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# Optical Coherence Tomography for Imaging of Coronary Arteries

| Table of Contents |
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| Related Policies (if applicable) |
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| None |
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Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

## Coverage

**This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.**

Optical coherence tomography **is considered experimental, investigational and/or unproven** when used as an adjunct to percutaneous coronary interventions with stenting.

Optical coherence tomography **is considered experimental, investigational and/or unproven** in all other situations, including but not limited to, risk stratification of intracoronary atherosclerotic plaques and follow-up evaluation of stenting.

## Policy Guidelines

None.

## Description

Optical coherence tomography (OCT) is an imaging technique that uses near-infrared light to image the coronary arteries. Potential applications in cardiology include but are not limited to evaluating the characteristics of coronary artery plaques for the purpose of risk stratification and following coronary stenting to determine the success of the procedure.

OCT has important similarities to intravascular ultrasound (IVUS), and also important differences. Ultrasound uses acoustic waves for imaging, while OCT uses near-infrared electromagnetic light waves. OCT generates cross-sectional images by using the time delay and intensity of light reflected from internal tissue structure. The main obstacle to OCT is the difficulty of imaging through blood, necessitating saline flushes or occlusion techniques to obtain images. Frequency-domain OCT (FD-OCT) is a newer generation device that partially alleviates this problem by allowing faster scanning and less need for blood clearing. (1)

OCT has a higher resolution than ultrasound but more shallow penetration of tissue. Tissue resolution of up to 5-10 µm has been achieved, which is approximately 10 times greater than ultrasound. However, the technique is limited by its inability to penetrate more than several millimeters in depth. (2) This is compared with IVUS, which has a penetration depth of approximately 10 mm. (1)

One goal of intravascular imaging has been to risk stratify atherosclerotic plaques regarding their risk of rupture. IVUS has defined a “vulnerable” coronary plaque that may be at higher risk for rupture. Characteristics of the vulnerable coronary plaque include a lipid-rich atheroma with a thin fibrous cap. Other features of vulnerable plaques include a large lipid pool within the vessel wall, a fibrous cap of 6 µm or less, and macrophages positioned near the fibrous cap. (3)

Another goal of intravascular imaging is as an adjunct to percutaneous coronary intervention (PCI) with stent placement. Stent features that are often evaluated immediately post-procedure include the position of the stent, apposition of the struts to the vessel wall, and presence of thrombus or intimal flaps. These features are a measure of procedural success and optimal stent placement. Subsequent follow-up intravascular imaging at several months to 1-year post stenting can be used to evaluate neo-endothelialization on the endoluminal surface of the stent. The presence of neointimal coverage of drug-eluting stents and the absence of stent thrombosis have been correlated with favorable outcomes. (2) Therefore, the adequacy of neointimal coverage has been proposed as an intermediate outcome in clinical trials of stenting.

**Regulatory Status**

Several intracoronary OCT products have been cleared for marketing through the U.S. Food and Drug Administration (FDA) through the FDA 510(k) process which include but are not limited to the following devices:

- C7 XR® Imaging system (August 2011) and the C7 XR Imaging system with Dragonfly imaging catheter (April 2010), acquired by St. Jude Medical, Inc., (St. Paul, MN). (4, 5)
- ILUMIEN OPTIS with Dragonfly™ Imaging Catheter (January 2013), (LightLab Imaging, Inc., Westford, MA). (6)

Please refer to <https://www.accessdata.fda.gov> for additional intracoronary OCT devices that are cleared for marketing through the FDA 510(k) process. FDA product code: NQQ.

## Rationale

This medical policy was created in January 2002 and has been regularly updated with searches of the PubMed database. The most recent literature update was performed through March 14, 2024.

Optical coherence tomography (OCT) is intended as an alternative to intravascular ultrasound (IVUS) for imaging the coronary arteries. Therefore, the most relevant type of studies in evaluating the utility of OCT includes a head-to-head comparison between OCT and IVUS. These studies are limited by the lack of a true criterion standard for intravascular imaging but nevertheless can compare the frequency and type of findings between the 2 types of imaging. Single-arm case series of OCT provide less useful information. Results from case series can characterize the findings that are obtained from OCT, use these findings to predict future events, and provide important information on adverse events. However, case series provide limited data on the comparative efficacy of OCT and IVUS.

**Technical Performance of OCT**

The reliability of OCT findings was examined by Gonzalo et al. (7) These authors used a second-generation, frequency-domain OCT (FD-OCT) and evaluated the reproducibility of OCT findings according to the interstudy, interobserver, and intraobserver variability. Overall, the reproducibility of the OCT findings was high. The reproducibility of stent features such as edge dissection, tissue prolapse, intrastent dissection, and stent malposition was 100% ($\kappa$=1.0). Plaque characteristics also had high reproducibility, with kappa ($\kappa$) values for interstudy, interobserver, and intraobserver variability of 0.92, 0.82, and 0.95, respectively.

Fedele et al. evaluated the reproducibility of OCT lumen and length measurements. (8) In this study, OCT measurements were taken twice at intervals of 5 minutes in 25 patients undergoing coronary angiography. The per-segment and per-frame analyses showed high correlation for interobserver, intraobserver, and intrapullback comparisons for lumen area and length ($R \geq 0.95$ and $p<0.001$ for all correlations), indicating excellent reproducibility. Similarly, Jamil et al. (9) reported good interstudy correlation for FD-OCT in evaluation of both stented and native coronary arteries in 18 patients undergoing PCI ($R2=0.99$ and $p<0.001$ for mean lumen area and minimal lumen area for repeat evaluations of the same coronary lesion). A limitation of the study is that it is a small sample size and lacks inter-observer analysis. This is also a single-center study, which the authors believe may imply potential biases. However, we recently reported

the observer-related variability of quantitative Fourier-domain OCT measurements in vivo. Liu et al. reported good intra- and interobserver reliability for stent length measurements, along with high correlation between OCT and IVUS for stent length measurements in 77 patients undergoing PCI with stenting. (10)

In contrast, Brugaletta et al. (11) demonstrated a higher level of variability in inter- and intraobserver measurements of stent strut coverage with FD-OCT, with kappa values of 0.32 to 0.4 for interobserver measurements, depending on the OCT zoom setting, and 0.6 to 0.75 for intraobserver measurements. Stent strut coverage assessment is less standardized than other measures of vessel plaques or stents, so increased variability in measurements may be expected but should be considered in studies that use FD-OCT to measure stent strut coverage.

**Identification, Risk Stratification, and Treatment of the "Vulnerable Plaque"**

A number of studies have compared OCT with IVUS for evaluation of the vulnerable plaque. One of the earliest of these studies was reported by Jang et al. in 2002. (12) These authors compared the findings of 42 coronary plaques in 10 patients who underwent angiography, IVUS, and OCT. OCT had higher axial resolution compared with IVUS (13 µm vs 98 µm). All of the fibrous plaques, microcalcifications, and echolucent areas identified by IVUS were also imaged by OCT. There were additional cases of echolucent regions and intimal hyperplasia that were imaged with OCT but not seen with IVUS.

