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Clinical Policy Bulletin:
Near-Infrared (NIR) Spectroscopy

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Policy

Aetna considers near-infrared intravascular ultrasound coronary imaging (e.g., the InfraReDx LipiScan™ IVUS Imaging System) experimental and investigational for all indications.

See also CPB 0382 Intravascular Ultrasound, and CPB 0520 - Magnetic Resonance Imaging of the Cardiovascular System - Cardiac MRI.

Background

Many heart attacks occur when a fatty coronary plaque ruptures, forming dangerous blood clots. Lipid content within coronary artery plaques are believed to correlate with the probability of plaque rupture as well as with the rate of progression of atherosclerosis. Pathologic studies of patients who died from a heart attack have identified a large lipid core among features of coronary artery disease that were associated with plaque rupture and thrombosis.

García-García et al (2008) stated that detection of coronary vulnerable plaques in-vivo is essential for studying their natural history and assessing potential treatment modalities and, therefore, may have an important impact on the prevention of acute myocardial infarction and death. Research is currently underway to determine how coronary artery plaques that are prone to rupture can best be identified before they cause a heart attack and several invasive and non-invasive techniques have been developed to assess the vulnerable plaque. Most of the techniques show exciting features, but none have proven their value in an extensive in-vivo validation study and all have a lack of prospective data (Schaar et al, 2007).

Near-infrared (NIR) spectroscopy (e.g., LipiScan Coronary Imaging System) is a catheter-based technique that is currently under investigation for detecting coronary vulnerable plaques (Lau et al, 2004). It identifies the chemical composition of substances based on the differential absorption of light in the NIR spectrum by different molecules. An important feature of NIR light is that it can penetrate tissue and can
therefore identify a tissue despite the presence of blood between the detector and the target. This is an important advantage for imaging within the human coronary artery. The application of NIR spectroscopy to identify lipid deposition within coronary arteries has shown promising results in pre-clinical ex-vivo studies (Moreno et al, 2002; Gardner et al, 2008). A limitation of NIR spectroscopy is that it is influenced by flowing blood, and its lack of structural definition restricts its independent use in vulnerable plaque detection (Cassis, 1993; Lau et al, 2004).

Waxman et al (2009) reported their initial results from the SPECTACL (SPECTroscopic Assessment of Coronary Lipid) trial, a parallel first-in-human multi-center, phase II-III study designed to demonstrate the applicability of the lipid core-containing plaques (LCP) detection algorithm in living patients. Intra-coronary NIR spectroscopy was performed in patients undergoing percutaneous coronary intervention. Acquired spectra were blindly compared with autopsy NIR spectroscopy signals with multi-variate statistics. To meet the end point of spectral similarity, at least 2/3 of the scans were required to have greater than 80 % of spectra similar to the autopsy spectra. A total of 106 patients were enrolled. Spectroscopic data could not be obtained in 17 (16 %) patients due to technical limitations, leaving 89 patients for analysis. Spectra from 30 patients were un-blinded to test the calibration of the LCP detection algorithm. Of the remaining 59 blinded cases, after excluding 11 due to inadequate data, spectral similarity was demonstrated in 40 of 48 spectrally adequate scans (83 % success rate, 95 % confidence interval: 70 % to 93 %, median spectral similarity/pullback: 96 %, inter-quartile range 10 %). The LCP was detected in 58 % of 60 spectrally similar scans from both cohorts. There were no serious adverse events attributed to NIR spectroscopy. The authors concluded that the intra-vascular NIR spectroscopy system safely obtained spectral data in patients that were similar to those from autopsy specimens and that the results demonstrate the feasibility of invasive detection of coronary LCP with this novel system.

The LipiScan Coronary Imaging System (InfraReDx, Inc., Burlington, MA) uses intra-vascular NIR spectroscopy during coronary angiography to take images of lesions within coronary arteries in order to detect the lipid content within coronary artery plaques. It was cleared for marketing through the U.S. Food and Drug Administration (FDA) 510(k) process in April 2008. The system measures light delivered through the blood and reflected from the artery wall and produces a map of the artery's chemical composition. The reflected wavelengths vary depending on how much fat and other substances are in the plaque in the illuminated portion of the wall.

Although initial results from the SPECTACL trial showed that signals obtained in patients were spectrally similar to those obtained in autopsy-validated lesions, there is insufficient evidence of how NIR spectroscopy impacts the clinical outcomes of patients with coronary artery disease. Prospective studies demonstrating the effectiveness of NIR spectroscopy in improving clinical outcomes are needed.

