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Comments and Responses Regarding Draft Local Coverage Determination: CARDIOVASCULAR NUCLEAR MEDICINE

As an important part of Medicare Local Coverage Determination (LCD) development, National Government Services solicits comments from the provider community and from members of the public who may be affected by or interested in our LCDs. The purpose of the advice and comment process is to gain the expertise and experience of those commenting.

We would like to thank those who suggested changes to the draft Cardiovascular Nuclear Medicine LCD. The official notice period for the final LCD begins on May 15 2008, and the final determination will become effective on July 1, 2008.

Several comments were received on the subject of medical necessity of nuclear stress tests done pre-operatively.

Comment:
The New York Anesthesia CAC representative took issue with the limitation that states tests done as pre-op evaluation will be denied as not medically necessary. There is published evidence of the value of pre-op tests for cardiac, liver transplant, major vascular, peripheral vascular and thoracic surgeries, as well as major abdominal surgery. It is clear that surgery involving major fluid shifts and significant fluid and blood administration may be more problematic. Stratification of risk goes to the issues of: appropriate intraoperative and postoperative monitoring; appropriate anesthetic techniques and medications; and length and venue for postoperative care (ICU, “step down” units, PACU, etc.). However, stratification of risk also becomes important when discussing risks and benefits preoperatively as part of the consent process.
The representative is not talking about the use of cardiac imaging as a screening test, but in the context of diagnosis in patients with suspected coronary artery disease. He listed three sources as references.

The New Jersey Cardiology CAC representative commented that the draft LCD does not allow nuclear stress tests for pre-operative clearance for patients with multiple cardiac risk factors. Most cardiologists, however, would acknowledge that older patients with diabetes, vascular disease, hypertension and abnormal electrocardiograms should undergo a full pre-operative cardiac evaluation possibly including a nuclear stress test, especially if the proposed surgery would be considered "major." The ACC guidelines and many of the insurance company guidelines acknowledge this indication for nuclear stress testing. The Journal of the American College of Cardiology 2007

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guidelines on Perioperative Cardiovascular Evaluation and Care for Noncardiac Surgery: Executive Summary was submitted. Pages 1715-1717 address stress testing and the risk factors for which pre-operative cardiac testing would be indicated.

The NJ representative also forwarded comments from a NJ provider recommending testing in high risk patients and supporting the concept that risk should be assessed, and revascularization be considered in patients with ischemic perfusion defects –before noncardiac (elective) surgery is considered.

A New York Cardiology representative commented that higher risk patients and higher risk surgeries are indications for pre-operative stress testing for non-cardiac surgery. Multiple studies have shown that nuclear testing can separate low risk patients from high risk and that intervention in high risk patients can lower the morbidity rate to that of low risk patients. However, different criteria have been used in studies for defining high risk and therefore it is difficult to analyze outcomes. There are also multiple factors affecting interventions, PCI, CABG, besides noninvasive results, so it is difficult to judge outcomes from the stress testing alone.

Response:

We have reviewed the comments from the New York and New Jersey CAC Cardiology representatives, and the New York Anesthesia CAC representatives. We agree that stress testing for pre-operative evaluation prior to non-cardiac surgery is commonly performed within these medical communities. However, while studies support the use for assessment of risk, it is unclear whether this affects outcomes. The Coronary Artery Revascularization Prophylaxis (CARP) Trial concluded that coronary artery revascularization prior to elective vascular surgery does not alter outcomes (NEJM 2004; 351: 2795-2804). Furthermore, empiric treatment with beta blockers does have a positive effect on outcomes. Nonetheless, we have considered these comments and revised this LCD consistent with the Appropriateness Criteria outlined by the American College of Cardiology, American Society of Nuclear Cardiology and the American Heart Association. We will cover preoperative stress testing for patients with intermediate clinical predictors undergoing high risk procedures or with poor functional capacities.

Comment:
Other comments from the New Jersey CAC members:

- First pass studies are add-ons to other studies and would additional studies be allowed.
- Questioned if high risk patients with symptoms would be allowed.
- Indications on page 5 disagreed with ICD-9-CM listing on page 17 that includes abnormal EKG.

Response:
Dr. Deutsch responded:

- If repeat studies are warranted and documented, they would be paid.

- Clinical evidence is needed for high risk patients and documentation would be reviewed if sent in.
- The diagnosis codes do not stand by themselves, they must support the indications.