyes)
 - *Rationale:* A single center, prospective study by Ibrahim et al (2010) looked at OCT for diagnosing keratoconjunctivitis sicca in 24 patients and 27 control subjects. Sensitivity and specificity were 67% and 81%, respectively. Further research is needed to identify the clinical outcomes using OCT for this indication.
- Posterior capsule opacification
- Neurodegenerative disorders affecting the optic nerve (e.g., multiple sclerosis and optic neuritis)
 - *Rationale:* While the role for optic nerve measurements using OCT has been outlined above, routine screening using OCT for neurodegenerative disorders that may affect the optic nerve is not indicated. OCT has not been adequately studied for this purpose.
- Papilledema, Unexplained vision loss, or Diabetic retinopathy
 - *Rationale:* Extensive literature review by the AAO states that there is not currently enough randomized evidence to use OCT for routine evaluation of unexplained vision loss, in routine screening for diabetic retinopathy, or for “other causes” of macular swelling. OCT is not mentioned as indicated or not indicated for other disease processes in the AAO guidelines.
- Identification of fungal endophthalmitis after cataract surgery
 - *Rationale:* The evidence for the use of AS-OCT in the identification of fungal infections after cataract surgery is limited to case reports (Kitahata 2016) and has not been validated in a randomized, prospective clinical trial.
- Imaging of extra- or intra-ocular musculature
 - *Rationale:* Several studies (Pihlblad 2016, Ngo 2015, Park 2014) have looked at AS-OCT for imaging of the ocular musculature. While the results on the ability to accurately and reproducibly measure the muscle insertion distances for pre-operative planning have been promising, the current evidence has not been validated in clinical studies nor has it demonstrated any improved clinical outcomes.

- Retinal vein occlusion diagnosis or the monitoring for progression or response to treatment
 - *Rationale:* The evidence for the use of OCT in the diagnosis or monitoring of retinal vein occlusion is limited to small studies and has not been clinically validated.
- Any other procedure or indication not meeting the above coverage criteria

Oscar considers “Intravascular OCT” experimental or investigational, as the current evidence is insufficient to demonstrate clear clinical benefit. This includes, but is not limited to:

- Diagnosis of spontaneous coronary artery dissection (SCAD)
- Diagnosis or assessment of coronary artery plaques
- Treatment of coronary disease (as an adjunct to percutaneous coronary intervention (PCI))
- Assessment or guidance of coronary artery stent placement (including evaluation of arterial bifurcations)
- Assessment of coronary artery stent failure
- Identification of angiographically unclear lesions
- Assessment of acute coronary syndromes
- Diagnosis or assessment of intracranial aneurysms, ruptured or intact
- Assessment of carotid artery stenosis and/or stroke risk
- Assessment of pulmonary arterial wall fibrosis

Clinical Evidence on Intravascular OCT

- A systematic review of 15 studies was published in 2015 by D’Ascenzo et al. to evaluate the accuracy of intravascular OCT and intravascular ultrasound (IVUS) in identifying functional coronary stenosis. The group found that both modalities had only a moderate diagnostic accuracy for hemodynamically significant lesions. The authors concluded that both the sensitivity and specificity were inadequate to guide revascularization. (D’Ascenzo F, Barbero U, Cerrato E, et al. *Accuracy of intravascular ultrasound and optical coherence tomography in identifying functionally significant coronary stenosis according to vessel diameter: a meta-analysis of 2,581 patients and 2,807 lesions. Am Heart J. 2015; 169(5):663-673*)
- The Society of Cardiovascular Angiography and Interventions released a consensus statement in 2014 evaluating IVUS and intravascular OCT, concluding that “the appropriate role for optical coherence tomography in routine clinical decision making has not been established”. (Lotfi A, Jeremias A, Fearon WF, et al. *Society of Cardiovascular Angiography and Interventions. Expert consensus statement on the use of fractional flow reserve, intravascular ultrasound, and optical coherence tomography: a consensus statement of the Society of Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv. 2014; 83(4):509-418*)

- The ILUMIEN III: OPTIMIZE PCI trial was performed to compare IVUS, OCT, and coronary angiography (CA) in guiding coronary stent placement. The randomized study demonstrated that IVUS and OCT were non-inferior, however CA was superior to both modalities. (Ali ZA, Maehara A, Généreux P, et al. *Optical coherence tomography compared with intravascular ultrasound and with angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised controlled trial. Lancet 2016; 388:2618.*)

Applicable Billing Codes (HCPCS & CPT Codes)

