Anthem

Medical Policy

Subject: Near-Infrared Coronary Imaging and Near-Infrared Intravascular Ultrasound Coronary Imaging
Document #: RAD.00057 **Publish Date:** 09/27/2023
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Description/Scope

This document addresses near-infrared coronary imaging and near-infrared intravascular ultrasound coronary imaging. Near-infrared coronary imaging, also referred to as near-infrared spectroscopy (NIRS), was created for the near-infrared examination of coronary arteries to detect plaques with large lipid cores in individuals undergoing cardiac angiography. Subsequently, near-infrared intravascular ultrasound coronary imaging was developed for the near-infrared examination of coronary arteries during invasive coronary angiography in combination with intravascular ultrasound (IVUS) examination of coronary intravascular pathology.

Position Statement

Investigational and Not Medically Necessary:

Near-infrared coronary imaging is considered **investigational and not medically necessary** for all indications.

Near-infrared intravascular ultrasound coronary imaging is considered **investigational and not medically necessary** for all indications.

Rationale

Near-infrared coronary imaging (LipiScan™ Coronary Imaging System, Infraredx, Inc., Burlington, MA) was cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process in April 2008. According to the 510(k) summary, the device is intended for the near-infrared examination of coronary arteries, for the detection of lipid-core-containing plaques of interest, and for the assessment of coronary artery lipid core burden. The LipiScan Coronary Imaging System uses the same basic catheter design and the same operating principle as the predicate device, the Infraredx NIR System (Infraredx, Inc., Burling, MA) which was cleared for marketing by the FDA 510(k) process in June 2006 and also intended for the near-infrared imaging of coronary arteries.

Near-infrared intravascular ultrasound coronary imaging (Infraredx LipiScan IVUS Imaging System, Infraredx, Inc., Burlington, MA) was cleared for marketing by the FDA 510(k) process in June 2010. This system combines both near-infrared and intravascular ultrasound technologies. According to the 510(k) summary, modifications from the LipiScan Coronary Imaging System to the LipiScan IVUS Imaging System are the inclusion of ultrasound imaging within the same dimensions of the catheter and an expanded indication for use (ultrasound examination of coronary intravascular pathology). The Infraredx LipiScan IVUS imaging system uses the same basic catheter design and the same operating principle as the predicate LipiScan Coronary Imaging system, while the ultrasound capabilities are functionally equivalent to the iLab™ Ultrasound Imaging System (Boston Scientific Corp., Fremont, CA).

The TVC Imaging System™ (Infraredx, Inc., Burlington, MA), also a dual-modality NIRS/IVUS imaging device, was cleared for marketing by the FDA 510(k) process in March 2013. The Makoto™ Intravascular Imaging System (Infraredx, Inc., Bedford, MA), which uses the Dualpro™ IVUS + NIRS catheter, is currently available in the U.S. It was cleared for marketing by the FDA 510(k) process in April 2019 based on the Lipid-Rich Plaque (LRP) study (NCT02033694). A similar Makoto Intravascular Imaging System which also includes a peripheral imaging catheter received 510(k) clearance from the FDA in December 2021.

The LRP study findings were published in 2019 by Waksman and colleagues. It was a prospective uncontrolled study which enrolled 1563 individuals with known or suspected coronary artery disease (CAD) who underwent cardiac catheterization with possible ad hoc percutaneous coronary intervention. Participants underwent NIRS-intravascular ultrasound imaging with the Infraredx device. All of the individuals with a large LRP (defined as $maxLCBI_{4mm} < 250$) detected by NIRS and a randomly selected half of the individuals with a small LRP were contacted for follow-up at 6-month intervals, up to 24 months. The primary outcome was non-culprit major adverse cardiovascular events (NC-MACE). The analysis included 1271 individuals with analyzable data who were followed for up to 24 months. During the follow-up period, NC-MACE was reported in 9% of participants (n=103). In a multivariate model controlling for demographic variables and co-morbidities, the $maxLCBI_{4mm}$ was significantly associated with NC-MACE. For $maxLCBI_{4mm}$ as a continuous variable, the adjusted hazard ratio [HR] of experiencing MACE for every 100-unit increase, was 1.18 (95% confidence interval [CI], 1.05 to1.32, p=0.043). $MaxLCBI_{4mm} > 400$ was associated with an HR of 1.89 (95% CI, 1.26 to 2.83, p=0.0021). A limitation of the study is that it did not compare outcomes in individuals who were managed with and without use of NIRS-intravascular ultrasound imaging.