In a review on imaging the vulnerable carotid artery plaque, Hermus and colleagues (2009) stated that imaging plays a key role in the selection of patients for carotid artery surgery. Indication for carotid endarterectomy or stenting is based on symptomatology and degree of stenosis as determined by angiography, duplex ultrasonography or computed tomographic angiography. Degree of stenosis has long time been assumed the most reliable predictor of stroke-risk in patients with carotid artery stenosis and accordingly, traditional imaging methods were focused on luminal stenosis. There is, however, growing evidence that other factors than degree of stenosis determine whether a carotid plaque will result in acute neurologic events or not. Various morphological characteristics and molecular processes have proven to be highly related to carotid plaque instability and symptomatology. As a result, the focus of imaging techniques in carotid artery disease is more and more shifting towards identification of the vulnerable plaque rather than the high-grade stenosis. In traditional imaging modalities, new insights of imaging beyond degree of stenosis have been explored and may be able to detect morphological characteristics of plaque vulnerability. In addition, advanced molecular imaging methods have been developed and are able to identify molecular and cellular processes in the vulnerable carotid artery plaque. It is clear that recent developments in carotid imaging are of great potential in the identification of the vulnerable carotid plaque. Near-infrared spectroscopy was not mentioned as a modality for imaging carotid plaques.
Yamaki et al (2011) examined whether the pre-operative level of deoxygenated hemoglobin (Hb) in the calf muscle during light-intensity exercise is useful for identifying patients at risk of developing deep vein thrombosis (DVT) after total knee or hip arthroplasty. A total of 68 patients undergoing total knee or total hip arthroplasty were enrolled. The Caprini risk assessment model was used to stratify patients into Caprini 5 to 6, Caprini 7 to 8, and Caprini greater than 8 groups. The pre-operative diameter of each venous segment was measured, and the time-averaged velocity (TAV) and time-averaged flow (TAF) of the popliteal vein (POPV) were assessed. Moreover, the prevalence of venous reflux in the POPV was evaluated pre-operatively. Near-infrared spectroscopy was used to measure the calf muscle Hb level. The calf venous blood filling index (FI-Hb) was calculated on standing, and then the calf venous ejection index (EI-Hb) was obtained after 1 tip-toe movement and the venous retention index (RI-Hb) after 10 tip-toe movements. All patients received low-dose unfractionated heparin pre-operatively and fondaparinux for post-operative thrombo-prophylaxis. Patients with arterial insufficiency, those who had pre-operative DVT, and those who developed bilateral DVT after surgery were excluded from the study. Four patients were excluded on the basis of the exclusion criteria. Among the 64 patients evaluated, 14 (21.9 %) were found to have DVT post-operatively. Among the risk factors for DVT, only the previous DVT was significantly predominant in patients who developed DVT (p = 0.001). The diameter of the popliteal vein was significantly smaller in patients who developed post-operative DVT than in those who did not (p = 0.001). Similarly, the diameter of the gastrocnemius vein was significantly larger in patients with post-operative DVT than in those without (p = 0.010). TAV and TAF were significantly increased in the popliteal vein in patients who developed post-operative DVT (p = 0.043, 0.046, respectively). Both groups showed a similar prevalence of reflux in the POPV (p = 0.841). The pre-operative NIR spectroscopy-derived RI was significantly increased in patients who developed DVT relative to those who did not (p = 0.004). The RI increased as the Caprini score progressed; however, there were no statistically significant differences between the 3 categories. Using ultrasound- and NIR spectroscopy-derived parameters of significance as a unit of analysis, an optimal RI cut-off point of greater than 2.3 showed the strongest ability to predict post-operative DVT, followed by a cut-off point greater than 0.25 cm for the diameter of the gastrocnemius vein (GV). The authors concluded that NIR spectroscopy-derived RI greater than 2.3 may be a promising parameter for identifying patients at risk of developing post-operative DVT despite pharmacologic DVT prophylaxis. A GV diameter of greater than 0.25 cm also seems to contribute to the development of post-operative DVT. The authors stated that these results might be helpful to physicians for deciding which patients require more intensive thrombo-prophylaxis.