Kubo et al. (13) compared OCT and IVUS for identifying and classifying vulnerable plaques. A total of 96 target lesions were examined by both OCT and IVUS, and the presence of a 'vulnerable plaque' was made using standard definitions for each procedure. OCT identified 18 vulnerable plaques as evidenced by thin fibrous caps of less than 65 µm. IVUS identified 16 of 18 vulnerable plaques for a sensitivity of 89% compared with OCT. IVUS also identified an additional 11 lesions as vulnerable that did not meet the criteria by OCT. These were assumed to be false-positive IVUS results, resulting in a specificity for IVUS of 86%. The positive and negative predictive values for IVUS were 59% and 97%, respectively.

Miyamoto et al. (14) studied 81 coronary lesions with a plaque burden of greater than 40%. IVUS and OCT gave somewhat different profiles of plaque characteristics. Vulnerable plaques identified by OCT had a larger plaque burden, more positive remodeling, and less fibrous plaque compared with IVUS. The natural history of the atherosclerotic plaque is not well understood. Prospective cohort studies that use OCT to define plaque characteristics, and that follow patients over time to determine the factors that predict poor outcomes such as acute coronary syndrome (ACS) or plaque progression, are important to better define the features of the vulnerable plaque that are associated with poor outcomes.

Uemura et al. (15) published a prospective cohort study in 2011 that evaluated the ability of OCT to predict the natural history of coronary plaques. This study enrolled 53 patients, with 69 nonobstructing coronary plaques, who had undergone both PCI and OCT. A second coronary angiogram was performed at a mean follow-up of 7 months to assess progression of plaques. There were 13 of 69 lesions (18.8%) that showed progression on angiography at follow-up.

There were several plaque characteristics defined by OCT that were predictive of progression, while the luminal diameter of the stenosis was not predictive. The factors that were found more frequently in lesions that progressed were intimal laceration (61.5% vs 8.9%, p<0.01), microchannel images (76.9% vs 14.3%, p<0.01), lipid pools (100% vs 60.7%, p=0.02), thin-cap fibroatheroma (76.9% vs 14.3%, p<0.01), macrophage images (61.5% vs 14.3%, p<0.01), and intraluminal thrombi (30.8% vs 1.8%, p<0.01). On regression analysis, the presence of fine-cap atheroma and microchannel images were strong predictors of progression, with odds ratios of approximately 20.

Cross-sectional studies of risk stratification by OCT have also been published. In these studies, angiography is performed 1 time, and characteristics of the plaque as defined by OCT are correlated with plaque rupture and/or other angiography findings. Yonetsu et al. (16) performed a cross-sectional study of 266 coronary plaques identified on angiography. A reliable measure of cap thickness was obtained in 188/266 patients (70.7%). The thickness of the fibrous cap was an independent predictor of plaque rupture, and the optimal cutoff for predicting plaque rupture was estimated to be less than 67 μm.

Guo et al. (17) performed a cross-sectional study to evaluate characteristics of coronary plaques associated with coronary artery thrombosis. The authors included 42 patients with coronary artery plaque rupture detected by OCT during evaluation of 216 native coronary artery lesions among 170 patients. Plaques were divided into those with and without thrombus, which occurred in 64% of coronary plaques. Ruptured plaques with thrombus had significantly thinner fibrous caps than those without thrombus (57 μm vs 96 μm, p=0.008).

Jia et al. (18) used data from a multicenter registry of patients who had undergone OCT imaging of coronary arteries to characterize the morphologic features on OCT of the culprit coronary plaques in ACS. They included 126 patients with ACS who underwent preintervention OCT imaging. Plaques were defined by OCT imaging as having plaque rupture (disrupted fibrous cap with underlying lipid), as an OCT-calcified nodule (disrupted fibrous cap with underlying calcium), as an OCT-erosion (intact fibrous cap), or other, and the category of culprit plaque pathology was compared with clinical and angiographic outcomes. The authors found significant differences in age, presentation with non-ST segmented elevation ACS, and vessel diameter across different types of plaque. Given these differences, the study suggests that different types of plaque features may be caused by different underlying pathologies and warrant different treatment approaches; however, without further study, this study is not sufficient to determine changes in treatment that should occur based on OCT results.

Gamou et al. (19) conducted a cross-sectional study of the association between OCT-determined coronary plaque morphology and deteriorated coronary flow after stent in 126 subjects undergoing stenting, 44 with ACS and 82 with stable angina pectoris. Patients were divided into the deteriorated flow group (n=21) and the reflow group (n=105) based on deterioration of Thrombolysis in Myocardial Infarction (TIMI) flow grade on angiography after mechanical dilatation, with significant differences in the presence of reflow based on presentation (ACS vs stable angina; p<0.000). The presence of thrombus or thin-cap

fibroatheroma on OCT was associated with deteriorated flow on angiography for patients with both ACS and stable angina. In multivariable modeling, thin cap fibroatheroma was independently predictive of deteriorated flow (hazard ration [HR], 12.32; 95% confidence interval [CI] 3.02 to 50.31; p<0.000).

In another study evaluating characteristics of high-risk coronary plaques, Galon et al. (20) compared plaque characteristics for non-culprit coronary plaques in patients with ST-elevation myocardial infarction (STEMI) compared with those with stable angina pectoris. The study included 67 patients, 30 with STEMI and 37 with stable angina who underwent OCT evaluation after stent implantation. Compared with plaques in patients with stable angina, coronary plaques in STEMI patients had more surface area for thin-cap fibroatheroma (0.43 $mm^2$ vs 0.15 $mm^2$; p=0.011), thinner minimum fibrous cap thickness (31.63µm vs 47.27 µm; p=0.012), greater fractional luminal area for thin-cap fibroatheroma (1.65% vs 0.74%; p=0.046), and greater macrophage index (0.0217% vs 0.0153%; p<0.01).

In 2012, Wykrzykowska et al. (21) reported on initial results of a pilot study that treated high-risk plaques with a nitinol self-expanding vShield® device. High-risk plaques were defined as the presence of a thin cap fibroatheroma on OCT examination. A total of 23 patients were randomized to vShield® (n=13) or medical therapy (n=10). After 6 months of follow-up, there were no dissections or plaque rupture after shield placement. There were no device-related adverse events at 6 months for patients treated with vShield®. The mean stent area increased by 9% at 6-month follow-up. This small pilot randomized controlled trial (RCT) demonstrates the feasibility of identifying patients with vulnerable plaque by OCT and treating with a vShield® device. A long-term larger randomized study with streamlined screening criteria is needed to evaluate the efficacy of this approach over medical therapy.