Gardner and colleagues (2008) studied autopsy specimens by assessing the correlation between NIRS and the gold standard of histology. Lipid core plaque (LCP) was found to be present in 115 (4.3%) sections from the 51 validation hearts. The authors noted that study limitations included lack of use of living tissue, lack of simulation of coronary motion, and avoidance of the tortuous anatomy of the in situ coronary vasculature. An additional limitation appears to be small sample size.

Several publications prior to 2011 studied the feasibility and limitations of NIRS to detect lipid core plaques in living humans. Garcia-Garcia (2008) and Schaar (2007) described NIRS techniques to detect vulnerable plaques in vivo. They both found that none of the techniques studied had proven value and additional clinical testing is needed. Potential problems of NIRS include acquisition time, blood scattering, and influence of pH and temperature (Schaar, 2007; Vaina, 2005). Suh and colleagues (2011) reported major limitations of NIRS as the detection of only one characteristic of vulnerable plaque and an inability to determine depth (superficial versus deep) of the lipid core.

In 2013, Madder and colleagues studied combined NIRS and IVUS findings of culprit lesions in ST-segment elevation myocardial infarction (STEMI). Autopsy findings indicate that most STEMI are caused by rupture of preexisting LCP. During this study, 20 individuals with acute STEMI had their culprit vessels evaluated with combined NIRS and IVUS. The STEMI culprit findings were compared to findings in nonculprit segments of the artery and also to findings in autopsy control segments. Culprit and control segments were analyzed for the maximum lipid core burden index in a 4 mm length of artery ($maxLCBI_{4mm}$). $MaxLCBI_{4mm}$ was 5.8-fold higher in STEMI culprit segments than in 87 nonculprit segments of the STEMI culprit vessel and 87-fold higher than in 279

coronary autopsy segments free of large LCP by histology. Within the STEMI culprit artery, NIRS accurately distinguished culprit from nonculprit segments (receiver-operating characteristic analysis area under the curve 0.90). A threshold of max$LCBI_{4mm}$ > 400 distinguished STEMI culprit segments from specimens free of large LCP by histology (sensitivity: 85%, specificity: 98%). This study did not prospectively validate the predictive ability of this threshold. The authors concluded that their data supports a long-term, large prospective study to test the hypothesis that intracoronary NIRS can provide accurate, site-specific prediction of coronary events.

Roleder and colleagues (2014) investigated the ability of a combined imaging catheter with NIRS plus IVUS to detect thin-cap fibroatheromas (TCFA) in individuals with stable CAD. Coronary segments with incomplete or poor quality NIRS, IVUS or optical coherence tomography (OCT) scans were excluded from the investigation (16 coronary segments), resulting in a final analysis of 76 coronary segments assessed in 60 individuals. OCT and combined NIRS-IVUS assessment were performed on identical coronary segments. OCT was used as the gold-standard reference to define TCFA (fibrous cap thickness < 65 micrometers [µm]). Plaque lipid content was estimated by NIRS (lipid core burden index [LCBI]). OCT-defined TCFA was present in 18 of 76 segments. IVUS revealed that OCT-defined TCFA were positively remodeled lesions with greater plaque burden and plaque volume, smaller cross sectional area, and longer plaque length. NIRS revealed greater LCBI per 2 mm segment ($LCBI_{2mm}$) (all p<0.001). Greatest accuracy for OCT-defined TCFA detection was achieved using $LCBI_{2mm}$ > 315 with remodeling index (RI) > 1.046 as a combined criterion value. The study did not prospectively validate the predictive value of this threshold. The authors concluded that OCT-defined TCFA are characterized by positive vessel remodeling, high plaque burden and greater lipid core burden as assessed by dual NIRS-IVUS imaging. Study limitations included a low number of subjects and the findings require validation with a larger prospective study.