Aries et al (2012) noted that there is uncertainty whether bilateral NIR spectroscopy can be used for monitoring of patients with acute stroke. In a pilot study, these researchers examined the NIR spectroscopy responsiveness to systemic and stroke-related changes over-night by assessing the effects of brief peripheral arterial oxygenation and mean arterial pressure alterations in the affected versus non-affected hemisphere in 9 patients with acute stroke. Significantly more NIR spectroscopy drops were registered in the affected compared with the non-affected hemisphere (477 drops versus 184, p < 0.001). In the affected hemispheres, nearly all peripheral arterial oxygenation drops (n = 128; 96 %) were detected by NIR spectroscopy; in the non-affected hemispheres only 23 % (n = 30; p = 0.17). Only a few mean arterial pressure drops were followed by a significant NIR spectroscopy drop. However, this was significantly different between both hemispheres (32 % versus 13 %, p = 0.01). The authors concluded that this pilot study found good responsiveness of NIR spectroscopy signal to systemic and stroke-related changes at the bedside; however, these findings require confirmation in a larger sample.

Cross et al (2009) examined if NIR could detect water concentration changes or edema formation in acute partial-thickness burn injuries. Adult burn patients within 72 hours post-injury, thermal etiology, partial-thickness burn depth, and less than 20 % total body surface area (TBSA) were included. Burn wounds were stratified into partial-thickness superficial or deep wounds based on histology and wound healing time. NIR devices were used to quantify edema in a burn and respective control sites. The sample
population consisted of superficial (n = 12) and deep (n = 5) partial-thickness burn injuries. The patients did not differ with respect to age (40 +/- 15 years), TBSA (5 +/- 4 %), and mean time for edema assessment (2 days). Water content increased 15 % in burned tissue compared with the respective control regions. There were no differences in water content at the control sites. At 48 hours, deep partial-thickness injuries showed a 23 % increase in water content compared with 18 % superficial partial-thickness burns. NIR could detect differences in water content or edema formation in partial-thickness burns and unburned healthy regions. The authors concluded that NIR holds promise as a non-invasive, portable clinical tool to quantify water content or edema in burn wounds.

In a pilot study, Weingarten et al (2010) examined the effectiveness of in-vivo diffuse NIR spectroscopy in predicting wound healing in diabetic foot ulcers. A total of 16 chronic diabetic wounds were followed and assessed for subsurface oxy-hemoglobin concentration using the NIR device. Weekly measurements were conducted until there was wound closure, limb amputation, or 20 completed visits without healing. Digital photography measured wound size, and the degree of wound contraction was compared with the NIR results. In the 16 patients followed, 7 wounds healed, 6 limbs were amputated, and 3 wounds remained opened after 20 visits. The initial values in subsurface hemoglobin concentration in all wounds were higher than the non-wound control sites. Healed wounds showed a consistent reduction of hemoglobin concentration several weeks before closure that approached control site values. In wounds that did not heal or resulted in amputation of the limb, the hemoglobin concentration remained elevated. In some cases, these non-healing wounds appeared to be improving clinically. A negative slope for the rate of change of hemoglobin concentration was indicative of healing across all wounds. The authors concluded that evaluation of wounds using NIR may provide an effective measurement of wound healing. These preliminary findings need to be validated by well-designed studies.

In June 2010, NIR-intravascular ultrasound (IVUS) coronary imaging (e.g., the InfraReDx LipiScan™ IVUS Imaging System [InfraReDx, Inc., Burlington, MA]) was cleared by the FDA for marketing via the 510(k) process. The system combines both NIR and IVUS technologies. According to the 510(k) summary the 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 utilizes 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). However, there is currently insufficient evidence to support the clinical value of near-infrared intravascular ultrasound imaging systems. Well designed studies are needed to ascertaining the effectiveness of near-infrared intravascular ultrasound coronary imaging in improving clinical outcomes.

Mallas et al (2011) stated that the use of intravascular imaging modalities for the detection and assessment of atherosclerotic plaque is becoming increasingly useful. Current clinical invasive modalities assess the presence of plaque using anatomical information and include IVUS and optical coherence tomography (OCT). However, such modalities cannot take into account underlying functional biological information, which can however be revealed with the use of molecular imaging. Consequently, intravascular molecular imaging is emerging as a powerful approach. These researchers have developed such a near-infrared fluorescence (NIRF) imaging system and showcased, in phantom as well as in-vivo (rabbit) experiments, its potential to successfully detect inflamed atherosclerotic plaques, using appropriate fluorescent probes. In this article, the authors discussed some limitations of the current system and suggested the combined use of the NIRF and IVUS imaging systems as a means for more accurate assessment of atherosclerotic plaque. They included some results and models that showcase the potential power of this kind of hybrid imaging.