In 2018 Jia et al. (22) performed a systematic review evaluating OCT in patients with ACS due to plaque erosion. Some physicians believe that ACS is caused by coronary thrombosis resulting from rupture of vulnerable plaque characterized by a thin fibrous cap overlying a large necrotic core and massive inflammatory cell infiltration. However, nearly 1/3 of ACS cases are caused by plaque erosion characterized by intact fibrous cap, less or absent necrotic core, less inflammation, and large lumen. Because of the limitations of current imaging modalities, including angiography and IVUS, the importance of plaque erosion as a cause of ACS is less well-known; OCT as an emerging modality with high resolution is the only intravascular imaging modality available for identification of PE in-vivo, which provides new insight into the mechanism of ACS. More importantly, the introduction of OCT to clinical practice enables researchers to differentiate the patients with ACS caused by plaque erosion from those caused by plaque rupture, thereby providing precise and personalized therapy-based on the different underlying mechanisms. The authors systematically reviewed the morphological characteristics of plaque erosion identified by OCT and its implications for the management of ACS which concluded that future studies are needed to validate this new therapeutic approach.

In 2020 Nogic et al. (23) noted that intermediate coronary artery stenosis, defined as visual angiographic stenosis severity of between 30% to 70%, is present in up to 1/4 of patients

undergoing coronary angiography. Patients with this particular lesion subset represent a distinct clinical challenge, with operators often uncertain on the need for re-vascularization. Although international guidelines appropriately recommend physiological pressure-based assessment of these lesions employing either FFR or quantitative flow ratio (QFR), there are specific clinical scenarios and lesion subsets where the use of such indices may not be reliable. Intravascular imaging, primarily IVUS and OCT represents an alternate and at times complementary diagnostic modality for the evaluation of intermediate coronary stenoses. Studies have attempted to validate these specific imaging measures with physiological markers of lesion-specific ischemia with varied results. Intravascular imaging, however, also provides additional benefits that include portrayal of plaque morphology, guidance on stent implantation and sizing and may portend improved clinical outcomes. The authors concluded that although invasive physiological assessment with FFR or instantaneous wave-free ratio (iFR) remains current gold standard, a number of clinical scenarios may push clinicians towards assessment of lesion severity using intravascular imaging Researchers stated that moving forward, the future of OCT and IVUS assessment may lie in coupling with computational fluid dynamics (CFD) simulations of coronary flow and pressure. Use of CFD technology has potential for clinicians to gather simultaneous anatomical and functional assessment of individual coronary lesions. There remain several hurdles though before this technology is more widely adopted. First, further validation work is needed in more diverse lesion and patient cohorts. Additionally, computational time for CFD is still relatively high and this precludes use in a high-paced catherization laboratory environment. Nevertheless, there is clear potential for the future and there are several industry-led collaborations attempting to deliver this technology to clinicians.

Section Summary: Identification, Risk Stratification, and Treatment of the "Vulnerable Plaque"
OCT can be used to evaluate morphologic features of atherosclerotic plaques and to risk-stratify plaques as to their chance of rupture. Limited evidence from studies that compare OCT with IVUS indicate that OCT picks up more abnormalities than does IVUS and is probably more accurate in classifying plaques as high risk. Because of the lack of a true criterion standard, the sensitivity and specificity of OCT for this purpose cannot be determined with certainty. Some experts consider OCT to be the criterion standard for this purpose and compare other tests with OCT.

Although OCT may be more accurate than other imaging modalities, the clinical utility is uncertain therefore additional studies are needed. It is not clear which patients should be assessed for a high-risk plaque, nor is it clear whether changes in management should occur as a result of testing. To date, the evidence is not sufficient to determine the effect of OCT on health outcomes when used for identification, risk stratification and/or assessment of coronary atherosclerotic plaques.

**Adjunctive Treatment to Percutaneous Coronary Interventions (PCIs)**
In 2016, Ali et al. (24) sought to establish whether OCT-based stent sizing strategy would result in a minimum stent area similar to or better than that achieved with IVUS guidance or with angiography guidance alone. This RCT recruited patients aged 18 years or older undergoing PCI

from 29 hospitals in 8 countries. Eligible patients had one or more target lesions located in a native coronary artery with a visually estimated reference vessel diameter of 2·25-3·50 mm and a length of less than 40 mm. Patients with left main or ostial right coronary artery stenoses, bypass graft stenoses, chronic total occlusions, planned two-stent bifurcations, and in-stent restenosis were excluded. Participants were randomly assigned (1:1:1; with use of an interactive web-based system in block sizes of three, stratified by site) to OCT guidance, IVUS guidance, or angiography-guided stent implantation. OCT-guided PCI was performed to establish stent length, diameter, and expansion according to reference segment external elastic lamina measurements. All patients underwent final OCT imaging (operators in the IVUS and angiography groups were masked to the OCT images). The primary efficacy endpoint was post-PCI minimum stent area, measured by OCT at a masked independent core laboratory at completion of enrollment, in all randomly allocated participants who had primary outcome data. The primary safety endpoint was procedural major adverse cardiac events (MACE). Non-inferiority of OCT guidance to IVUS guidance (with a non-inferiority margin of 1·0 $mm^2$), superiority of OCT guidance to angiography guidance, and superiority of OCT guidance to IVUS guidance were tested. Between May 13, 2015, and April 5, 2016, the investigators randomly allocated 450 patients (158 [35%] to OCT, 146 [32%] to IVUS, and 146 [32%] to angiography), with 415 final OCT acquisitions analyzed for the primary endpoint (140 [34%] in the OCT group, 135 [33%] in the IVUS group, and 140 [34%] in the angiography group). The final median minimum stent area was 5·79 $mm^2$ (IQR 4·54-7·34) with OCT guidance, 5·89 $mm^2$ (4·67-7·80) with IVUS guidance, and 5·49 $mm^2$ (4·39-6·59) with angiography guidance. OCT guidance was non-inferior to IVUS guidance (one-sided 97·5% lower CI -0·70 $mm^2$; p=0·001), but not superior (p=0·42). OCT guidance was also not superior to angiography guidance (p=0·12). We noted procedural MACE in four (3%) of 158 patients in the OCT group, one (1%) of 146 in the IVUS group, and one (1%) of 146 in the angiography group (OCT vs IVUS p=0·37; OCT vs angiography p=0·37). The study concluded that OCT-guided PCI using a specific reference segment external elastic lamina-based stent optimisation strategy was safe and resulted in similar minimum stent area to that of IVUS-guided PCI and that data warrant a large-scale randomized trial to establish whether or not OCT guidance results in superior clinical outcomes to angiography guidance.

In 2021 Ali et al. (25) published data related to the 12-month follow-up of the ILUMIEN III trial. OCT-guided PCI, using an external elastic lamina-based protocol, was compared to operator-directed IVUS guided or angiography guided PCI in 450 randomized patients with non-complex lesions who were undergoing PCI. Target lesion failure (TLF) and major adverse cardiovascular events (MACE) were adjudicated at 12 months by a blinded clinical events committee. There were no significant differences in the rates of TLF (2.0% OCT, 3.7% IVUS, 1.4% angiography), MACE (9.8% OCT, 9.1% IVUS, 7.9% angiography), or any of the individual components of these outcomes among the groups. No independent predictors of 12-month stent-related clinical events were identified from final OCT. The authors concluded that in this underpowered study, OCT-guided PCI of non-complex lesions did not show a statistical difference in clinical outcomes at 12 months compared with IVUS or angiography guidance. An appropriately powered trial, including only complex patients and lesions, is underway to substantiate the potential clinical benefit of OCT-guided PCI.

