May 19, 2004

James D. Cross, MD
National Medical Director
Medical Policy and National Transplant
1301 McCormick Drive
Largo, Maryland 20774

Dear Dr. Cross:

As requested by Cheryl Pegus, MD this letter describes both the physician work and the clinical staff work for CPT codes 78478 (wall motion) and 78480 (ejection fraction. The American Society of Nuclear Cardiology (ASNC) welcomes Aetna's willingness to consider the facts presented to the Practice Expense Advisory Committee (PEAC) in January, 2002 and accepted by the Relative Value Update Committee (RUC) in April, 2002 and subsequently accepted by the Centers for Medicare and Medicaid Services (CMS) as announced in the Medicare Fee Schedule in November, 2002. In addition to the data submitted to the PEAC, RUC, and CMS, this letter describes in detail the physician work involved in both CPT code 78478 and CPT code 78480.

ASNC is a professional medical society of some 4,500 members which provides a variety of continuing medical education programs related to Nuclear Cardiology, develops standards and guidelines for training and practice, promotes accreditation and certification in this sub-specialty field, and is a voice for advocacy of nuclear cardiology.

CPT Code 78478 (wall motion)

Clinical Staff Work (Valued at 23 minutes by the PEAC)

CPT Long Descriptor:

Myocardial perfusion study with wall motion, qualitative or quantitative study (List separately in addition to code for primary procedure)

Pre-Service Clinical Labor Activities:

The nuclear medicine technologist (NMT) confirms the test order with the nuclear physician regarding technique and making any necessary changes based upon the patient's particular history and/or present condition.

Intra-Service Clinical Labor Activities:

Before beginning the procedure, the NMT reviews with the patient the indicated procedure. The NMT prepares the patient by replacing the ECG electrode to achieve better skin-electrode contact and to enhance computer acquisition quality.

The NMT positions the patient on the nuclear medicine imaging table, positions the camera, defines computer acquisition parameters and acquires the required diagnostic imaging set. The NMT monitors the patient during acquisition for possible motion, comfort, and clinical safety. The NMT inspects the imaging set to ensure accurate positioning and placement in addition to appropriate target to background organ isolation before the procedure is completed.

The room must be cleaned, removing and disposing any patient-specific materials in preparation for the next patient procedure.

The NMT dismisses the patient with after-care instructions and any additional education regarding radiation safety in the home environment. The dismissal instructions must include counseling on precautions to reduce radiation exposure to the general public, friends, and family members.

Post-Service Clinical Labor Activities:

The NMT then qualitatively and quantitatively processes all acquired imaging data for review by the interpreting physician. Any pertinent anomalies that occurred during the procedure are noted and reviewed later with the reading physician. The NMT displays the camera/computerized data for the physician's review including placing this on the physician's reading station, printing images, retrieving and displaying prior studies and obtaining archived data on other related procedures and/or laboratory results. The NMT archives each new patient data set.

Wall motion – Physician Work Component

The physician reviews the raw images of radiotracer uptake in the thorax, including the heart, for quality control determining if patient motion under the camera has occurred or if overlying structures obscure the cardiac image. For a single headed camera 32 images are reviewed or in the case of a double or triple headed camera, 64 images are reviewed. This review includes a) noncardiac structures that take up radiotracer including the stomach, large and small intestine and liver - each may overlap the left ventricle distorting or obscuring myocardial wall motion and b) soft tissue such as breast tissue and pectoral muscle that absorbs myocardial radioactivity resulting in a diminishment of observed myocardial radioactive uptake. If the patient moved under the camera and the nuclear technologist has applied a motion correction computer algorithm, the physician reviews the motion corrected images to determine if the algorithm was successful at reorienting the heart into a stable position. If patient motion has occurred but the technologist had not applied the motion correction software, the physician requests that the technologist reprocess the study with motion correction. These images are then reviewed.

