Intraoperative Fluorescence Imaging Systems

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Policy
Intraoperative fluorescence imaging (SPY® Imaging) to evaluate vascular patency and tissue viability in coronary artery bypass graft surgery, solid organ transplant, and plastic, micro- and reconstructive surgery is considered inclusive to the primary procedure.

Considerations
When billed with procedures in which assessment is an integral component, intraoperative fluorescence imaging would edit as incidental.

Description of Procedure or Service
Coronary artery bypass graft (CABG) surgery is among the most frequently performed operations in the United States. Favorable patient outcomes are dependent on the success of the union and patency of the transplanted graft vessels. Approximately 4 to 12 percent of patients who undergo CABG surgery experience an occlusion in a transplanted graft vessel during the operation, placing them at increased risk for a heart attack post-operatively.

Currently, the gold standard for evaluating the patency of newly a transplanted coronary artery graft is via conventional x-ray angiography. However, cardiac angiography is not typically performed during course of a CABG, when it would be most ideal to detect a graft failure and would subsequently allow the surgeon to intervene before the patient leaves the operating room. The most widely used technique for intraoperative graft assessment is transit-time flowmetry (TTF). TTF uses the principles of ultrasound to detect coronary artery graft failures, and its ease of use intraoperatively is an advantage over coronary angiography.

Since intraoperative imaging has emerged as a practical approach for early assessment and identification of coronary artery graft failures, alternative technologies have been developed. The SPY® fluorescence imaging system (Novadaq Technologies, Inc.) is an intraoperative imaging technique that employs the fluorescence of indocyanine green (ICG) dye to visualize the patency of newly transplanted coronary artery grafts. Once the graft vessels have been
transplanted, the patient is injected with ICG, which quickly binds to plasma proteins. A low intensity laser illuminates the dye as it passes through the grafts via the patient’s bloodstream. The SPY fluorescence imaging system consists of a video camera and a laser light source. The camera, positioned above the patient’s heart, captures images of the fluorescent graft vessels and displays them on a monitor. If the images reveal a compromised graft, revisions can be performed while the patient’s chest is still open.

Other applications intraoperative fluorescence imaging include the evaluation of tissue perfusion used in plastic, micro- and reconstructive surgical procedures, such as flap skin perfusion in breast reconstruction, and tissue perfusion during organ transplant procedures.

**Rationale**

Balacumarswami et al. performed a prospective observational study to assess intraoperative graft patency in patients undergoing CABG by using an intraoperative fluorescence imaging system (IFI) and TTF. Between 2003 and 2004, the researchers assessed the intraoperative patency of 266 grafts in 100 CABG patients. The results showed that IFI and TTF confirmed adequate flow in 241 (91%) grafts in 75 patients (75%). Transient poor flow was detected with both IFI and TTF in 7 (2.6%) grafts in 7 (7%) patients. Both IFI and TTF confirmed persistent poor flow in 8 (3%) grafts in 8 (8%) patients that necessitated graft revision. However, in a further 10 (3.8%) grafts in 10 (10%) patients, TTF indicated persistently poor flows on the basis of mean graft flow and pulsatility index values, whereas IFI demonstrated satisfactory flow. These grafts were not revised. The researchers concluded that both IFI and TTF are useful to confirm intraoperative graft patency. However, the researchers added that the “lack of angiographic follow-up precludes understanding the fate of the grafts with initial or persistent poor flow” and that “long-term angiographic patency data would be invaluable in determining the natural history of these grafts.” Without appropriate controls in place, it is unclear if the graft revisions that were performed resulted in improved outcomes.

Between 2002 and 2005, Waseda et al. conducted a study to evaluate the intraoperative fluorescence imaging (IFI) system in the real-time assessment of graft patency during off-pump coronary artery bypass graft. Patients undergoing off-pump coronary artery bypass graft received IFI analysis, intraoperative TTF, and postoperative X-ray angiography. A total of 507 grafts in 137 patients received IFI analysis. Of all the IFI analyses, 379 (75%) grafts were visualized clearly up to the distal anastomosis. With regard to anastomosis location, anterior location was associated with a higher percentage of fully analyzable images (90%). More than 80% of images were analyzable, irrespective of graft type. Six grafts with acceptable TTF results were diagnosed with graft failure by IFI, which required on-site graft revision. All revised grafts' patency was confirmed by post-operative X-ray angiography. Conversely, 21 grafts with unsatisfactory TTF results demonstrated acceptable patency with IFI. Graft revision was considered unnecessary in these grafts, and 20 grafts (95%) were patent by post-operative
X-ray angiography. The authors noted that “graft patency assessment using IFI was not in perfect agreement with those of postoperative angiography. Nine grafts were found to be occluded at the time of postoperative angiography, but the IFI system revealed acceptable intraoperative graft patency.”