OCT as an Adjunct to PCI: Comparison with IVUS

One randomized trial, and a number of nonrandomized comparative studies have compared OCT with IVUS as an adjunct to PCIs. Habara et al. (26) performed a small open-label RCT comparing OCT with IVUS in 70 patients undergoing stent implantation. Outcomes were primarily measures of optimal stent deployment, such mean stent area and stent expansion immediately following the procedure. There were no significant differences on the majority of procedural and stent-related outcomes measures. However, there were several outcomes that were superior for the IVUS group. The mean stent area was greater for IVUS compared with OCT (8.7±2.4 mm vs 7.5±2.5 mm, $p<0.05$); the percent focal and diffuse stent expansion was greater for the IVUS group (80.3+13.4% vs 64.7%±13.7%, and 98.8%±16.5% vs 84.2%±15.8%; both $p<0.05$); the frequency of distal edge stenosis was lower for the IVUS group (22.9% vs 2.9%, $p<0.005$). These results suggest an advantage for IVUS over OCT in achieving optimal stent deployment.

A matched comparison of patients undergoing angiography alone versus angiography plus OCT was published by Prati et al. in 2012. (27) A total of 335 patients were treated with OCT as an adjunct to angiography and PCI, these were matched with 335 patients undergoing PCI without adjunct OCT. The primary end point was the 1-year rate of cardiac death or myocardial infarction (MI). In 34.7% of cases in the OCT group, additional findings on OCT led to changes in management. Patients in the OCT group had a lower rate of death or MI at 1 year, even following multivariate analysis with propensity matching (odds ratio, 0.49; 95% CI, 0.25 to 0.96; $p=0.037$).

Yamaguchi et al. (28) studied 76 patients from 8 medical centers who were undergoing angiography and possible PCI. Both IVUS and OCT were performed in a single target lesion selected for a native coronary artery with a visible plaque that is less than 99% of lumen diameter. Procedural success was 97.3% for OCT compared with 94.5% for IVUS. There were 5 cases in which the smaller OCT catheter could cross a tight stenosis where the IVUS catheter could not. There were no deaths or major complications of the procedures. Minimal lumen diameter was highly correlated between the 2 modalities ($r=0.91$, $p<0.001$). Visibility of the lumen border was superior with OCT, with poor visibility reported for 6.1% of OCT images compared with 17.3% by IVUS ($p<0.001$).

Kawamori et al. (29) reported on 18 patients who were undergoing stenting and had both OCT and IVUS performed. The lumen area of the culprit vessel was smaller on OCT images compared with IVUS. OCT was more sensitive in identifying instances of stent malapposition compared with IVUS (30% vs 5%, $p=0.04$). OCT also picked up a greater number of cases with stent edge dissection (10% vs 0%) and with stent thrombosis (ST; 15% vs 5%). These results were interpreted as demonstrating the higher resolution and greater detail obtained with OCT compared with IVUS. Further study is warranted to assess its clinical utility.

Bezerra et al. (30) compared IVUS with both frequency-domain (FD) and time-domain (TD) OCT in both stented and unstented vessels. The authors included 100 matched FD-OCT and IVUS evaluations in 56 nonstented and 44 stented vessels and 127 matched TD-OCT and IVUS

evaluations in stented vessels, all in 187 patients who were undergoing percutaneous coronary interventions in several trials. The results from their evaluations in stented vessels follow. The authors included comparisons between 44 matched FD-OCT and IVUS evaluations and 127 matched TD-OCT and IVUS evaluations in stented vessels. (27) In the immediate post-PCI stent evaluations, tissue protrusion and malposition areas were significantly larger by FD-OCT compared with IVUS (for tissue protrusion, OCT-IVUS difference 0.16 $mm^2$, $p<0.001$; for malposition areas, OCT-IVUS difference 0.24 $mm^2$, $p=0.017$). Acute malposition rates were 96.2% with FD-OCT compared with 42.3% with IVUS ($k=0.241$, $p<0.001$). However, measurements of mean area were larger for IVUS compared with FD-OCT (OCT-IVUS difference -0.50 $mm^2$, $p=0.002$). For follow up of stented vessels, compared with IVUS, FD-OCT detected smaller minimal stent lumen areas (3.39 $mm^2$ vs 4.38 $mm^2$, $p<0.001$) and a greater neointimal hyperplasia area (1.66 $mm^2$ vs 1.03 $mm^2$, $p<0.001$). Similar findings were seen when TD-OCT was compared with IVUS. These results corroborate other studies' findings that FD-OCT may be associated with greater detail resolution than IVUS in assessing coronary artery stents. The direction of the difference in immediate post-PCI stent area measurements between FD-OCT and IVUS measurements were counter to the authors' expectations; on reevaluation of imaging, they determined that patients with post-PCI imaging had more calcification than those who had follow up imaging and hypothesized that the calcification may have affected detection of the stent-liminal interface on immediate post procedure IVUS images.

Sohn et al. (31) compared detection rates for tissue prolapse after drug eluting stent implantation between OCT and IVUS among 38 patients undergoing stent placement for coronary artery disease. Tissue prolapse was detected in 38 of 40 lesions (95%) on OCT, compared with 18 of 40 lesions (45%) on IVUS. Thirty patients were followed clinically for 2 years post-procedure, during which time 1 case of sudden cardiac death occurred, but no cases of MI, target vessel revascularization (TVR), or stent thrombosis (ST). The clinical significance of the OCT detection rate is unclear given that the presence of tissue prolapse was not correlated with major cardiac adverse events during follow-up.

In a study with similar findings regarding cardiac adverse events, Sugiyama et al. (32) compared tissue prolapse measurements on OCT with stent morphologic characteristics among 178 native coronary lesions in patients undergoing PCI with stent placement. Although higher degrees of tissue prolapse on OCT were associated with the presence of thin-cap fibroatheroma, there was no association between the presence of tissue prolapse and clinical events during 9 months of follow-up.

In 2015, Ann et al. (33) compared detection rates for edge dissection after drug eluting stent implantation between angiography, IVUS, and OCT among 58 patients who underwent balloon-expandable stent placement. Stent edge dissection was detected in 24/100 stent edges (24%) on OCT imaging, compared with 3/100 (3%) of stent edges on angiography and 4/100 (4%) stent edges on IVUS. Over 1 year of follow-up, 1 patient with an edge dissection showed an angiographic in-stent restenosis; no cases of death, MI, target lesion revascularization (TLR), or ST occurred.