Following completion of the quality control function, the physician reviews the images to evaluate wall motion of the 17 prespecified myocardial segments (ACC/AHA/ASNC guidelines) grading wall motion in each of these segments as normal, hypokinetic, akinetic or dyskinetic, or a gradation between these categories. In low count areas (e.g. areas of past myocardial infarction or severe ischemia) in which too few counts are present to evaluate wall motion on the initial images, the physician adjusts the contrast to increase count intensity and better characterize wall motion. The physician then correlates wall motion assessment with their interpretation of the myocardial perfusion performed separated by review of the static perfusion images. This correlation includes the evaluation of myocardium for infraction, stunning or hibernation as well as the potential that a perfusion defect is actually secondary to artifact rather than a lack of blood flow. The physician then generates a report of his findings.

CPT 78480 (ejection fraction)

Clinical Staff Work (Valued at 23 minutes by the PEAC)

PT Long Descriptor:

Myocardial perfusion study with ejection fraction (List separately in addition to code for primary procedure)

Pre-Service Clinical Labor Activities:

The nuclear medicine technologist (NMT) confirms the test order with the nuclear physician regarding technique and making any necessary changes based upon the patient's particular history and/or present condition.

Intra-Service Clinical Labor Activities:

Before beginning the procedure, the NMT reviews with the patient the indicated procedure. The NMT prepares the patient by replacing the ECG electrode to achieve better skin-electrode contact and to enhance computer acquisition quality.

The NMT positions the patient on the nuclear medicine imaging table, positions the camera, defines computer acquisition parameters and acquires the required diagnostic imaging set. The NMT monitors the patient during acquisition for possible motion, comfort, and clinical safety. The NMT inspects the imaging set to ensure accurate positioning and placement in addition to appropriate target to background organ isolation before the procedure is completed.

The room must be cleaned, removing and disposing any patient-specific materials in preparation for the next patient procedure.

The NMT dismisses the patient with after-care instructions and any additional education regarding radiation safety in the home environment. The dismissal instructions must

include counseling on precautions to reduce radiation exposure to the general public, friends, and family members.

Post-Service Clinical Labor Activities:

The NMT then qualitatively and quantitatively processes all acquired imaging data for review by the interpreting physician. Any pertinent anomalies that occurred during the procedure are noted and reviewed later with the reading physician. The NMT displays the camera/computerized data for the physician's review including placing this on the physician's reading station, printing images, retrieving and displaying prior studies and obtaining archived data on other related procedures and/or laboratory results. The NMT archives each new patient data set.

Ejection Fraction- Physician Work Component

The physician reviews the raw images of radiotracer uptake in the thorax, including the heart, for quality control determining if patient motion under the camera has occurred or if overlying structures obscure the cardiac image. For a single headed camera 32 images are reviewed or in the case of a double or triple headed camera, 64 images are reviewed. Gating is performed of these images to bin the myocardial images into 8 time frames ranging from the end of diastole to the end of systole ultimately providing an end-diastolic and end-systolic image. Automated contours are drawn of these latter two images by the computer program purchased to calculate ejection fraction (EF, the percent blood volume expelled with each cardiac cycle) using the calculation of the subtraction of the volume of the left ventricle on the end-systolic image from the volume of the end-diastolic image. The physician reviews the raw images observing for overlapping structures that would make the automated contours incorrect. The contours themselves are then reviewed. In addition, the raw images are reviewed to determine if patient motion has occurred which also would render calculated EF as inaccurate. If patient motion under the camera has occurred and the technologist has applied a motion correction computer algorithm, the physician reviews the motion corrected images to determine if the algorithm was successful at cardiac reorientation. If patient motion has occurred but the technologist had not applied the motion correction software, the physician requests that the technologist reprocess the study with motion correction. These images are then reviewed.

The histogram showing the percentage of accepted beats is reviewed by the physician. This preformed as an arrhythmia occurring during the gating period will result in differing RR intervals and, if this has occurred frequently in a particular patient, gating becomes inaccurate. If this has occurred, the EF is ignored as it is erroneous and is therefore not reported.

