



Kansas City

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Optical Coherence Tomography for Imaging of Coronary Arteries

Policy Number: 2.02.29

Last Review: 9/2014

Origination: 3/2012

Next Review: 3/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for optical coherence tomography for imaging of coronary arteries. This is considered investigational.

When Policy Topic is covered

Not Applicable

When Policy Topic is not covered

Optical coherence tomography is considered **investigational** when used as an adjunct to percutaneous coronary interventions with stenting.

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

Description of Procedure or Service

Optical coherence tomography (OCT) is an imaging technique that uses near-infrared light to image the coronary arteries. Potential applications in cardiology include evaluating the characteristics of coronary artery plaques for the purpose of risk stratification and following coronary stenting to determine the success of the procedure.

Background

Optical coherence tomography (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 structures. (1) 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 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 to 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. Intravascular ultrasound 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 neoendothelialization on the endoluminal surface of the stent. The presence of neo-intimal coverage of drug-eluting stents and the absence of stent thrombosis have been correlated with favorable outcomes. (2) Therefore, the adequacy of neo-intimal coverage has been proposed as an intermediate outcome in clinical trials of stenting.

Regulatory Status

There are several OCT systems that have been cleared for marketing through the U.S. Food and Drug Administration's (FDA) 510(k) program. For example, Lightlab Imaging, Inc. (acquired by St. Jude Medical in 2010) received FDA marketing clearance in April 2010 for its C7 Xr® Imaging System and in August 2011 for its next generation frequency domain C7 Xr® Imaging System. In January 2013, it received clearance based on substantial equivalence for its next generation C7 Xr® Imaging System with Fractional Flow Reserve (Illumien™ Optis™) system.

Rationale

This policy was created in February 2012 and updated periodically with literature reviews, most recently through January 2, 2014.

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.

Literature Review

Literature was identified in the following general categories of OCT use. These were:

- Technical performance of OCT
- Identification and risk stratification of the "vulnerable plaque"
- Adjunctive treatment as part of percutaneous coronary interventions (PCIs)
- Follow-up evaluation poststent placement

Technical performance of OCT

The reliability of OCT findings was examined by Gonzalo et al.(4) These authors used a second-generation, frequency-domain 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 malapposition was 100% ($k=1.0$). Plaque characteristics also had high reproducibility, with 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.(5) 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 (6) reported good interstudy correlation for frequency-domain (FD)-OCT in evaluation of both stented and native coronary arteries in 18 patients undergoing PCI ($R^2=0.99$ and $p < 0.001$ for mean lumen area and minimal lumen area for repeat evaluations of the same coronary lesion).

In contrast, Brugaletta et al(7) 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.(8) 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 mm vs 98 mm). 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(9) 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(10) 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(11) 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 stenoses 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.

Another prospective cohort study that evaluated OCT in predicting the natural history of plaques was published in 2012 by Uemura et al(11) This study enrolled 53 consecutive patients undergoing PCI and followed them for 7 months, at which time angiography was repeated. Of the 69 total obstructing lesions, 13 showed evidence of progression while 56 did not. OCT parameters predictive of progression were intimal laceration (61.5% vs 8.9%, $p<0.01$), presence of microchannels (76.9% vs 14.3%, $p<0.01$), lipid pools (100% vs 60.7%, $p=0.02$), macrophage images (61.5% vs 14.3%, $p<0.01$), and intraluminal thrombi (30.8% vs 1.8%, $p<0.01$).

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(12) 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(13) 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(14) 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 acute coronary syndrome. They included 126 patients with acute coronary syndrome 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.

Wykrzykowska et al reported on initial results of a pilot study that treated high-risk plaques with a nitinol self-expanding vShield device.(15) 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 months' 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.

Section summary

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. 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. One clinical trial has used OCT to select patients for treatment of vulnerable plaques, but no outcome data have been reported yet. Therefore, the evidence is not sufficient to determine the effect of OCT on health outcomes when used to assess coronary atherosclerotic plaques.

Adjunctive treatment as part of percutaneous coronary interventions

Several studies have demonstrated that the use of IVUS as an adjunct to PCI results in improved outcomes.(16-18) Guidelines from the American College of Cardiology/American Heart Association for use of IVUS as an adjunct to PCI(19) include the following:

- Assessment of the adequacy of deployment of coronary stents, including the extent of stent apposition and determination of the minimum luminal diameter within the stent
- Determination of the mechanism of stent restenosis and to enable selection of appropriate therapy
- Assessment of a suboptimal angiographic result following PCI
- Establish presence and distribution of coronary calcium in patients for whom adjunctive rotational atherectomy is contemplated
- Determination of plaque location and circumferential distribution for guidance of directional coronary atherectomy

Comparisons 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 performed a small open-label RCT comparing OCT with IVUS in 70 patients undergoing stent implantation.(20) 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.(21) 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 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% confidence interval, 0.25 to 0.96; p=0.037).

Yamaguchi et al(22) 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(23) 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 (15% vs 5%). These results were interpreted as demonstrating the higher resolution and greater detail obtained with OCT compared with IVUS.

Bezerra et al compared IVUS with both frequency-domain (FD) and time-domain (TD) OCT in both stented and unstented vessels.(24) 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.(24) In the immediate post-PCI stent evaluations, tissue protrusion and malapposition areas were significantly larger by FD-OCT compared with IVUS (for tissue protrusion, OCT-IVUS difference 0.16 mm^2 , $p<0.001$; for malapposition areas, OCT-IVUS difference 0.24 mm^2 , $p=0.017$). Acute malapposition 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-luminal interface on immediate postprocedure IVUS images.

