

Protocol

Optical Coherence Tomography for Imaging of Coronary Arteries

(20229)

Medical Benefit	Effective Date: 07/01/12	Next Review Date: 03/15
Preauthorization	No	Review Dates: 03/12, 03/13, 03/14

*The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. **Preauthorization is not required but is recommended if, despite this Protocol position, you feel this service is medically necessary.** Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.*

Description

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

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 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 one 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.

Related Protocol

Optical Coherence Tomography (OCT) of the Anterior Eye Segment

Policy (Formerly Corporate Medical Guideline)

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.

Benefit Application

Because the scientific evidence is limited and the clinical significance is not demonstrated resulting in our position that this is investigational, we will not pay separately for it when performed in addition to the primary procedure.

Services that are the subject of a clinical trial do not meet our Technology Assessment Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this Protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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30. Local Coverage Determination (LCD) for Category III CPT® Codes (L25275), Revision Effective Date for services performed on or after 02/01/2014.