CPT/HCPCS Codes covered if criteria are met:	
<i>Code</i>	<i>Description</i>
92133	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; optic nerve
92134	Scanning computerized ophthalmic diagnostic imaging, posterior segment, with interpretation and report, unilateral or bilateral; retina
ICD-10 codes covered if criteria are met:	
B50.0 - B54	Malaria
C69.20 - C69.32	Malignant neoplasm of the retina and choroid
D18.09	Malignant neoplasm of the retina and choroid
D31.20 - D31.32	Benign neoplasm of the retina and choroid
E08.311 - E08.3599, E09.311 - E09.3599, E10.311 - E10.3599, E11.311 - E11.3599, E13.311 - E13.3599	Diabetes mellitus due to underlying condition with ophthalmic complications
G40.201 - G40.219	Localization-related (focal)(partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, not intractable and intractable [screening for vigabatrin (Sabril) toxicity]
G40.401 - G40.419	Other generalized epilepsy and epileptic syndromes, not intractable and intractable, with and without status epilepticus [screening for vigabatrin (Sabril)]

	toxicity]
G40.821 - G40.824	Epileptic spasms [screening for vigabatrin (Sabril) toxicity]
G93.2	Benign intracranial hypertension [pseudotumor cerebri]
H46.00 - H47.399	Disorders of optic nerve
H35.311 - H35.3293	Macular degeneration
H35.341 - H35.349	Macular cyst, hole or pseudohole
H35.81	Retinal edema
H40.001 - H40.9	Glaucoma
H43.811 - H43.819	Vitreous degeneration
Q15.0	Congenital glaucoma
T37.2x1 - T37.2x4	Poisoning by antimalarials and drugs acting on other blood protozoa
ICD-10 codes not covered:	
C69.10 - C69.12	Malignant neoplasm of cornea
C69.40 - C69.42	Malignant neoplasm of ciliary body
D31.10 - D31.12	Benign neoplasm of cornea
D31.40 - D31.42	Benign neoplasm of ciliary body
D89.810 - D89.813	Graft-versus-host disease
G35	Multiple sclerosis
G47.33	Obstructive sleep apnea
H04.121 - H04.129	Dry eye syndrome
H16.221 - H16.239	Keratoconjunctivitis sicca, not specified as Sjogren's
H16.001 - H22	Diseases of the cornea, iris and ciliary body
H25.011 - H28	Cataracts
H34.8 - H34.9	Retinal vascular occlusions

H46.0 - H46.9	Optic neuritis
H47.10 - H47.14	Papilledema
H49.00 - H52.7	Disorders of ocular muscles, binocular movement, accommodation and refraction
H53.121 - H53.139	Visual loss
K20.0 - K31.9	Diseases of esophagus, stomach and duodenum
K50.00 - K52.9	Noninfective enteritis and colitis
K55.011 - K64.9	Other diseases of intestines
M35.0 - M35.09	Sicca syndrome [Sjogren]
Q12.0 - Q12.9	Congenital lens malformations
Z13.5	Encounter for screening for eye and ear disorders
Z46.0	Encounter for fitting and adjustment of spectacles and contact lenses

CPT/HCPCS codes not covered for indications listed in this guideline:	
<i>Code</i>	<i>Description</i>
92132	Scanning computerized ophthalmic diagnostic imaging, anterior segment, with interpretation and report, unilateral or bilateral
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel [when specified as OCT; add-on]
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel [when specified as OCT; add-on]

0351T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; real time intraoperative
0352T	Optical coherence tomography of breast or axillary lymph node, excised tissue, each specimen; interpretation and report, real-time or referred
0353T	Optical coherence tomography of breast, surgical cavity; real-time intraoperative
0354T	Optical coherence tomography of breast, surgical cavity; interpretation and report, real-time or referred

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Clinical Guidelines

American Academy of Ophthalmology AAO) - Preferred Practice Patterns (PPP):

1. Diabetic Retinopathy PPP - Updated 2016 <https://www.aao.org/preferred-practice-pattern/diabetic-retinopathy-ppp-updated-2016>
2. Recommendations on Screening for Chloroquine and Hydroxychloroquine Retinopathy - 2016 Mar 2016. <https://www.aao.org/clinical-statement/revised-recommendations-on-screening-chloroquine-h>
3. Age-Related Macular Degeneration PPP - Updated 2015 <https://www.aao.org/preferred-practice-pattern/age-related-macular-degeneration-ppp-2015>

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