Madder et al (2013) noted that recent studies emphasized the importance of direct intra-coronary imaging techniques that provide insights regarding not only lesion architecture but also plaque composition,
especially the presence or absence of lipid-core plaque (LCP). A recently introduced catheter provides simultaneous near-infrared spectroscopy (NIRS) spectral data co-registered with standard IVUS images in a single intra-coronary pullback. The case-series study illustrated the data obtained by this combined NIRS-IVUS device and highlighted its potential clinical applications.

Zynda et al (2013) examined if there was a relationship between angiographic lesion complexity and the extent of LCP identified by catheter-based NIRS. A total of 78 patients who underwent coronary angiography and target-vessel NIRS were selected from the Chemometric Observations of Lipid Core Containing Plaques of Interest in Native Coronary Arteries Registry, an industry sponsored registry to collate clinical findings in all patients undergoing NIRS evaluation. A lipid-core burden index (LCBI) was obtained from the scan of the proximal 50 mm of the target vessel. Three-vessel SYNTAX (total, tSYN) and target single-vessel (only NIRS-interrogated vessel) SYNTAX (1vSYN) scores were calculated and compared to LCBI. High LCBI was defined as (greater than 110) and was compared to tertile scores for 1vSYN score (low: 0 to 5, intermediate: 6 to 10, high: greater than or equal to11) and previously established tertiles for ISYN score (low: 0 to22, intermediate: 23 to 32, high: greater than or equal to 33). Patients had mean age of 63 years with prevalence of females (10 %), diabetes mellitus (28 %), hypertension (88 %), and smoking history (72 %); 1vSYN and ISYN scores correlated poorly with LCBI [(r (2) = 0.25; p = 0.02; n = 78) and (r(2) = 0.24; p = 0.04; n = 78), respectively]. Mean LCBI did not differ significantly across all tertiles of 1vSYN or tSYN scores. The authors concluded that angiographic SYNTAX score only weakly correlated with LCBI. It is of interest as well that high LCBI was also present in cases of low SYNTAX scores. The disparity between the degree of angiographic complexity and the amount of LCP supports postulated mechanisms of the adverse event propensity even in patients who demonstrate low angiographic complexity. They stated that future studies are needed to ascertain the clinical significance of high LCBI in patients with low-to-intermediate angiographic complexity and their potential for percutaneous coronary intervention-related complications.

Pu et al (2012) tested the hypothesis that NIRS combined with IVUS would provide novel information of human coronary plaque characterization. Greyscale-IVUS, virtual histology (VH)-IVUS, and NIRS were compared in 131 native lesions (66 vessels) that were interrogated during catheterization by all 3 modalities. Greyscale-IVUS detected attenuated and echo-lucent plaques correlated with NIRS-detected lipid-rich areas. Attenuated plaques contained the highest NIRS probability of lipid core, followed by echo-lucent plaques. By VH-IVUS, 93.5 % of attenuated plaques contained confluent necrotic core (NC) and were classified as VH-derived fibro-atheromas (FAs). Although 75.0 % of echo-lucent plaques were classified as VH-FAs, VH-NC was seen surrounding an echo-lucent zone, but not within any echo-lucent zone. Furthermore, echo-lucent zones themselves contained fibro-fatty and/or fibrous tissue. All calcified plaques with arc greater than 90° contained greater than 10 % VH-NC (range of 16.0 % to 41.2 %) and were classified as calcified VH-FAs, but only 58.5 % contained NIRS-detected lipid core. A positive relationship between VH-derived % NC and NIRS-derived LCBI was found in non-calcified plaques, but not in calcified plaques. The authors concluded that combining NIRS with IVUS contributes to the understanding of plaque characterization in-vivo. They stated that further studies are needed to examine if combining NIRS and IVUS will contribute to the assessment of high-risk plaques to predict outcomes in patients with coronary artery disease.

Nishikawa (2009) noted that non-invasive monitoring of regional cerebral oxygen saturation has been introduced in clinical settings for estimation of cerebral perfusion and cerebral blood flow (CBF). The author described several issues regarding the usefulness and clinical limitations associated with the use of NIRS or NIRS cerebral oximetry, as well as relevant information on basic principles of monitoring. The author concluded that there is currently insufficient clinical data concerning critical levels of measured variables that are essential for safe peri-operative management of patients susceptible for cerebral ischemia.
Near-Infrared (NIR) Spectroscopy