A single center, prospective, observational sub-study by Oemrawsing and colleagues (2014) assessed the prognostic value of coronary NIRS imaging. Between April 2009 and January 2011, 203 individuals were enrolled prior to coronary angiography for stable angina pectoris (SAP) or acute coronary syndrome (ACS). The pre-specified primary endpoint was the composite of all-cause mortality, nonfatal ACS, stroke, and unplanned coronary revascularization. Median follow-up was 1 year, and follow-up was completed in all of the study participants. The cumulative incidence of the primary endpoint was 10.4% at 1 year. Cumulative 1-year rates in those with an LCBI at and above the median (43.0) versus those with LCBI values below the median were 16.7% versus 4.0% (adjusted hazard ratio 4.04; 95% CI, 1.33-12.29; p=0.01). Similar relationships were reported between LCBI and the primary endpoint in subjects with initial SAP and ACS. Study limitations included a small sample size and small corresponding number of events. This study did not investigate whether NIRS could be used to guide treatment in a way that improves health outcomes. The authors noted that their results were hypothesis generating and needed confirmation by larger trials.

In 2016, Madder and colleagues evaluated NIRS and IVUS findings in pre-existing stents. A comparison was made between NIRS findings in pre-existing stents in which an increased lipid signal possibly indicated neoatherosclerosis and NIRS findings in a control group of newly implanted stents. In the group of pre-existing stents IVUS was used to determine if neointimal tissue was present at the location of lipid-rich plaque (LRP) detected by NIRS. LCBI and maximum LCBI were measured within stented segments. Of 60 pre-existing stents, NIRS detected LRP in 33%. At the location of LRP, IVUS found no neointimal tissue in 35% of cases. NIRS findings in pre-existing stents were reported as indistinguishable from those of the newly implanted stents. The authors concluded that detection of LRP in a pre-existing stent by NIRS alone is not reliable evidence of neoatherosclerosis but that IVUS may provide insight into the potential source of the lipid signal in pre-existing stents. Study limitations included a small sample size and single-center design. Future studies are needed to determine the clinical relevance of NIRS-IVUS findings in pre-existing stents.

Danek and colleagues (2017) performed a retrospective registry study to find factors associated with MACE during the follow-up of individuals who had NIRS imaging. The primary endpoint was the incidence of MACE defined as the composite of cardiac death, acute coronary syndrome, unplanned coronary revascularization, and stroke. The researchers reviewed the records of 239 subjects who had NIRS between 2009 and 2011. They used a Multivariable Cox regression analysis to find variables independently associated with MACE. At a median follow-up of 5.4 years, MACE occurred in 100 subjects (41.8%), and 31 MACE events were related to the target vessel. The Kaplan-Meier estimated MACE rate was 37.5% at 5 years. Factors independently associated with MACE were diabetes, prior MI, percutaneous coronary intervention performed at index procedure, and non-target vessel LCBI. The adjusted HR for non-target vessel LCBI ≥ 77 was 14.05 (95% CI, 2.47 to 133.51; p=0.002). The 5-year cumulative incidence of MACE in the non-target LCBI group was 58% compared to 13.1% in the below threshold group. The researchers concluded that “non-target vessel lipid burden measured using NIRS appears to be a predictor of MACE during long-term follow-up.” Limitations of the study included the retrospective design, potential selection bias, and small sample size. This study did not investigate whether NIRS could be used to guide treatment in a way that improves health outcomes.

Schuurman and colleagues (2018) conducted a follow-up study to determine the long-term prognostic value of lipid-rich core-containing plaques evaluated by NIRS in individuals with CAD. The researchers combined the populations of two previous studies, the ATHEROREMO-NIRS (Oemrawsing, 2014) and the IBIS-3-NIRS (Netherlands trial register NTR2872). The primary endpoint was MACE, which included all-cause death, non-fatal acute coronary syndrome, and unplanned coronary revascularization during long-term follow-up. Between 2009 and 2013, 275 subjects underwent NIRS for acute coronary syndrome or stable angina. In January 2015, the researchers sent follow-up questionnaires to all living subjects to identify adverse events. If an event was identified, the researchers reviewed hospital discharge records. Hospital records were also investigated for subjects who did not return the questionnaire. At a median of 4.1 years follow-up, 79 subjects had MACE. For every $MaxLCBI_{4mm}$ increase of 100 units, there was a 19% increase in MACE (HR 1.19; 95% CI, 1.07 to 1.32; p=0.001). The researchers concluded that “LCBI values were significantly and independently associated with the incidence of adverse cardiac outcome in patients with CAD over 4 years of follow-up.” Limitations of the study included that the IBIS-3 population received rosuvastatin after the index procedure, there was a 10% loss to follow-up for the questionnaire, and the study had a small sample size. This study did not investigate whether NIRS could be used to guide treatment in a way that improves health outcomes.