OCT as an Adjunct to PCI: Guidance for Coronary Stent Implantation

In 2022, Siddiqi et al. (34) stated that OCT is an adjunct to angiography-guided coronary stent placement; however, in the absence of dedicated, appropriately powered RCTs, the impact of OCT on clinical outcomes is unclear. In a systematic review and meta-analysis, investigators examined all available studies comparing OCT-guided versus angiography-guided and IVUS guided coronary stent implantation. Medline and Cochrane Central were queried from their inception through July 2022 for all studies that sought to compare OCT-guided PCI to angiography-guided and IVUS guided PCI. The primary endpoint was minimal stent area (MSA) compared between modalities. Clinical endpoints of interest were all-cause and cardiovascular mortality, MACE, MI, TLR, TVR, and ST. Mean differences (MDs) and Risk ratios (RRs) with their corresponding 95 % CIs were pooled using a random-effects model. A total of 13 studies (8 RCTs and 5 observational studies) enrolling 6,312 participants were included. OCT was associated with a strong trend toward increased MSA compared to angiography (MD = 0.36, p = 0.06). OCT-guided PCI was also associated with a reduction in the incidence of all-cause mortality (RR = 0.59, 95 % CI: 0.35 to 0.97), p = 0.04] and cardiovascular mortality [RR = 0.41, 95 % CI: 0.21 to 0.80), p = 0.009] compared with angiography-guided PCI. Point estimates favored OCT relative to angiography in MACE [RR = 0.75, 95 % CI: 0.47 to 1.20), p = 0.22] and MI [RR = 0.75, 95 % CI: 0.53 to 1.07), p = 0.12]. No differences were detected in ST [RR = 0.71, 95 % CI: 0.21 to 2.44), p = 0.58], TLR [RR = 0.71, 95 % CI: 0.17 to 3.05), p = 0.65], or TVR rates [RR = 0.89, 95 % CI: 0.46 to 1.73), p = 0.73]. Compared with IVUS guidance, OCT guidance was associated with a non-significant reduction in the MSA (MD = -0.16, p = 0.27). The rates of all-cause and cardiovascular mortality, MACE, MI, TLR, TVR, or ST were similar between OCT guided and IVUS guided PCI. The authors concluded that OCT guided PCI was associated with reduced all-cause and cardiovascular mortality compared to angiography guided PCI. Moreover, researchers stated that these findings should be considered hypothesis-generating as the mechanisms for improved outcomes were unclear as no differences were detected in the rates of TLR, TVR, or ST. OCT and IVUS guided PCI resulted in similar post-PCI outcomes. In addition, authors stated that this meta-analysis had several drawbacks. First, this meta-analysis was carried out under the assumption that the baseline characteristics of the patients in the included studies were similar. While discrepancies in patient characteristics and background therapies could have possibly contributed to clinical heterogeneity, a low statistical heterogeneity was noted in this study. Second, timing of OCT assessment in the included studies was arbitrary and at relatively short follow-up times. OCT imaging at longer follow-up periods may provide additional information and detect clinically significant differences. Third, only 6 studies from the 13 included studies examined MSA, warranting more RCTs assessing MSA and its association with post-OCT outcomes. Fourth, the studies were limited by small sample size and non-randomized designs of the observational studies although via subgroup analysis these researchers attempted to differentiate the findings between the RCTs and observational studies.

In 2022, Niu et al. (35) noted that traditional angiography only displays 2D images of the coronary arteries during stent implantation; however, intravascular imaging can reveal the structure of the vascular wall, and plaque characteristics. In a systematic review and meta-analysis, these investigators examined the effectiveness of intravascular imaging-guided drug-eluting stent (DES) implantation. They carried out a literature search of RCTs of intravascular

imaging- guided, including patients with DES implantation guided by intravascular US or OCT and traditional angiography. The databases of PubMed, Embase, web of science, and Cochrane Library were searched. The primary outcome was TLR. The secondary outcomes included the TVR, MI, ST, cardiac death, all-cause death, and MACE during the 6 to 24 months follow-up. The fixed-effects model was used to calculate the RR and 95 % CI of the outcome event. This meta-analysis included 14 RCTs with 7,307 patients. Compared with angiography-guided, intravascular imaging-guided DES implantation could significantly reduce the risk of TLR (RR 0.63, 95 % CI: 0.49 to 0.82, p = 0.0004), TVR (RR 0.66, 95 % CI: 0.52 to 0.85, p = 0.001), cardiac death (RR 0.58; 95 % CI: 0.38 to 0.89; p = 0.01), MACE (RR 0.67, 95 % CI: 0.57 to 0.79; p < 0.00001) and ST (RR 0.43, 95 % CI: 0.24 to 0.78; p = 0.005). While there was no significant difference regarding MI (RR 0.77, 95 % CI: 0.57 to 1.05, p = 0.10) and all-cause death (RR 0.87, 95 % CI: 0.58 to 1.30, p = 0.50). The authors concluded that compared with traditional angiography, DES implantation guided by intravascular imaging could reduce the risk of TLR, TVR, cardiac death, MACE, and ST. Furthermore, patients with complex lesions would benefit more in MACE. However, whether it is necessary to routinely use intravascular imaging to guide stent implantation still needs to be further examined. In addition, the authors stated that this meta-analysis had several drawbacks. First, most of the included RCTs had small-sample trials, with a low incidence of positive events and wide CIs, which reduced the quality of evidence. Second, trial sequential analysis (TSA) showed that outcome of cardiac death, MI, and all-cause death need further investigation. Furthermore, the different definitions of MACE and MI in the included trials, which may be one of the reasons for the heterogeneity of MACE outcomes. MI did not get a positive outcome. Meanwhile, MI and MACE was not used as the primary outcome in this meta-analysis. Third, intravascular imaging described in this study included IVUS and OCT. Meanwhile, this study included all types of DES; new generation of DES may lead to better clinical outcomes. However, the subgroup analysis of the 1st or 2nd-generation and new-generation DES in this study did not get a positive result, which may be related to insufficient sample size and different trials have been associated with different definitions of clinical outcomes. Thus, further investigation is needed on the relationship between different DES types and intravascular imaging types. Fourth, the underlying disease of patients, the location of lesions, the number of disease vessels, and the specific treatment strategies may also affect the clinical outcome; however, this study was a study-level analysis, further analysis could not be performed.

In 2022 Hu et al. (36) stated that coronary angiography (CAG) is the standard imaging modality for guiding PCI. Intra-coronary imaging techniques such as IVUS and OCT, and hemodynamic parameter like FFR could overcome some limitations of CAG. In an updated systematic review and Bayesian network meta-analysis, investigators examined the clinical outcomes of different PCI guidance modalities in the era of DES. They carried out a network meta-analysis of 28 randomized trials and 11,860 patients undergoing different modalities- guided PCI in the era of DES; OR with 95 % CIs were calculated. In comparison with CAG, IVUS was associated with a significant reduction in MACE (OR: 0.60; 95 % CI: 0.46 to 0.79), cardiovascular death (OR: 0.46; 95 % CI: 0.20 to 0.94), TVR/TLR (OR: 0.55; 95 % CI: 0.41 to 0.74), and a trend toward decreased risk of ST (OR: 0.44; 95 % CI: 0.17 to 1.00). FFR/QFR could significantly reduce stroke compared with CAG, IVUS, and OCT/optical frequency domain imaging (OFDI); however, MI, all-cause