Transcranial Doppler for the identification of patients at risk for cerebral hyperperfusion syndrome (CHS) following carotid endarterectomy (CEA) can not be performed in 10 to 15% of patients because of the absence of a temporal bone window. Pennekamp and colleagues (2009) stated that NIRs may be of additional value in these patients. These researchers compared (i) the value of NIRs related to existing cerebral monitoring techniques in prediction of peri-operative cerebral ischemia, and (ii) the relation between NIRs and the occurrence of CHS. A systematic literature search relating to NIRs and CEA was conducted in PubMed and EMBASE databases. Those included were: (i) prospective studies; (ii) on NIRs for brain monitoring during CEA; (iii) including comparison of NIRs to any other intra-operative cerebral monitoring systems; and (iv) on either symptomatic or asymptomatic patients. These investigators identified a total of 16 studies, of which 14 focused on the prediction of intra-operative cerebral ischemia and shunt indication. Only 2 studies discussed the ability of NIRs in predicting CHS. Values obtained from NIRs correlated well with those from transcranial Doppler and electroencephalography indicating ischemia. However, a threshold for post-operative cerebral ischemia could not be determined. Neither could a threshold for selective shunting be determined since shunting criteria varied considerably across studies. The evidence suggesting that NIRs is useful in predicting CHS is modest. The authors concluded that NIRs seems a promising monitoring technique in patients undergoing CEA. Yet the evidence to define clear cut-off points for the presence of peri-operative cerebral ischemia or identification of patients at high risk of CHS is limited. They stated that a large prospective cohort study addressing these issues is urgently needed.

Mittnacht (2010) summarized recent developments and available data on the use of NIRs in children at risk for low perfusion. During states of low cardiac output, CBF and thus cerebral NIRs may be better preserved than in somatic tissue sites. Consequently, sites other than the frontal cerebral cortex have been investigated for a possible correlation with invasive measures of systemic perfusion and oxygenation (e.g., abdomen, flank, and muscle). The abdominal site seems preferable to the flank site NIRs (kidney region) application. In order to increase the sensitivity, specificity, and positive predictive value of tissue oximetry to detect systemic hypoperfusion, multi-site NIRs such as a combination of cerebral and somatic site NIRs has been suggested. Near-infrared spectroscopy has also been used to evaluate systemic perfusion in patients undergoing first-stage palliation for hypoplastic left heart syndrome. The authors concluded that despite shortcomings in the ability of NIRs technology to accurately reflect validated and directly measured parameters of systemic oxygen delivery and blood flow, NIRs can certainly assist in the detection of low-flow states (low cardiac output). They stated that large, randomized, prospective studies with well-defined outcome parameters are still missing and warranted in order to clearly define the role of NIRs in children at risk for low perfusion.

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The American College of Cardiology Foundation/American Heart Association clinical practice guideline on coronary artery bypass graft surgery (2011) stated that the effectiveness of routine use of intra-operative or early post-operative monitoring of cerebral oxygen saturation via NIRS to detect cerebral hypoperfusion in patients undergoing CABG is uncertain.

Aries et al (2012) noted that there is uncertainty whether bilateral NIRS can be used for monitoring of patients with acute stroke. In a pilot study, the NIRS responsiveness to systemic and stroke-related changes was studied over-night by assessing the effects of brief peripheral arterial oxygenation and mean arterial pressure alterations in the affected versus non-affected hemisphere in 9 patients with acute stroke. Significantly more NIRS drops were registered in the affected compared with the non-affected hemisphere (477 drops versus 184, p < 0.001). In the affected hemispheres, nearly all peripheral arterial oxygenation drops (n = 128; 96 %) were detected by NIRS; in the non-affected hemispheres only 23 % (n = 30; p = 0.17). Only a few mean arterial pressure drops were followed by a significant NIRS drop. This was however significantly different between both hemispheres (32 % versus 13 %, p = 0.01). The authors concluded that this pilot study found good responsiveness of NIRS signal to systemic and stroke-related changes at the bedside but requires confirmation in a larger sample.

Lipcsey et al (2012) stated that near infrared spectroscopy of the thenar eminence (NIRSth) is a non-invasive bedside method for assessing tissue oxygenation. The NIRS probe emits light with several wavelengths in the 700- to 850-nm interval and measures the reflected light mainly from a predefined depth. Complex physical models then allow the measurement of the relative concentrations of oxy and deoxyhemoglobin, and thus tissue saturation (StO2), as well as an approximation of the tissue hemoglobin, given as tissue hemoglobin index. These investigators reviewed the current knowledge of the application of NIRSth in anesthesia and intensive care. They performed an analytical and descriptive review of the literature using the terms "near-infrared spectroscopy" combined with "anesthesia," "anesthesiology," "intensive care," "critical care," "sepsis," "bleeding," "hemorrhage," "surgery," and "trauma" with particular focus on all NIRS studies involving measurement at the thenar eminence. They found that NIRSth has been applied as clinical research tool to perform both static and dynamic assessment of StO2. Specifically, a vascular occlusion test (VOT) with a pressure cuff can be used to provide a dynamic assessment of the tissue oxygenation response to ischemia. StO2 changes during such induced ischemia-reperfusion yield information on oxygen consumption and micro-vasculatory reactivity. Some evidence suggested that StO2 during VOT can detect fluid responsiveness during surgery. In hypovolemic shock, StO2 can help to predict outcome, but not in septic shock. In contrast, NIRs parameters during VOT increase the diagnostic and prognostic accuracy in both hypovolemic and septic shock. Minimal data are available on static or dynamic StO2 used to guide therapy. The authors concluded that although the available data are promising, further studies are necessary before NIRSth can become part of routine clinical practice.