In 2022, Omatsu and colleagues conducted a single-center prospective observational study aimed at correlating measurements of yellow plaque obtained by angioscopy with LCBI on NIRS. A total of 95 lesions in 44 subjects were analyzed both by NIRS-IVUS followed by coronary angioscopy. Angioscopy results were classified into 4 yellow color grades (0, white; 1, slight yellow; 2, yellow; and 3, intensive yellow) at a location of maximal LCBI on NIRS in each lesion. Angioscopic yellow color grade and LCBI were found to be positively correlated (95% CI 122.9–206.7; p<0.001). LCBI was significantly different among different yellow color grades determined by coronary angioscopy (ANOVA, p<0.001). The authors concluded that the qualitative angioscopic assessment was objectively validated by the quantitative NIRS evaluation. However, there were some limitations to the study. The sample size was small, limiting the statistical power and impairing the generalizability of the findings. There was also a potential for selection bias since individuals with small or tortuous vessels not suitable for angioscopic examination were excluded. The results of this single-center study might not be generalizable to other settings. This study showed a relationship between angioscopy and NIRS but did not show that NIRS can be used to improve health outcomes.

In 2023, Bass and colleagues performed a systematic review and meta-analysis of the ability of NIRS to identify vulnerable individuals and plaques. A total of seven observational studies with prospective follow-up involving 2948 subjects were included in the study. All studies were considered at high overall risk of bias based on the Cochrane Risk of Bias tool. In the pooled meta-analysis, identification of vulnerable plaques with NIRS was associated with 2.93 times increased odds of major adverse cardiovascular or

cerebrovascular events (95% CI, 1.82–4.73, I^2 = 58.7%). The authors concluded that NIRS is an effective tool for identifying vulnerable individuals and plaques. However, limitations include the observational nature of the studies, high risk of bias, relatively short-term follow-up (most of the included studies were less than 4 years), and the fact that the primary outcomes for each study included a range of LCBI value thresholds to determine the odds ratio. The authors acknowledged that a definitive optimal LCBI threshold for prediction of subsequent adverse events has yet to be determined.

Currently, there is insufficient evidence available in the peer-reviewed, published literature to determine the clinical utility of both near-infrared coronary imaging and near-infrared intravascular ultrasound imaging systems. Large, well-designed studies demonstrating the effectiveness of these technologies in improving clinical outcomes are needed.

Background/Overview

Coronary artery plaque is a deposit consisting of cholesterol-rich fat, calcium, and other substances found in the blood. As plaque accumulates on the artery wall, it reduces blood flow to the heart muscle and increases the risk of blood clots, which can lead to a heart attack. Vulnerable plaque is coronary artery plaque that is unstable and at high risk of rupturing, thereby causing a clinical cardiovascular event.

The LipiScan Coronary Imaging System is a device created to detect and evaluate coronary artery plaque. It works by inserting a fiberoptic laser into the artery and measuring the wavelengths that are reflected back from the artery wall. The light reflected back at different wavelengths is analyzed to detect the chemical composition of the coronary plaque. A color-coded map is produced by the device console showing the intensity and location of lipid core within plaques of interest in the artery. A lipid core burden index is also reported, which is a measure of the total amount of lipid core containing plaques of interest in the coronary artery.

The InfraReDx LipiScan IVUS Imaging System has a similar intended use and functionality as the LipiScan Coronary Imaging System and also includes intravascular ultrasound imaging of coronary intravascular pathology. A catheter accesses the coronary vasculature and the device output is an image of the artery wall, as an adjunct to coronary angiography.

In a similar manner to the InfraReDx Lipiscan IVUS, the TVC Imaging System uses integrated near-infrared and intravascular ultrasound technology to identify lipid-core plaque and intravascular pathology.