death, ST, and any re-vascularization presented similar risks for different PCI guidance modalities. The authors concluded that this network meta-analysis provided evidence that IVUS-guided PCI resulted in less MACE, cardiovascular death, and TVR/TLR. FFR/QFR-guided PCI resulted in decreased risk of stroke in the DES era. Moreover, researchers stated that further studies are warranted to validate the rationality of different modalities in guiding PCI in the era of DES. The authors recognized this study had several drawbacks. First, this was a study-level meta- analysis providing average treatment effects. The absence of patient-level data prevented the authors from examining the effect of baseline clinical characteristics in PCI guidance modalities that might affect clinical outcomes. Second, subgroup analysis based on stable or acute coronary symptom was impossible because both stable and acute coronary symptom patients were included in the same trial. However, the ADAPT-DES study revealed that IVUS-guided PCI was superior to CAG-guided PCI in both stable and acute coronary symptom patients. Third, just 6 studies (n = 4,214) in total reported 17 (0.40 %) stroke events, which was too small in scale and maybe the reason for wide CI; thus, more randomized trials are warranted to validate the rationality of different modalities in guiding PCI in the era of DES. Fourth, IVUS has been used clinically for almost 30 years and extensive clinical experience has been gained. However, the same scenario was not obtained for other PCI guidance modalities (i.e., OCT). Considering the fact that a long learning curve is needed to obtain a new PCI guidance modality, thus, unfamiliarity with a newly developed PCI guidance modality may negatively affect prognosis.

Evaluation of Treatment Pathways Using OCT-Assisted PCI

A small body of literature has addressed whether a treatment pathway guided by OCT measurements is feasible or leads to improvements in outcomes. One potential role for OCT-guided therapy is in the use of repeat OCT measurements in the acute setting for guiding treatment decisions for patients with ACS who have undergone revascularization, particularly those with large thrombus burden who have undergone thrombus aspiration. OCT may be useful in these patients in determining the need for stent placement post-thrombus aspiration, based on the size and appearance of any residual clot. Controlled trials of OCT-assisted PCI versus a standard approach are needed to determine whether OCT guided PCI improves outcomes.

Souteyrand et al. conducted a uncontrolled, prospective observational cohort study to evaluate outcomes for invasive treatment decisions guided by OCT in patients with ACS with a large thrombus burden. (37) Based on results of OCT, 63 (62.4%) patients underwent stenting, while the remainder were managed medically. Over 12 months of follow-up, no sudden deaths or MIs occurred.

In 2014, Cervinka et al. reported results of a pilot study to assess whether OCT guidance could guide intervention during primary PCI with the goal of avoiding balloon angioplasty and stenting. (38) The study included 100 patients with STEMI and who underwent thrombus aspiration followed by OCT. Based on OCT imaging, 20 patients were treated with thrombus aspiration only. At follow-up angiography 1-week post-procedure, all 20 treated with thrombus aspiration only had a “normal vessel” without significant stenosis and evidence of

nonobstructive thin-cap fibroatheroma. No major adverse clinical events occurred at 30-day, 9-month, or 12-month follow-up in either group.

These uncontrolled studies demonstrate the feasibility of an OCT-guided approach to stent placement following thrombus aspiration. However, this evidence does not permit conclusions about whether OCT-guided treatment decisions improve outcomes compared with standard approaches, given the lack of a control group. Further high-quality comparative trials are needed.

Section Summary: Adjunctive Treatment as Part of Percutaneous Coronary Interventions (PCIs)
The evidence on use of OCT as an adjunct to PCI consists of 1 small RCT, several nonrandomized studies comparing the results of OCT with IVUS, several systematic reviews evaluating OCT as an adjunct to PCI to evaluate stent placement, and several nonrandomized studies assessing the feasibility of an OCT-guided treatment strategy of deferred stenting. Because of the lack of a true criterion standard, it is not possible to determine the accuracy of OCT for detecting abnormalities of stent placement with certainty. The available studies report that OCT picks up more abnormalities than does IVUS, including abnormalities such as stent malposition that lead to changes in management. The RCT comparing OCT with IVUS did not report any advantage of OCT over IVUS, and in fact IVUS was superior to OCT on a number of outcome measures. Overall, the evidence is limited and not sufficient to determine the degree of improvement with OCT or the clinical significance of this improvement. As a result, it is not possible to determine whether OCT improves health outcomes when used as an adjunct to PCI.

**Follow-up Evaluations Post Stent Placement**
A large number of studies use OCT as a research tool, primarily for studies of coronary stenting. OCT is used to assess the degree of neoendothelial coverage of the stent within the first year of placement. Stent coverage is considered an important intermediate outcome, as it has been shown to be predictive of clinical outcomes for patients undergoing stenting. (39) These types of studies do not provide any relevant information on the clinical utility of OCT and will therefore not be discussed further in this policy.

A smaller number of studies evaluate the clinical utility of OCT for follow-up evaluation post stenting. Capodanno et al. (40) compared OCT with IVUS for stent evaluation in 20 patients who had stent implantation 6 months before. The parameters that were compared included stent length, vessel luminal area, stent area, and the percent of stent coverage with neoendothelial cells. The measurement of stent length was similar between IVUS and OCT (16.3±3.0 mm vs 16.2±3.8 mm, p=0.82). However, the other measured parameters differed between groups. Vessel luminal area was significantly lower by OCT compared with IVUS (3.83±1.60 $mm^2$ vs 4.05±1.44 $mm^2$, p=0.82), while stent area was significantly higher with OCT (6.61±1.39 $mm^2$ vs 6.17±1.07 $mm^2$, p<0.001). The percentage of tissue coverage was also higher with OCT (43.4%±16.1% vs 35.5%±16.4%), suggesting that IVUS underestimates stent coverage compared with OCT.

Inoue et al. (41) used OCT to evaluate 25 patients who had previously undergone PCI with drug-eluting stents. OCT was performed at a mean of 236±39 days post-PCI. OCT identified neointimal coverage of the stent in 98.4% of cases. In 0.52%, there was evidence of stent malapposition and a lack of neointimal coverage. Full neointimal coverage was evident in 37% of stents. In 7.2% of patients, there was evidence of a low-intensity area surrounding the struts, which is thought to be indicative of abnormal neointimal maturation. There were no intrastent thrombi identified and no major complications of the procedure.

Section Summary: Follow-up Evaluations Poststent Placement

The use of OCT as a follow-up to stenting can determine the extent of neoendothelial covering within the first year of stenting. This parameter is predictive of future stent-related events and has been used as an intermediate outcome in stenting trials. However, the clinical relevance of measuring stent neo-endothelialization has not been demonstrated. While this might provide prognostic information, it is not clear how management would change, or health outcomes improved. As it can for native vessel lesions, OCT may be able to identify stenosis within stents. However, evidence is currently lacking to link its use to identify stent stenosis to clinical outcomes.

**Other Potential Uses**

OCT for the Evaluation of Coronary Artery Abnormalities in Pediatric Kawasaki Disease

In one small case series, Harris et al. (42) evaluated the feasibility of OCT for the evaluation of coronary artery abnormalities in pediatric Kawasaki disease (n=5) and heart transplants (n=12). This study had a small population and currently the overall evidence is insufficient to determine the efficacy of OCT for these uses.

