MEDICAL POLICY

POLICY TITLE	OPTICAL COHERENCE TOMOGRAPHY FOR IMAGING OF CORONARY ARTERIES
POLICY NUMBER	MP-5.057

Original Issue Date (Created):	**4/1/2015**
Most Recent Review Date (Revised):	**8/21/2020**
Effective Date:	**11/1/2020**

I. POLICY

Optical coherence tomography is considered **investigational** when used as an adjunct to percutaneous coronary interventions with stenting as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

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 as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-2.085 Optical Coherence Tomography (OCT) of the Anterior Eye Segment

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital BlueCross. Please see additional information below, and subject to benefit variations as discussed in Section VI below.

FEP PPO-The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

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III. DESCRIPTION/BACKGROUND

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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.

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. 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.

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. This is compared with IVUS, which has a penetration depth of approximately 10 mm.

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.

Another goal of intravascular imaging is as an adjunct to percutaneous coronary intervention (PCI) with stent placement. Stent features that are often evaluated immediately postprocedure 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

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.

IV. RATIONALE

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SUMMARY OF EVIDENCE

Optical coherence tomography (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. 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 have reported that OCT picks up additional abnormalities not detected by IVUS, implying that OCT is a more sensitive test than 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 randomized controlled trial did not report any advantage of OCT over IVUS for achieving optimal stent placement. Several noncomparative studies have addressed 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 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 post stent implantation

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Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

V. DEFINITIONS

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N/A

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VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital BlueCross. Members and providers should consult the member's health benefit plan for information or contact Capital BlueCross for benefit information.

VII. DISCLAIMER

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Capital BlueCross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital BlueCross' Provider Services or Member Services. Capital BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Investigational; therefore not covered:

CPT Codes®								
92978	92979							

IX. REFERENCES

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1. *Prati F, Regar E, Mintz GS, et al. Expert review document on methodology, terminology, and clinical applications of optical coherence tomography: physical principles, methodology of image acquisition, and clinical application for assessment of coronary arteries and atherosclerosis. Eur Heart J. Feb 2010;31(4):401-415. PMID 19892716*
2. *Lindsay AC, Viceconte N, Di Mario C. Optical coherence tomography: has its time come? Heart. Sep 2011;97(17):1361-1362. PMID 21730261*
3. *Low AF, Tearney GJ, Bouma BE, et al. Technology Insight: optical coherence tomography--current status and future development. Nat Clin Pract Cardiovasc Med. Mar 2006;3(3):154-162; quiz 172. PMID 16505861*
4. *Gonzalo N, Tearney GJ, Serruys PW, et al. Second-generation optical coherence tomography in clinical practice. High-speed data acquisition is highly reproducible in patients undergoing percutaneous coronary intervention. Rev Esp Cardiol. Aug 2010; 63(8):893-903. PMID 20738934*
5. *Fedele S, Biondi-Zoccai G, Kwiatkowski P, et al. Reproducibility of coronary optical coherence tomography for lumen and length measurements in humans (The CLI-VAR [Centro per la Lotta contro l'Infarto-VARiability] study). The American journal of cardiology. Oct 15 2012; 110(8):1106-1112. PMID 22748353*
6. *Jamil Z, Tearney G, Bruining N, et al. Interstudy reproducibility of the second generation, Fourier domain optical coherence tomography in patients with coronary artery disease and comparison with intravascular ultrasound: a study applying automated contour detection. Int J Cardiovasc Imaging. Jan 2013;29(1):39-51. PMID 22639296*
7. *Liu Y, Shimamura K, Kubo T, et al. Comparison of longitudinal geometric measurement in human coronary arteries between frequency-domain optical coherence tomography and intravascular ultrasound. Int J Cardiovasc Imaging. Feb 2014; 30(2):271-277. PMID 24272334*
8. *Brugaletta S, Garcia-Garcia HM, Gomez-Lara J, et al. Reproducibility of qualitative assessment of stent struts coverage by optical coherence tomography. Int J Cardiovasc Imaging. Jan 2013; 29(1):5-11. PMID 22415543*
9. *Jang IK, Bouma BE, Kang DH, et al. Visualization of coronary atherosclerotic plaques in patients using optical coherence tomography: comparison with intravascular ultrasound. J Am Coll Cardiol. Feb 20 2002;39(4):604- 609. PMID 11849858*
10. *Kubo T, Nakamura N, Matsuo Y, et al. Virtual histology intravascular ultrasound compared with optical coherence tomography for identification of thin-cap fibroatheroma. Int Heart J. 2011;52(3):175-179. PMID 21646741*
11. *Miyamoto Y, Okura H, Kume T, et al. Plaque characteristics of thin-cap fibroatheroma evaluated by OCT and IVUS. JACC Cardiovasc Imaging. Jun 2011;4(6):638-646. PMID 21679899*
12. *Uemura S, Ishigami KI, Soeda T, et al. Thin-cap fibroatheroma and microchannel findings in optical coherence tomography correlate with subsequent progression of coronary atheromatous plaques. Eur Heart J. Aug 10 2011. PMID 21831910*