In 2004-2005, Desai et al. compared the diagnostic accuracy of intraoperative IFI and TTF. Patients undergoing isolated coronary artery bypass grafting with no contraindications for postoperative angiography were enrolled in the study. Patients were randomly assigned to be evaluated with either IFI and then TTF or TTF and then IFI. Patients underwent x-ray angiography on postoperative day 4. The primary end point of the trial was to determine the sensitivity and specificity of the two techniques versus reference standard x-ray angiography to detect graft occlusion or greater than 50% stenosis in the graft or perianastomotic area. A total of 106 patients were enrolled in this study and x-ray angiography was performed in 46 patients. In total, 139 grafts were reviewed with all three techniques and 12 grafts (8.2%) were demonstrated to have greater than 50% stenosis or occlusion by the reference standard. The sensitivity and specificity of IFI to detect greater than 50% stenosis or occlusion was 83.3% and 100%, respectively. The sensitivity and specificity of TTF to detect greater than 50% stenosis or occlusion was 25% and 98.4%, respectively. The researchers concluded that IFI provides better diagnostic accuracy for detecting clinically significant graft errors than does TTF. Although the results support the idea that IFI is more accurate in identifying grafts with significant stenosis following CABG, there is no evidence that it is more effective in identifying completely occluded grafts. Additionally, there is no evidence that intraoperative revision of grafts based on IFI assessment leads to improved patient outcomes.

Singh et al. sought to establish whether intraoperative graft assessment with criteria for graft revision would decrease the proportion of patients with one or more graft occlusions or stenoses or major adverse cardiac events one year after CABG. In a single-center, single-blinded, controlled clinical trial, patients were randomized to one of two groups: intraoperative graft patency assessment using IFI angiography and TTF. Patients underwent follow-up angiography at one year. Between September 2005 and August 2008, 156 patients undergoing isolated CABG were enrolled (imaging, n = 78; control, n = 78). Angiography was performed at one year in 107 patients (imaging, 55 patients/160 grafts; control, 52 patients/152 grafts). The proportion of patients with one or more graft occlusions was comparable in the imaging (30.9%) and control (28.9%) groups, as were other graft patency end points. The researchers concluded that routine intraoperative graft assessment is safe but does not lead to a marked reduction in graft occlusion one year post-CABG.

Clinical studies indicate that SPY imaging is safe and correlates well with TTF, but there is no evidence to demonstrate that it is superior to TTF. Comparisons of SPY imaging to postoperative coronary angiography are less known. Additionally, there is no evidence to show that intraoperative coronary artery graft revisions based on the results of SPY imaging leads to improved clinical outcomes, which presents questions as to the diagnostic utility of this technique.
No evidence-based guidelines were identified regarding the intraoperative assessment of the integrity and patency of coronary artery bypass grafts. Standardized approaches to the intraoperative evaluation of graft patency are lacking.

The clinical literature referencing intraoperative fluorescence imaging for use in plastic, micro- and reconstructive surgical procedures and tissue perfusion during organ transplants revealed small case studies and active clinical trials. Larger prospective studies are needed to determine the long term clinical outcomes that result from this technology.

References:

**Billing Coding/Physician Documentation Information**

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<th>Description</th>
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<tr>
<td>15860</td>
<td>Intravenous injection of agent (eg, fluorescein) to test vascular flow in flap or graft</td>
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<td>76499</td>
<td>Unlisted diagnostic radiographic procedure</td>
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<td>C9733</td>
<td>Nonophthalmic fluorescent vascular angiography</td>
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**Additional Policy Key Words**

N/A

**Policy Implementation/Update Information**

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<tr>
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<tr>
<td>1/1/16</td>
<td>No policy statement changes.</td>
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<tr>
<td>1/1/17</td>
<td>No policy statement changes. Changed “subset” to “incidental” in the considerations section.</td>
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