OCT for the Assessment of Pulmonary Artery Fibrosis in Patients with Pulmonary Artery Hypertension (PAH)

Domingo et al. (2013) correlated pulmonary arterial remodeling estimated by pulmonary artery fibrosis in patients with pulmonary artery hypertension (PAH) with clinical follow-up. Histology of pulmonary artery specimens was also performed. (43) A total of 19 patients, aged 54 ± 16 (4 men), functional class II to III were studied with right heart catheterization, pulmonary artery (PA)-IVUS and OCT in inferior lobe segment. Pulmonary arterial wall fibrosis was obtained by OCT (area of fibrosis/PA cross sectional area × 100). Patients' follow-up was blind to OCT. Events were defined as mortality, lung transplantation, need of intravenous prostaglandins or onset of right ventricular failure. OCT measurements showed high intra- and inter-observer agreement. There was a good correlation between OCT and histology in PA fibrosis from explanted lungs. Area of fibrosis was 1.4 ± 0.8 mm(2), % fibrosis was 22.3 ± 8. Follow-up was 3.5 years (2.5 to 4.5). OCT % Fib was correlated with PA capacitance ($r = -0.536$) and with pulmonary vascular resistance ($r = 0.55$). Patients were divided according to the median value of PA fibrosis. There were 10 patients with a high (greater than or equal to 22 %) and 9 with a low fibrosis (less than 22 %). Events occurred in 6 (1 death, 1 lung transplantation, 2 intravenous prostaglandins, and 2 right heart failure) out of 10 patients with high and in 0 out of 9 patients with low fibrosis ($p < 0.01$). The authors concluded that in PAH, the severity of PA remodeling assessed by OCT wall fibrosis was predictive of severely unfavorable clinical

outcome. Moreover, they stated that in-vivo assessment of pulmonary arterial wall fibrosis by intra-vascular OCT in PAH is a promising new prognostic marker of adverse clinical outcome. A limitation of OCT is its limited penetration depth, although the vessels imaged in this study (2-3 mm) are in the range of OCT performance. Although, there is a correlation between histological intimal fibrosis and OCT fibrosis, additional clinical-pathological correlation studies will be important to further define PA wall tissue characteristics by OCT assessments. Additionally, this study was performed on a small patient population, therefore additional larger long term RCTs are warranted to determine the impact on health outcomes in utilizing OCT to assess pulmonary artery fibrosis in patients with PAH.

Detection of Coronary Vascular Changes Following Heart Transplantation

McGovern et al. (2019) described the initial findings from the International Pediatric Optical Coherence Tomography (OCT) registry in pediatric heart transplant recipients; OCT and angiography of the coronary arteries were performed in pediatric heart transplant recipients at participating centers. (44) Demographics, clinical data, medications, episodes of rejection, and angiographically confirmed CAV were collected for each case; OCT and angiography images were analyzed in a central core imaging laboratory. Intimal thickness and intima/media cross sectional area (I/M CSA) ratios were calculated for each case. Intimal thickness of greater than or equal to 0.25 mm was defined as abnormal and greater than or equal to 0.4 mm as severe intima thickening; I/M CSA ratio of ≥1 was defined as abnormal. OCT findings were compared to angiographic findings for each case. Across 3 centers, a total of 110 cases were analyzed from 76 patients. Intimal thickening was present in 26 of 110 cases; 11 of these cases had severe intima thickening (greater than or equal to 0.4 mm) and notably, angiography results were normal in 8 cases. All 5 cases with a median I/M CSA ratio of greater than or equal to 2 had normal angiography. The maximal intima thickness was greater than or equal to 0.25 mm in 24 % and greater than or equal to 0.4 mm in 10 % of cases. Median I/M CSA ratio was greater than or equal to 1 for 80 % of cases; I/M CSA ratio was significantly higher in cases with concurrent CAV ($p = 0.03$). Maximal intima thickness was significantly greater in cases with current or previous rejection ($p = 0.01$); I/M CSA ratio was significantly lower in patients treated with statins ($p = 0.01$). OCT findings alone prompted a change to medical management in 17 % of cases. The authors concluded that OCT provided important insights into coronary vascular changes not detected by angiography in pediatric transplant recipients. Moreover, they recommend that the use of OCT for pediatric heart transplant recipients should be further investigated, given its potential to impact the management of CAV.

Optical Coherence Tomography–Guided Reperfusion in ST-Segment Elevation MI

In 2022, Jia et al. (45) sought to evaluate whether OCT guidance would provide additional information beyond that obtained by angiography which could lead to a shift in reperfusion strategy and improved clinical outcomes in individuals with STEMI with early infarct artery patency. Currently, angiography is limited in assessing the underlying pathophysiological mechanisms of the culprit lesion. The EROSION III study is an open-label, prospective, multicenter, randomized, controlled study. Individuals with STEMI who had angiographic diameter stenosis ≤ 70% and TIMI (Thrombolysis in Myocardial Infarction) flow grade 3 at presentation or after antegrade blood flow restoration were recruited and randomized to

either OCT guidance or angiographic guidance. The primary efficacy endpoint was the rate of stent implantation. Among 246 randomized patients, 226 (91.9%) constituted the per protocol set (112 with OCT guidance and 114 with angiographic guidance). The median diameter stenosis was 54.0% (IQR: 48.0%-61.0%) in the OCT guidance group and 53.5% (IQR: 43.8%-64.0%) in the angiographic guidance group (P = 0.57) before randomization. Stent implantation was performed in 49 of 112 patients (43.8%) in the OCT group and 67 of 114 patients (58.8%) in the angiographic group (P = 0.024), demonstrating a 15% reduction in stent implantation with OCT guidance. In patients treated with stent implantation, OCT guidance was associated with a favorable result with lower residual angiographic diameter stenosis (8.7% ± 3.7% vs 11.8% ± 4.6% in the angiographic guidance group; P < 0.001). Two patients (1 cardiac death, 1 stable angina) met the primary safety endpoint in the OCT guidance group, as did 3 patients (3 cardiac deaths) in the angiographic guidance group (1.8% vs 2.6%; P = 0.67). Reinfarction was not observed in either group. At 1 year, the rates of predefined cardiocerebrovascular events were comparable between the groups (11.6% after OCT guidance vs 9.6% after angiographic guidance; P = 0.66). In patients with STEMI with early infarct artery patency, OCT guidance compared with angiographic guidance of reperfusion was associated with less stent implantation during primary percutaneous coronary intervention. These results indicate the possible value of OCT imaging in optimizing the reperfusion strategy of patients with STEMI, although additional studies with larger population and longer follow-up are warranted to explore the clinical benefits of OCT guidance of reperfusion. In addition, the authors noted the following limitations of this study: 1) Only individuals with STEMI with a residual diameter stenosis under 70% were enrolled therefore the results cannot be generalized to individuals with more than 70% stenosis; 2) The sample size was relatively small and the powered primary endpoint aimed at reducing the rate of stent implantation, with underpowered clinical endpoints; and 3) Due to limited evidence on non-stenting criteria available at the time of trial design, adoption of a non-stenting strategy in plaque erosion, spontaneous coronary artery dissection (SCAD), or ruptures without dissection was tentative and exploratory creating a potential bias to the decision-making process. In addition, the rate of stent implantation might be hard to assess, given the unblinded nature of this trial.