13. *Yonetsu T, Kakuta T, Lee T, et al. In vivo critical fibrous cap thickness for rupture-prone coronary plaques assessed by optical coherence tomography. Eur Heart J. May 2011;32(10):1251-1259. PMID 21273202*
14. *Guo J, Chen YD, Tian F, et al. Thrombosis and morphology of plaque rupture using optical coherence tomography. Chin Med J (Engl). Mar 2013;126(6):1092-1095. PMID 23506584*
15. *Jia H, Abtahian F, Aguirre AD, et al. In vivo diagnosis of plaque erosion and calcified nodule in patients with acute coronary syndrome by intravascular optical coherence tomography. J Am Coll Cardiol. Nov 5 2013;62(19):1748-1758. PMID 23810884*
16. *Gamou T, Sakata K, Matsubara T, et al. Impact of thin-cap fibroatheroma on predicting deteriorated coronary flow during interventional procedures in acute as well as stable coronary syndromes: insights from optical coherence tomography analysis. Heart Vessels. Jul 19 2014. PMID 25037112*
17. *Galon MZ, Wang Z, Bezerra HG, et al. Differences determined by optical coherence tomography volumetric analysis in non-culprit lesion morphology and inflammation in ST-segment elevation myocardial infarction and stable angina pectoris patients. Catheter Cardiovasc Interv. Sep 1 2014. PMID 25178981*
18. *Wykrzykowska JJ, Diletti R, Gutierrez-Chico JL, et al. Plaque sealing and passivation with a mechanical selfexpanding low outward force nitinol vShield device for the treatment of IVUS and OCT-derived thin cap fibroatheromas (TCFAs) in native coronary arteries: report of the pilot study vShield Evaluated at Cardiac hospital in Rotterdam for Investigation and Treatment of TCFA (SECRITT). EuroIntervention. Dec 20 2012;8(8):945-954. PMID 22669133*
19. *Fitzgerald PJ, Oshima A, Hayase M, et al. Final results of the Can Routine Ultrasound Influence Stent Expansion (CRUISE) study. Circulation. Aug 1 2000;102(5):523-530. PMID 10920064*
20. *Jakabcin J, Spacek R, Bystron M, et al. Long-term health outcome and mortality evaluation after invasive coronary treatment using drug eluting stents with or without the IVUS guidance. Randomized control trial. HOME DES IVUS. Catheter Cardiovasc Interv. Mar 1 2010;75(4):578-583. PMID 19902491*
21. *Roy P, Steinberg DH, Sushinsky SJ, et al. The potential clinical utility of intravascular ultrasound guidance in patients undergoing percutaneous coronary intervention with drug-eluting stents. Eur Heart J. Aug 2008;29(15):1851-1857. PMID 18550555*
22. *Smith SC, Jr., Dove JT, Jacobs AK, et al. ACC/AHA guidelines for percutaneous coronary intervention (revision of the 1993 PTCA guidelines)-executive summary: a report of the American College of Cardiology/American Heart Association task force on practice guidelines (Committee to revise the 1993 guidelines for percutaneous transluminal coronary angioplasty) endorsed by the Society for Cardiac Angiography and Interventions. Circulation. Jun 19 2001;103(24):3019-3041. PMID 11413094*
23. *Habara M, Nasu K, Terashima M, et al. Impact of frequency-domain optical coherence tomography guidance for optimal coronary stent implantation in comparison with intravascular ultrasound guidance. Circ Cardiovasc Interv. Apr 2012;5(2):193-201. PMID 22456026*