Clark et al (2012) stated that brain injury remains a source of morbidity associated with congenital heart surgery. Intra-operative neuro-monitoring is used by many centers to help minimize neurologic injury and improve outcomes. Neuro-monitoring at the authors’ institution is performed using a combination of NIRS, transcranial Doppler ultrasound, electroencephalography (EEG), and somatosensory evoked potentials. Adverse or concerning parameters instigate attempts at corrective intervention. A review of the literature regarding neuro-monitoring studies in pediatric cardiac surgery showed that evidence is limited to demonstrate that intra-operative neuro-monitoring is associated with improved neurologic outcomes. The authors concluded that further clinical research is needed to assess the utility and cost-effectiveness of intra-operative neuro-monitoring for pediatric heart surgery.

Zheng et al (2013) noted that NIRS is used during cardiac surgery to monitor the adequacy of cerebral perfusion. These investigators evaluated available data for adult patients to determine (i) whether decrements in cerebral oximetry during cardiac surgery are associated with stroke, post-operative cognitive dysfunction (POCD), or delirium; and (ii) whether interventions aimed at correcting cerebral
oximetry decrements improve neurologic outcomes. They searched PubMed, Cochrane, and Embase databases from inception until January 31, 2012, without restriction on languages. Each article was examined for additional references. A publication was excluded if it did not include original data (e.g., review, commentary) or if it was not published as a full-length article in a peer-reviewed journal (e.g., abstract only). The identified abstracts were screened first, and full texts of eligible articles were reviewed independently by 2 investigators. For eligible publications, these researchers recorded the number of subjects, type of surgery, and criteria for diagnosis of neurologic end points. They identified 13 case reports, 27 observational studies, and 2 prospectively randomized intervention trials that met inclusion criteria. Case reports and 2 observational studies contained anecdotal evidence suggesting that regional cerebral oxygen saturation (rSO2) monitoring could be used to identify cardiopulmonary bypass cannula malposition. Six of 9 observational studies reported an association between acute rSO2 desaturation and POCD based on the Mini-Mental State Examination (n = 3 studies) or more detailed cognitive testing (n = 6 studies). Two retrospective studies reported a relationship between rSO2 desaturation and stroke or type I and II neurologic injury after surgery. The observational studies had many limitations, including small sample size, assessments only during the immediate post-operative period, and failure to perform risk adjustments. Two randomized studies evaluated the effectiveness of interventions for treating rSO2 desaturation during surgery, but adherence to the protocol was poor in one. In the other study, interventions for rSO2 desaturation were associated with less major organ injury and shorter intensive care unit hospitalization compared with non-intervention. The authors concluded that reductions in rSO2 during cardiac surgery may identify cardiopulmonary bypass cannula malposition, particularly during aortic surgery. Only low-level evidence links low rSO2 during cardiac surgery to post-operative neurologic complications, and data are insufficient to conclude that interventions to improve rSO2 desaturation prevent stroke or POCD.