Upon completion of the quality control steps, the physician reviews the images to assess overall left ventricular myocardial motion performing a visual evaluation of ejection fraction. This visual EF is then compared with the calculated ejection fraction of the quantitative computer program. The calculated EF is either accepted and reported as such, or if the physician’s qualitative evaluation of EF differs from the calculated EF, the physician reports

either their estimation of EF or asks the nuclear technologist to reprocess the images to manually draw the contour of the left ventricle at end-systole and end-diastole to more accurately calculate EF. If this latter task is performed the physician rereviews the images to determine if the newly calculated EF is consistent with their visual evaluation.

Both 78478 and 78480 provide tremendous information to the referring physician. A number of studies have been published demonstrating the increased diagnostic accuracy of MPI when performed with wall motion evaluation (78478). (1-3 represent several.) In particular, the addition of wall motion information limits the number of false positive studies, which, if unrecognized, often lead to substantial downstream costs. As well, the induction of wall motion abnormalities post stress as observed by wall motion evaluation provides enhanced ability to diagnose severe, high grade coronary artery disease.(4,5) Recent information demonstrates that wall motion evaluation not only increases accuracy but provides independent prognostic information in the risk stratification of patients with and without known coronary artery disease.(6)

As well, ejection fraction obtained from gated SPECT (78480) has been demonstrated in multiple studies to provide additional incremental prognostic information above and beyond that obtained from only perfusion information (78465) (7-10).

In sum, the ability to perform wall motion evaluation and ejection fraction has greatly improved the ability of a comprehensive myocardial perfusion study to diagnose coronary artery disease and to predict prognosis. Each component, however, requires significant staff and physician time meriting compensation. This time investment has been recognized by the PEAC, RUC and CMS, to name just a few entities.

Lastly, it is important to point out that on March 23, 1999 the ASNC Board of Directors approved a position statement on ECG-Gating of Myocardial Perfusion SPECT Scintigrams. “When feasible it is useful to perform ECG-gating with myocardial perfusion SPECT acquisitions at rest and/or post-stress for quality control, improved diagnostic accuracy, and improved prognostic value by combined assessment of ventricular function and myocardial perfusion.”

I trust that the detailed information submitted in this letter will convince Aetna that further discussion of this matter with clinical experts is necessary. This misunderstanding between Aetna and cardiology has continued for far too long, and it is time to resolve the matter. ASNC joins with the American College of Cardiology in asking for a face-to-face meeting within the next thirty days with you and other medical directors at Aetna to discuss and resolve this issue.

Sincerely,

Robert C. Hendel, MD

Robert C. Hendel, MD
President

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3. Links JM, DePuey EG, Taillefer R, Becker LC. Attenuation correction and gating synergistically improve the diagnostic accuracy of myocardial perfusion SPECT. J Nucl Cardiol 2002; 9:183-7.
4. Sharir T, Bacher-Stier C, Dhar S, et al. Identification of severe and extensive coronary artery disease by postexercise regional wall motion abnormalities in Tc-99m sestamibi gated single-photon emission computed tomography. Am J Cardiol 2000; 86:1171-5.
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7. Sharir T, Germano G, Kavanagh PB, et al. Incremental prognostic value of post-stress left ventricular ejection fraction and volume by gated myocardial perfusion single photon emission computed tomography. Circulation 1999; 100:1035-42.
8. Sharir T, Germano G, Kang X, et al. Prediction of myocardial infarction versus cardiac death by gated myocardial perfusion SPECT: risk stratification by the amount of stress-induced ischemia and the poststress ejection fraction. J Nucl Med 2001;42:831-7.
9. Kroll D FW, McKendall GR, et al. Prognostic value of stress-gated Tc-99m sestamibi SPECT after acute myocardial infarction. Am J Cardiol 2001; 87:381-6
10. Thomas GS, Miyamoto MI, Morello AP, 3rd, et al. Technetium 99m sestamibi myocardial perfusion imaging predicts clinical outcome in the community outpatient setting. The Nuclear Utility in the Community (NUC) Study. J Am Coll Cardiol 2004;43:213-23.

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