**UpToDate**

Evaluation of Carotid Artery Stenosis

The 2024 UpToDate review on “Evaluation of Carotid Artery Stenosis” (46) discusses diagnostic modalities that are used to directly image the carotid artery; iit does not mention OCT as a diagnostic tool.

Intravascular Ultrasound, Optical Coherence Tomography, and Angioscopy of Coronary Circulation.

A 2023 UpToDate review (47) on "Intravascular ultrasound, optical coherence tomography, and angioscopy of coronary circulation" states that "today, no clinical indications for OCT imaging are established. There are no randomized data supporting a prognostic role for OCT in catheter-based intervention .... Preliminary data on OCT indicate that it can change the operator’s intention-to-treat and modify the overall revascularization strategy, potentially avoiding unnecessary interventional procedures. OCT might be efficient in complex interventions

including treatment of left main stem, bifurcations as well as in all cases of angiographically ambiguous lesions, and in-stent failures. Two other potential uses of OCT are identification of an angiographically unclear lesion and assessment of stent failure".

**Summary of Evidence**

The past two decades have witnessed the generation of an enormous amount of data from cardiac optical coherence tomography (OCT) research. OCT has some advantages over intravascular ultrasound (IVUS) for imaging coronary arteries. It has a higher resolution and provides greater detail for accessible structures compared with IVUS. Some studies have demonstrated that OCT can be performed with a high success rate and few complications. OCT can be used to evaluate morphologic features of atherosclerotic plaques and to risk-stratify plaques as to their chance of rupture. Limited evidence from studies that compare OCT with IVUS indicate that OCT picks up more abnormalities than does IVUS and is probably more accurate in classifying plaques as high risk. Because of the lack of a true criterion standard, the sensitivity and specificity of OCT for this purpose cannot be determined with certainty. Some experts consider OCT to be the criterion standard for this purpose and compare other tests with OCT. While OCT may be more accurate than other imaging modalities the clinical utility is still uncertain. It is not clear which patients should be assessed for a high-risk plaque, nor is it clear whether changes in management should occur as a result of testing. To date, the evidence is not sufficient to determine the effect of OCT on health outcomes when used for identification, risk stratification and/or assessment of coronary atherosclerotic plaques. Therefore, the use of OCT for identification, risk stratification, and treatment of vulnerable plaque(s) is considered experimental, investigational, and/or unproven.

As an adjunct to percutaneous coronary intervention (PCI), OCT may improve on the ability of IVUS to pick up clinically relevant abnormalities, and this may lead to changes in management. RCTs do not report any advantage of OCT over IVUS for achieving optimal stent placement. Several noncomparative studies have been conducted to address whether an OCT-guided treatment strategy involving deferred stenting is feasible. However, no comparative studies have been conducted to demonstrate improved clinical outcomes with such a strategy. Overall, the current evidence is limited in patients who have been evaluated by OCT. Currently, it is not possible to determine the degree of improvement with OCT, or the clinical significance of this improvement. Several systematic reviews identified multiple flaws in each study therefore further studies are warranted to validate the rationality of different modalities in the utilization of OCT as an adjunct to PCI. Therefore, the use of OCT as an adjunct to PCI is considered experimental, investigational, and/or unproven.

For the indications of risk stratification of coronary plaques and follow-up of stenting, OCT may also be more accurate than IVUS for imaging of superficial structures. However, the clinical utility of IVUS has not been demonstrated for these indications, because test results do not lead to changes in management that improve outcomes. Therefore, clinical utility has not been demonstrated for OCT for the same reasons. As a result, OCT is considered experimental,

investigational, and/or unproven for risk stratification of coronary plaques and for follow-up post stent implantation.

OCT is actively being investigated for imaging of other cardiovascular conditions, including but not limited to the evaluation of coronary artery abnormalities in pediatric patients with Kawasaki Disease, for the assessment of pulmonary artery fibrosis in patients with pulmonary artery hypertension (PAH), and to detect coronary vascular changes following heart transplant, and OCT guided reperfusion in STEMI (ST-elevation myocardial infarction) with early infarct artery patency. To date, there is insufficient evidence to evaluate the long-term safety and efficacy in this population and the impact on health outcomes therefore, OCT is considered experimental, investigational, and/or unproven for the assessment and treatment of all other cardiovascular uses.

**Practice Guidelines and Position Statements**

American College of Cardiology

In a 2011 guideline for PCI intravascular ultrasound, OCT and angioscopy of coronary circulation and the American College of Cardiology (ACC) stated that "the appropriate role of optical coherence tomography in routine clinical decision making has not been established". (48)

American College of Cardiology (ACC), American Heart Association (AHA) and the Joint Committee on Clinical Practice Guideline

A 2021 joint guideline for coronary artery revascularization (published in January 2022) states the effectiveness of OCT for imaging ostial left main disease is limited. (49)

Society of Cardiovascular Angiography and Interventions

In 2018, the Society of Cardiovascular Angiography and Interventions published a consensus statement on the use of FFR, IVUS, and OCT, which made the following statements regarding the benefit of OCT (50):

- Probably Beneficial: Determination of optimal stent deployment (sizing, apposition, lack of edge dissection), with improved resolution compared with IVUS.
- Possibly Beneficial:
    - OCT can be useful for the assessment of plaque morphology.
    - During PCI, OCT can assess presence and extent of coronary dissection.
    - During PCI, OCT can assess hazy lesions of uncertain etiology or severity, or post-PCI suspected edge dissections.
- No Proven Value/Should be Discouraged: OCT should not be performed to determine stenosis functional significance.

## Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

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|---|---|
| **CPT Codes** | 92978, 92979 |
| **HCPCS Codes** | None |

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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## Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

## Policy History/Revision

| Date | Description of Change |
|---|---|
| 12/31/2025 | Document became inactive. |
| 05/15/2024 | Document updated with literature review. Coverage unchanged. Added references 34-36, 45, 49, 50; others updated; some removed. |
| 03/15/2023 | Reviewed. No changes. |
| 05/15/2022 | Document updated with literature review. Coverage unchanged. Added references 5, 22, 23, 28, 43, 44; others updated; some removed. |
| 02/15/2021 | Reviewed. No changes. |
| 04/15/2020 | Document updated with literature review. Coverage unchanged. Reference number 51 revised and 55 added. |
| 10/01/2018 | Reviewed. No changes. |
| 01/15/2018 | Document updated with literature review. Coverage unchanged. |
| 11/01/2016 | Document updated with literature review. Coverage unchanged. |
| 05/15/2015 | Reviewed. No changes. |
| 06/15/2014 | Document updated with literature review. Coverage unchanged. CPT/HCPCS code(s) updated. |
| 01/01/2012 | New medical document. Optical coherence tomography (OCT) is considered experimental, investigational and unproven for imaging of coronary arteries, including but not limited to as an adjunct to percutaneous coronary interventions (PCI) with stenting; risk stratification of intracoronary atherosclerotic plaques; or follow-up of stenting. |