Shellhaas et al (2013) evaluated the utility of amplitude-integrated EEG (aEEG) and rSO2 measured using NIRS for short-term outcome prediction in neonates with hypoxic ischemic encephalopathy (HIE) treated with therapeutic hypothermia. Neonates with HIE were monitored with dual-channel aEEG, bilateral cerebral NIRS, and systemic NIRS throughout cooling and rewarming. The short-term outcome measure was a composite of neurologic examination and brain MRI scores at 7 to 10 days. Multiple regression models were developed to assess NIRS and aEEG recorded during the 6 hours before re-warming and the 6-hour re-warming period as predictors of short-term outcome. A total of 21 infants, mean gestational age 38.8 ± 1.6 weeks, median 10-minute Apgar score 4 (range of 0 to 8), and mean initial pH 6.92 ± 0.19, were enrolled. Before re-warming, the most parsimonious model included 4 parameters (adjusted R(2) = 0.59; p = 0.006): lower values of systemic rSO2 variability (p = 0.004), aEEG bandwidth variability (p = 0.019), and mean aEEG upper margin (p = 0.006), combined with higher mean aEEG bandwidth (worse discontinuity; p = 0.013), predicted worse short-term outcome. During re-warming, lower systemic rSO2 variability (p = 0.007) and depressed aEEG lower margin (p = 0.034) were associated with worse outcome (model-adjusted R(2) = 0.49; p = 0.005). Cerebral NIRS data did not contribute to either model. The authors concluded that during day 3 of cooling and during re-warming, loss of physiologic variability (by systemic NIRS) and invariant, discontinuous aEEG patterns predicted poor short-term outcome in neonates with HIE. The authors concluded that these parameters, but not cerebral NIRS, may be useful to identify infants suitable for studies of adjuvant neuroprotective therapies or modification of the duration of cooling and/or re-warming. Moreover, they stated that “additional work is required before these findings could be applied directly at the bedside …. However, the value of cerebral NIRS monitoring remains uncertain in this patient population”.

Brugaletta and Sabate (2014) stated that atherosclerosis is the main cause of coronary artery disease (CAD), which is today the leading cause of death worldwide and will continue to be the first in the world in 2030. Vulnerable coronary plaques are usually characterized by a high content of necrotic core, a thin inflamed fibrous cap (intense accumulation of macrophages) and scarce presence of smooth muscle
cells. None of these characteristics can be estimated by coronary angiography, which on the contrary under-estimates the magnitude of atherosclerotic burden, particularly in earlier stage disease when positive vascular remodeling may allow “normal” lumen caliber despite substantial vascular wall plaque. The recognition of the ubiquity of substantial but non-flow limiting lesions that may be at high-risk for subsequent plaque rupture has resulted in a paradigm shift in thinking about the pathophysiology of CAD, with the focus no longer solely on the degree of arterial luminal narrowing. This growing need for more information about coronary atherosclerosis in order to identify patients and lesions at risk for complications during percutaneous coronary intervention (PCI) and for future adverse cardiac events has been the primary impetus for the development of novel intra-coronary imaging methods able to detect plaque composition, in particular presence of a necrotic core/lipid pool, such as IVUS virtual histology and NIRS.

Ranger et al (2014) stated that nurses play a crucial role in the evaluation and treatment of pain in the critically ill patient. This responsibility is all the more critical with this particular population because many may not be able to self-report their pain level and the typical behavioral signs of pain may be subtle or absent. According to recent recommendations, vital signs should not be used as primary indicators of pain but rather considered as a cue to begin further assessment. Other than vital signs, human brain reactivity to pain has been extensively studied with the use mainly of MRI and positron-emission tomography (PET). However, the use of these sophisticated methods may be unrealistic in the critically ill. Of interest to assessing these patients in a clinical setting is the non-invasive measurement of regional cerebral tissue oxygenation with NIRS technique. There are indications that NIRS is capable of detecting the cerebral hemodynamic changes associated with sensory stimuli, including pain. The objective of this review paper was to provide nurses with a better understanding of NIRS technology, including a review of the literature on functional studies that have used NIRS in critically ill populations, and how it could be used in both research and practice. The authors concluded that current NIRS techniques have well recognized limitations that must be considered carefully during the measurement and interpretation of signals. Thus, its clinical use is yet to be fully established. Nonetheless, cerebral NIRS technique as an approach to assess brain activity in response to pain should not be abandoned.

Neshat Vahid and Panisello (2014) noted that the decreasing post-operative mortality in patients with congenital heart disease (CHD) has enabled an increasing interest in preventing morbidity, especially from the central nervous system; and the use of NIRS in the intensive care unit has gained popularity over the last decade. This review aimed to ascertain its ability to affect outcome. Recent studies have started to incorporate cerebral NIRS in the assessment, evolution, and outcomes of surgical patients with CHD. These studies often represent small single-center high-risk cohorts who were evaluated in a retrospective or an observational manner. Nevertheless, new data are starting to indicate that NIRS may be helpful not only in the assessment of critical care parameters, such as cardiac output performance or likelihood of adverse events, but, most notably, in the long-term neurological outcome. The authors concluded that in addition to additional corroborative trials from different centers, a critical question that remains to be answered is whether targeting cerebral NIRS values, as part of goal-directed therapy protocols, can help to improve outcome overall.