Section summary

The evidence on this question consists of 1 small RCT and several nonrandomized studies that compare the results of OCT with IVUS as an adjunct to PCI to evaluate stent placement. 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 malapposition that lead to changes in management. The single RCT 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 evaluation(s) poststent 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. 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 poststenting. Capodanno et al(25) 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 ($16.3\pm 3.0 \text{ mm}$ vs $16.2\pm 3.8 \text{ mm}$, $p=0.82$). However, the other measured parameters differed between groups. Vessel luminal area was significantly lower by OCT compared with IVUS ($3.83\pm 1.60 \text{ mm}^2$ vs $4.05\pm 1.44 \text{ mm}^2$, $p=0.82$), while stent area was significantly higher with OCT ($6.61\pm 1.39 \text{ mm}^2$ vs $6.17\pm 1.07 \text{ mm}^2$, $p<0.001$). The percentage of tissue coverage was also higher with OCT ($43.4\%\pm 16.1\%$ vs $35.5\%\pm 16.4\%$), suggesting that IVUS underestimates stent coverage compared with OCT.

Inoue et al(26) 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

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 be changed 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.

Safety

The safety of optical coherence tomography (OCT) was evaluated in a large multicenter case series of 468 patients.(27) These patients underwent OCT for the indications of: evaluation of plaque (40%), adjunct to percutaneous coronary intervention (PCI) (28.2%), and follow-up of stenting (31.8%). The most common side effect of the procedure was transient chest pain and electrocardiogram changes that occurred in 48% of patients. Major complications were rare, with a total of 9 major complications occurring in 468 patients (1.9%). Major complications included 5 cases of ventricular fibrillation associated with balloon occlusion, 3 cases of air embolism, and 1 case of vessel dissection. There was no periprocedural myocardial infarction (MI) or other major cardiac adverse events that occurred as a result of the procedure.

In a smaller single-center case series, Lehtinen et al(28) evaluated the safety of OCT in 230 OCT evaluations in 210 patients. PCI was performed in 44.3% of examinations. OCT was successful in 87.8% of examinations. Periprocedural complications were rare; chest pain was the most commonly seen, occurring in 10.9% of OCT examinations. One patient died of heart failure after PCI for acute MI.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

In response to requests, input was received from 3 academic medical centers while this policy was under review in 2011-2012. While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted. All reviewers agreed that OCT should be considered investigational for each of the indications queried. Reviewers mainly cited the lack of sufficient published evidence as the reason for considering OCT investigational.

Summary

Optical coherence tomography (OCT) is an imaging technique that 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. Case series have demonstrated that OCT can be performed with a high success rate and few complications. Head-to-head comparisons of OCT and IVUS report that OCT picks up additional abnormalities that are not detected by IVUS, implying that OCT is a more sensitive test compared with IVUS.

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. A single small RCT did not report any advantage of OCT over IVUS for achieving optimal stent placement. Overall, the current evidence is limited and includes relatively small numbers of patients who have been evaluated by OCT. As a result, it is not possible to determine the degree of improvement with OCT, or

the clinical significance of this improvement. Therefore, the use of OCT as an adjunct to PCI is considered investigational.

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 investigational for risk stratification of coronary plaques and for follow-up poststent implantation.

Practice Guidelines and Position Statements

A consensus report on standardization and validation of techniques and reporting for OCT was published in 2012 by the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation.(29) This document provided guidance on the following areas that are important to the use of OCT in both research and clinical care:

- Equipment needed
- Image acquisition protocols
- Image display techniques
- Reporting standards
 - Definition of terms
 - Qualitative results
 - Quantitative measurements

Medicare National Coverage

None.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov on January 23, 2014, identified the several ongoing randomized trials relevant to the use of OCT in coronary artery assessment:

- **Does Optical Coherence Tomography Optimise Results of Stenting (NCT01743274).** This study will randomize patients with acute coronary syndrome undergoing PCI with stenting to an intervention group, which will undergo OCT measurements to optimize the stent procedure, or a control group, which will receive usual care. The primary outcome measure is the functional result of the PCI procedure as assessed by FFR. Target enrollment is 230. The estimated study completion date is listed as September 2015.
- **FFR or OCT Guidance to Revascularize Intermediate Coronary Stenosis Using Angioplasty (NCT01743274).** This study will randomize patients with acute coronary syndrome undergoing PCI to 1 of 2 active comparator groups: PCI with OCT-guidance or PCT with FFR-guidance. The primary outcome measure is the occurrence of angina at 13 months postprocedure. Target enrollment is 400. The estimated study completion date is listed as April 2016.

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Billing Coding/Physician Documentation Information

- 0291T** Intravascular optical coherence tomography (coronary native vessel or graft) during diagnostic evaluation and/or therapeutic intervention, including imaging supervision, interpretation, and report; initial vessel (List separately in addition to primary procedure)
- 0292T** Intravascular optical coherence tomography (coronary native vessel or graft) during diagnostic evaluation and/or therapeutic intervention, including imaging supervision, interpretation, and report; each additional vessel (List separately in addition to primary procedure)

Policy Implementation/Update Information

- 3/1/12 New policy; considered investigational.
- 9/1/12 No policy statement changes.
- 3/1/13 No policy statement changes.
- 9/1/13 No policy statement changes.
- 3/1/14 No policy statement changes.
- 9/1/14 No policy statement changes.

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