Definitions

Coronary arteries: Blood vessels supplying blood to the heart.

Fibroatheroma: Lipid-rich plaque suspected to be a type of vulnerable plaque.

Lipid: A small molecule soluble in non-polar solvents and insoluble in polar solvents such as water. In medicine, the term lipid commonly refers to triglycerides, fats, and sterols.

Lipid core plaque: an atherosclerotic lesion with a dense accumulation of extracellular lipids occupying an extensive but well-defined region of the intima known as the lipid core.

Lipid core burden index (LCBI): a measure of the total amount of lipid core containing plaque assessed by imaging of the coronary arteries.

Major Adverse Cardiovascular Event (MACE): an overlapping range of adverse cardiovascular-related events that can include atherosclerotic or other cardiovascular death, non-fatal myocardial infarction, acute coronary syndrome, coronary or peripheral revascularization, unstable angina, and stroke, as well as heart failure, re-infarction, non-fatal re-infarction, re-hospitalization for cardiovascular-related illness, repetition of percutaneous coronary intervention, and all-cause mortality.

Near-infrared coronary imaging: also referred to as near-infrared spectroscopy, is an imaging modality for the examination of coronary vessels that uses near-infrared light to measure diffuse reflectance signals to detect coronary lipid-rich lesions in individuals undergoing cardiac angiography.

Near-infrared intravascular ultrasound coronary imaging: an intracoronary catheter based imaging modality that combines near-infrared spectroscopy with intravascular ultrasound technology to quantify lipid accumulation measured as the Lipid Core Burden Index and associate it with other characteristics such as lumen size and plaque architecture.

Near-infrared spectroscopy (NIRS): also referred to as near-infrared coronary imaging, is an imaging modality for the examination of coronary vessels that uses near-infrared light to measure diffuse reflectance signals to detect coronary lipid-rich lesions in individuals undergoing cardiac angiography.

Neoatherosclerosis: A phenomenon in which lipid-rich plaques develop within pre-existing stents.

Thin-cap fibroatheromas (TCFA): atherosclerotic lesions composed of a lipid-rich core containing many lipid-laden macrophage foam cells derived from blood monocytes with a thin, friable cap.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:

CPT	
93799	Unlisted cardiovascular service or procedure [when specified as intravascular catheter-based coronary vessel or graft spectroscopy (eg, infrared) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report, each vessel]
ICD-10 Procedure	
8E023DZ	Near infrared spectroscopy of circulatory system, percutaneous approach
ICD-10 Diagnosis	
	All diagnoses

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Government Agency, Medical Society, and Other Authoritative Publications:

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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	08/11/2022	MPTAC review. Rationale and References sections updated.
Reviewed	08/12/2021	MPTAC review. Rationale, Definitions, References, and Index sections updated.
Reviewed	08/13/2020	MPTAC review. Rationale and References sections updated.
	12/31/2019	Updated Coding section with 01/01/2020 CPT changes; added 93799 replacing 0205T deleted 12/31/2019.
Reviewed	08/22/2019	MPTAC review. Rationale and References sections updated.
Reviewed	09/13/2018	MPTAC review. Rationale, References, and Index sections updated.
Reviewed	11/02/2017	MPTAC review. Description/Scope, Rationale, Background/Overview and References sections updated. The document header wording updated from “Current Effective Date” to “Publish Date.”
Reviewed	11/03/2016	MPTAC review. Rationale, Definition and References sections updated.
Reviewed	11/05/2015	MPTAC review. Rationale and Reference sections updated. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Description, Rationale and References sections updated.
Reviewed	11/14/2013	MPTAC review. Rationale and References sections updated.
Reviewed	11/08/2012	MPTAC review. Rationale, References and Index sections updated.
Reviewed	11/17/2011	MPTAC review. Description, Rationale, Background, and References updated.
Revised	11/18/2010	MPTAC review. Title, Description, Rationale, Background, References, and Index updated. Clarified existing position statement and added a position statement addressing near-infrared intravascular ultrasound coronary imaging.
Reviewed	11/19/2009	MPTAC review. Description, Rationale, Background, References, and Definitions sections updated. Updated Coding section with 01/01/2010 CPT changes.
New	11/20/2008	MPTAC review. Initial document development.
