Oscar Clinical Guideline: Optical Coherence Tomography (OCT) (CG025, Ver. 9)

Optical Coherence Tomography (OCT)

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 much higher spatial 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. In the eyes, OCT allows for imaging of the retina and optic nerve. This imaging is helpful in monitoring and treating retinal disorders or optic nerve disorders such as glaucoma. 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, and is most often due to diabetes or hypertension. Diabetic retinopathy can be "proliferative" or "nonproliferative", depending on the severity of the disease.

"Macular Degeneration" is a 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 a 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, diabetic retinopathy, and retinal vein occlusions.

"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 spatial 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. OCT can be used to evaluate the retinal, optic nerve, and anterior chamber.

- "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.
- "OCT Angiography" or "Intravascular OCT" refers to OCT imaging conducted with specialized, miniature devices from within a blood vessel.

"Posterior Segment" refers to the back two-thirds of the eye, and includes the vitreous humor, retina, choroid, macula, and optic nerve

"Anterior Segment" refers to the anterior one-third of the eye, and includes the cornea, iris, ciliary body, and lens.

"Glaucoma Suspect" refers to an individual with clinical findings and/or risk factors that indicate an elevated risk of developing primary open angle glaucoma. Risk factors include age older than 50 years, family history of glaucoma, and black race. Clinical findings include optic nerve or nerve fiber layer defect suggestive of glaucoma, visual field abnormality consistent with glaucoma, and/or elevated intraocular pressure (IOP) >21 mm Hg.

Clinical Indications

The Plan considers Optical Coherence Tomography medically necessary when any ONE of the following criteria is 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 is 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 is 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 posterior segment structures in members who have a diagnosis of at least ONE of the following:
    a. Age-related macular degeneration; *or*
    b. Central Serous Retinopathy (CSR); *or*
    c. Diabetic retinopathy; *or*
    d. Glaucoma or glaucoma suspect, no more than once per year; *or*
    e. Inherited retinal dystrophy (e.g., RPE65 gene mutations); *or*
    f. Macular hole; *or*
    g. Macular edema; *or*
    h. Retinal vein occlusion; *or*
    i. Pseudotumor cerebri; or
    j. Posterior vitreous detachment (vitreous degeneration); *or*
    k. Vitreomacular adhesion or vitreomacular traction; *or*
    l. Vogt-Koyanagi-Haradas

Experimental or Investigational / Not Medically Necessary

The Plan 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), as it has not been shown to improve net health outcomes
    - *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 ultrasound biomicroscopy (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 rigid gas-permeable (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*, including but not limited to the following:
    - Glaucoma, pre-glaucoma, or ocular hypertension
        - *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
  - *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)
- Corneal conditions, including but not limited to keratitis, Thygeson's disease
- Keratoconjunctivitis sicca (i.e., 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 orders that may affect the optic nerve is not indicated. OCT has not been adequately studied for this purpose.
- Papilledema, Unexplained vision loss, (not caused by diabetic retinopathy or pseudotumor cerebri)
  - *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.
- Any other procedure or indication not meeting the above medical necessity criteria

The Plan considers "OCT Angiography" or "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 (malposition)
- 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 IV study (NCT NCT03507777) is underway for a prospective, single-blind clinical investigation randomizing subjects to OCT-guided coronary stent implantation vs. angiography-guided coronary stent implantation in a 1:1 ratio. The clinical investigation will be conducted at approximately 125 centers in North America (US and Canada), Europe, Middle East and Asia-Pacific. After hospital discharge, all patients will have clinical follow-up at 30 days, 1 year, and 2 years. 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 angiography to guide coronary stent implantation (ILUMIEN III: OPTIMIZE PCI): a randomised controlled trial. Lancet 2016; 388:2618.*)

- For coronary plaque characterization and stent implantation for coronary artery revascularization, the FDA has 510(k) clearance for Tigereye Cto-Crossing Catheter, Pantheris System, Optis Mobile Next Imaging System, Optis Integrated Next Imaging System, Otis 2.1 Optical Coherence Tomography System, Thia Optical Coherence Tomography System, Apollovue S100 Image System. The 2021 ACC/AHA/SCA Guideline states that, "In patients undergoing coronary stent implantation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease"(2a) and "In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure. (2a)" However, because OCT requires blood clearance, its effectiveness for imaging ostial left main disease is limited. The results of the ILUMIEN IV study will be pivotal for practice guidance.

Applicable Billing Codes (HCPCS & CPT Codes)

CPT/HCPCS Codes considered medically necessary if criteria are met:	
Code	*Description*
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 considered medically necessary 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]
H20.821-H20.823	Vogt-Koyanagi syndrome, right eye, left eye, bilateral
H34.8 - H34.9	Retinal vascular occlusions
H35.00 - H35.23	Other retinal disorders and retinopathy
H35.30 - H35.3293	Macular degeneration
H35.341 - H35.343	Macular cyst, hole or pseudohole
H35.711-H35.713	Central serous chorioretinopathy right eye, left eye, bilateral
H35.81	Retinal edema
H40.001 - H40.9	Glaucoma
H43.811 - H43.813	Vitreous degenerations
H43.821-H43.823	Vitreomacular adhesion or traction
H44.11 - H44.113	Panuveitis
H47.11	Papilledema associated with increased intracranial pressure
Q15.0	Congenital glaucoma
T37.2x1A - T37.2x4S	Poisoning by antimalarials and drugs acting on other blood protozoa
Z79.899	Other long term (current) drug therapy
ICD-10 codes *NOT* considered medically necessary, or experimental or investigational:	
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
G93.2	Benign intracranial hypertension [pseudotumor cerebri]
H04.121 - H04.129	Dry eye syndrome
H16.221 - H16.239	Keratoconjunctivitis sicca, not specified as Sjogren's
H16.001 - H22	Disorders of the cornea, iris and ciliary body
H25.011 - H28	Cataracts
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* considered medically necessary, or experimental or investigational:	
Code	*Description*

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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