24. *Prati F, Di Vito L, Biondi-Zoccai G, et al. Angiography alone versus angiography plus optical coherence tomography to guide decision-making during percutaneous coronary intervention: the Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) study. EuroIntervention. Nov 22 2012;8(7):823-829. PMID 23034247*
25. *Yamaguchi T, Terashima M, Akasaka T, et al. Safety and feasibility of an intravascular optical coherence tomography image wire system in the clinical setting. Am J Cardiol. Mar 1 2008;101(5):562-567. PMID 18307999*
26. *Kawamori H, Shite J, Shinke T, et al. The ability of optical coherence tomography to monitor percutaneous coronary intervention: detailed comparison with intravascular ultrasound. J Invasive Cardiol. Nov 2010;22(11):541-545. PMID 21041851*
27. *Bezerra HG, Attizzani GF, Sirbu V, et al. Optical coherence tomography versus intravascular ultrasound to evaluate coronary artery disease and percutaneous coronary intervention. JACC Cardiovasc Interv. Mar 2013;6(3):228-236. PMID 23517833*
28. *Sohn J, Hur SH, Kim IC, et al. A comparison of tissue prolapse with optical coherence tomography and intravascular ultrasound after drug-eluting stent implantation. Int J Cardiovasc Imaging. Oct 2 2014. PMID 25273918*
29. *Sugiyama T, Kimura S, Akiyama D, et al. Quantitative assessment of tissue prolapse on optical coherence tomography and its relation to underlying plaque morphologies and clinical outcome in patients with elective stent implantation. Int J Cardiol. Sep 2014;176(1):182-190. PMID 25042663*
30. *Ann SH, Lim KH, De Jin C, et al. Multi-modality imaging for stent edge assessment. Heart Vessels. Jan 31 2014. PMID 24481539*
31. *Souteyrand G, Amabile N, Combaret N, et al. Invasive management without stents in selected acute coronary syndrome patients with a large thrombus burden: a prospective study of optical coherence tomography guided treatment decisions. EuroIntervention. Jul 19 2014. PMID 25033106*
32. *Cervinka P, Spacek R, Bystron M, et al. Optical coherence tomography-guided primary percutaneous coronary intervention in ST-segment elevation myocardial infarction patients: a pilot study. Can J Cardiol. Apr 2014;30(4):420-427. PMID 24680171*
33. *Radu MD, Raber L, Heo J, et al. Natural history of optical coherence tomography-detected non-flow-limiting edge dissections following drug-eluting stent implantation. EuroIntervention. Jan 22 2014;9(9):1085-1094. PMID 24064426*
34. *Capodanno D, Prati F, Pawlowsky T, et al. Comparison of optical coherence tomography and intravascular ultrasound for the assessment of in-stent tissue coverage after stent implantation. EuroIntervention. Nov 2009;5(5):538-543. PMID 20142173*
35. *Inoue T, Shite J, Yoon J, et al. Optical coherence evaluation of everolimus-eluting stents 8 months after implantation. Heart. Sep 2011;97(17):1379-1384. PMID 21051456*
36. *Harris KC, Manouzi A, Fung AY, et al. Feasibility of optical coherence tomography in children with Kawasaki disease and pediatric heart transplant recipients. Circ Cardiovasc Imaging. Jul 2014;7(4):671-678. PMID 24874056*

37. *Barlis P, Gonzalo N, Di Mario C, et al. A multicentre evaluation of the safety of intracoronary optical coherence tomography. EuroIntervention. May 2009;5(1):90-95. PMID 19577988*
38. *Lehtinen T, Nammas W, Airaksinen JK, et al. Feasibility and safety of frequency-domain optical coherence tomography for coronary artery evaluation: a single-center study. Int J Cardiovasc Imaging. Jun 2013;29(5):997-1005. PMID 23417516*
39. *Meneveau N, Ecarnot F, Souteyrand G, et al. Does optical coherence tomography optimize results of stenting? Rationale and study design. Am Heart J. Aug 2014;168(2):175-181 e171-172. PMID 25066556*
40. *Lotfi A, Jeremias A, Fearon WF, et al. Expert consensus statement on the use of fractional flow reserve, intravascular ultrasound, and optical coherence tomography: a consensus statement of the Society of Cardiovascular Angiography and Interventions. Catheter Cardiovasc Interv. Mar 1 2014;83(4):509-518. PMID 24227282*
41. *Tearney GJ, Regar E, Akasaka T, et al. Consensus standards for acquisition, measurement, and reporting of intravascular optical coherence tomography studies: a report from the International Working Group for Intravascular Optical Coherence Tomography Standardization and Validation. J Am Coll Cardiol. Mar 20; 2012;59 (12):1058-1072. PMID 22421299*
42. *Blue Cross Blue Shield Association Medical Policy Reference Manual. 2.02.29, Optical Coherence Tomography for Imaging of Coronary Arteries. October 2016 (Archived).*

X. POLICY HISTORY

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MP-5.057	**CAC 11/25/14 New policy BCBSA adopted.** Optical coherence tomography for imaging of coronary arteries is considered investigational. FEP variation added. Policy coded.
	CAC 11/24/15 Consensus review. No changes to the policy statements Reference and rationale update. Coding reviewed.
	CAC 11/29/16 Consensus review. No changes to the policy statements**.** Variations reformatted. Coding reviewed. End dated codes 0291T, 0292T removed and added replacement codes 92978, 92979; effective 1/1/17.
	12/19/17 Consensus review. No changes to the policy statements. Coding reviewed.
	11/6/18 Consensus review. No change to the policy statements. References reviewed. Rationale revised.
	8/26/2019 Consensus review. Policy statement unchanged. References reviewed.
	8/21/2020: Consensus Review. No changes to policy Statement; Coding reviewed, no changes. References reviewed, updated. Product Variation Statement updated.

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