Nielsen (2014) determined non-cardiac surgical procedures that provoke a reduction in rScO2 and evaluated whether an intra-operative reduction in rScO2 influences post-operative outcome. The PubMed and Embase database were searched from inception until April 30, 2013 and inclusion criteria were intra-operative NIRS determined rScO2 in adult patients undergoing non-cardiac surgery. The type of surgery and number of patients included were recorded; a total of 113 articles and evidence suggested that rScO2 is reduced during thoracic surgery involving single lung ventilation, major abdominal surgery, hip surgery, and laparoscopic surgery with the patient placed in anti-Tredelenburg’s position. Shoulder arthroscopy in the beach-chair position (BCP) and carotid endarterectomy with clamped internal carotid artery (ICA) also cause pronounced cerebral desaturation. A greater than 20 % reduction in rScO2 coincided with indices
of regional and global cerebral ischemia during carotid endarterectomy. Following thoracic surgery, major orthopedic surgery, and abdominal surgery the occurrence of post-operative cognitive dysfunction (POCD) might be related to intra-operative cerebral desaturation. The authors concluded that certain non-cardiac surgical procedures were associated with an increased risk for the occurrence of rScO2. Moreover, they stated that evidence for an association between cerebral desaturation and post-operative outcome parameters other than cognitive dysfunction needs to be established.

Pant and colleagues (2014) examined the risks of shoulder arthroscopy in the BCP as opposed to the lateral decubitus position. The challenge during general anesthesia, particularly with the patient in the BCP, has been to ascertain the lower limit of blood pressure auto-regulation, correctly measure mean arterial pressure, and adequately adjust parameters to maintain cerebral perfusion. There is increasing concern about the BCP and its association with intra-operative cerebral desaturation events (CDEs). Assessment of CDEs intra-operatively remains difficult; the emerging technology NIRS may provide non-invasive, inexpensive, and continuous assessment of cerebral perfusion, offering an “early warning” system before irreversible cerebral ischemia occurs. These investigators performed a systematic review to determine the incidence of intra-operative CDEs as measured by NIRS and whether it is possible to risk-stratify patients for intra-operative CDEs, specifically the degree of elevation in the BCP. Searching Medline, Embase, and the Cochrane Central Register of Controlled Trials from inception until December 30, 2013, these researchers found 9 studies (n = 339) that met the search criteria. The Level of Evidence was III or IV. The authors concluded that there remains a paucity of high-level data. The mean incidence of CDEs was 28.8%. They found a strong positive correlation between CDEs and degree of elevation in the BCP (p = 0.056). Emerging evidence (Level IV) suggested that it may be able to stratify patients on the basis of age, history of hypertension and stroke, body mass index, diabetes mellitus, obstructive sleep apnea, and height. The challenge remains, however, in defining the degree and duration of cerebral desaturation, as measured by NIRS, required to produce measureable neurocognitive decline post-operatively.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes not covered for indications listed in the CPB:

+ 0205T
0286T

Other CPT codes related to the CPB:

+ 92978
+ 92979

ICD-9 codes not covered for indications listed in the CPB (not all-inclusive):

414.00 - 424.07 Coronary atherosclerosis
430 - 432.9 Subarachnoid and intracranial hemorrhage [acute]
433.00 - 436 Occlusion and stenosis of pre-cerebral and cerebral arteries
435.0 - 435.9 Transient cerebral ischemia
436 Acute, but ill-defined, cerebrovascular disease
453.40 - 453.42 Acute venous embolism and thrombosis of deep vessels of lower extremity
671.30 - 671.44 Venous complications in pregnancy and the puerperium; deep phlebothrombosis
768.70 - 768.73  Hypoxic-ischemic encephalopathy (HIE)
852.00 â€“ 852.19  Subarachnoid, subdural, and extradural hemorrhage, following injury [acute]
890.0 - 894.2  Open wound of lower limb
959.01  Head injury, unspecified [acute]
997.02  Iatrogenic cerebrovascular infarction or hemorrhage [acute]
997.2  Peripheral vascular complications
V45.89  Other postprocedural status [neurosurgery]
V72.81  Preoperative cardiovascular examination
V72.82  Preoperative respiratory examination
V72.83  Other specified preoperative examination
V72.84  Preoperative examination, unspecified
V72.85  Other specified examination
V81.0  Special screening for ischemic heart disease
V81.2  Special screening for other and unspecified cardiovascular conditions
V82.89  Special screening for other specified conditions [evaluating risk of developing post -operative deep vein thrombosis]
The above policy is based on the following references: