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Attached: Medicare Advantage Medical Policy Bulletin, R-5

Medicare Advantage Medical Policy Bulletin

Section: Radiology Number: R-5

Topic: Cardiac Radionuclide Imaging

Effective Date: October 1, 2008 Issued Date: January 26, 2009

General Policy

The two types of radionuclide studies commonly used for cardiac evaluation are myocardial perfusion imaging and ventriculography. Myocardial perfusion imaging is used primarily for the evaluation of coronary artery disease. Ventriculography is sometimes referred to as multiple gated acquisition scanning (MUGA) and is primarily used to evaluate valvular disease and cardiomyopathies. Either type of study may be obtained at rest or with stress. Stress may be provided by exercise or with pharmacologic agents.

Myocardial perfusion imaging is a diagnostic procedure that evaluates blood flow to cardiac muscle using radionuclides. A gamma camera is used to record images in planar or tomographic (single photon emission computed tomography (SPECT)) projections. Use of dual radiopharmac euticals permits concurrent studies at rest and after stress, which are then compared and interpreted by a nuclear physician. Since the radiopharmaceutical accumulates in the myocardium in relation to blood flow, is chemic and infracted myocardium can be detected.

With the use of technetium based radiopharmaceuticals, the perfusion imaging may be linked to a equisition of "first pass" data to visualize blood flow through the right heart, lungs and left heart giving diagnostically useful information about cardiac chamber shunts, wall motion, cardiac

Indications and Limitations of Coverage

Myocardial Perfusion Imaging (Codes 78460-78465, 78478, 78480, 78491, 78492)

output, ejection fraction, left ventricular volume, shunt fraction and valvular regurgitation.

Patients with a high pretest probability of disease are usually not candidates for this study unless determination of the size and reversibility of a defect are required for clinical decision making. Patients whose diagnosis is in question benefit most from this study. Patients with a low pretest probability of disease are usually not studied except when a prior exercise stress test by treadmill ECG or echo is a presumed false positive. Stress myocardial perfusion imaging, preceded by satisfactory stress echocardiography (code 93350), is not medically necessary. Effective January 26, 2009, a provider cannot bill the member for the denied service unless the provider has given advance written notice, informing the member that the service may be deemed not medically necessary and providing an estimate of the cost. The member must agree in writing to assume financial responsibility, in advance of receiving the service. The signed agreement, in the form of a Pre-Service Denial Notice, should be maintained in the provider's records.

PET scars performed at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA approved radiopharmaceutical Rubidium 82 (Rb 82) are covered, provided the requirements below are met:

- The PET scan, whether at rest alone, or rest with stress, is performed in place of, but not in addition to, a single photon emission computed tomography (SPECT); or
- The PET scan whether at rest a lone or rest with stress is used following a SPECT that was found to be inconclusive. In these cases the
 PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the
 patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or
 discordant with a patient's other clinical data and must be documented in the patient's file.)

For a dditional coverage information on myocardial PET imaging, see Medicare Advantage Medical Policy Bulletin X-29.

Cardiac Blood Pool Imaging (Codes 78472, 78473, 78481, 78483, 78494, 78496)

These services are allowed for the evaluation of ventricular size, wall motion, stroke volume, and ejection fraction when this information is medically necessary to direct further evaluation and management of the cardiac condition.

Indications

- Acute myocardial infarction Myocardial perfusion imaging is not typically performed during the acute period of myocardial infarction, if the diagnosis is established by other means. In selected patients, imaging is appropriate in the assessment of:
 - Disease severity;
 - Risk assessment and/or prognosis;
 - Efficacy of acute reperfusion therapy;
 - Evidence of myocardial salvage;
 - Suspected infarction when the combination of history and other tests is not diagnostic.
- Unstable angina Myocardial perfusion imaging may be useful as an adjunct to other tests in the diagnosis or treatment of unstable angina only when the combination of history and other tests is not diagnostic. In selected patients, imaging is appropriate for:
 - Identification of ischemia in the distribution of a known lesion or in remote areas:
 - · Identification of the severity/extent of disease in patients with medically unstable angina or ongoing ischemia;
- Measurement of left ventricular function.
- Chronic ischemic heart disease The use of myocardial perfusion imaging is well established in the diagnosis and management of coronary artery disease (CAD) and is covered in these situations:
 - Diagnosis of CAD, especially in patients with atypical chest pain;
 - Evaluation of abnormal or suspected false positive stress ECG;
 - Evaluation of other symptoms suspicious for the diagnosis of CAD such as syncope and ventricular arrhythmia;
 - Assessment of myocardial viability after revascularization or medical management;
 - Planning PTCA to identify lesions causing ischemia, if unknown;
 - Evaluation of suspected or known CAD prior to high risk surgical procedures;

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- Identification of the presence, location, extent, and severity of myocardial ischemia;
- Assessment of drug therapy;
- Assessment of symptoms suggesting restenosis following PTCA;
- Assessment of symptoms suggesting ischemia following CABG;
- Follow up of symptomatic ischemic heart disease.
- Cardiomyopathy Cardiac blood pool imaging is covered for:
 - Diagnosis of hypertrophic cardiomyopathy and /or myocardial ischemia;
 - Differentiation of ischemic from non-ischemic cardiomyopathy.
- Congenital heart disease Echocardiography is the method of choice for evaluating patients with known or suspected congenital heart disease. Selected patients may benefit from myocardial perfusion imaging when assessing for:
 - Diagnosis of anomalies of the coronary circulation;
 - Kawasaki's disease.
- Post-transplant cardiac disease.
 - Assessment of coronary arteriopathy;
 - Evaluation for ventricular dysfunction with post-transplant rejection.

Studies performed for other indications will be considered not medically necessary. A provider cannot bill the member for the denied service.

Pharmacologic Stress Agents (Codes J0152, J0280, J0460, J1245, J1250)

For those patients who are unable to reach 75-100% of their age predicted maximum heart rate by physiologic exercise, vasodilation can be achieved with the use of either dipyridamole or adenosine. Use of pharmacologic agents in myocardial perfusion imaging (codes 78460-78465) is not a standard of care and is not medically necessary unless exercise is not possible. In some cases dobutamine may be used to effect stress through its inotropic effect.

- Dipyridamole is typically administered intravenously at 0.56 mg/Kg over a 4-minute period. The maximum dose should not exceed 60 mg. Since the dilation effect persists, after injection of the radiopharmaceutical, its effect is typically reversed with intravenous aminophylline, which must be available to reverse ischemia when it occurs. Dipyridamole is relatively contraindicated in patients with:
 - Known bronchospastic lung disease (asthma);
 - Systemic hypotension (systolic BP below 100 mm Hg.);
 - Acute myocardial infarction less than 48 hours old;
 - Unstable angina.
- Adenosine is administered intravenously at 140 mcg/Kg/min over 6 minutes (0.84mg/Kg.). The vasodilation effect is short lived.
 Adenosine is contraindicated in patients with:
 - Sec and or third degree AV block;
 - Sinus node disease, except those with a functioning pacemaker;
 - Known or suspected bronchoconstrictive or bronchospastic lung disease;
 - Known hypersenstivity to a denosine.
- Dobutamine is administered intravenously, starting at 5-10 mcg/Kg and titrated to reach the maximum heart rate for 2-5 minutes. The
 maximum dose is 50 mcg/Kg. Atropine may be added in appropriate doses IV. Dobutamine is contraindicated in patients with:
 - Idiopathic subsortic stenosis;
 - Acute myocardial infarction.

Physician Supervision Requirements

Myocardial perfusion and blood pool imaging require general supervision by a qualified physician licensed to administer radioactive materials. Cardiovascular stress procedures (codes 93015-93018) performed in conjunction with nuclear myocardial perfusion imaging studies are covered only when performed under the direct supervision of a qualified physician, who provides:

- Medical expertise required for performance of the test;
- Medical treatment for complications and side effects of the test;
- Medical services required as part of the test such as injections of medications;
- Medical expertise in the interpretation of the cardiovascular stress test component, some of which has to be provided during the test and before the patient is discharged from the testing site.

Reasons for Noncoverage

The following studies are considered investigational and will not be covered:

- Ambulatory radionuclide cardia c monitoring;
- Monoclonal anti-myosin imaging;
- Radionuclide imaging of thrombi;
- Radionuclide imaging of cardiac adrenergic nerves.

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and the reason for additional services is not justified by documentation.

Documentation Requirements

The patient's medical record must document the medical necessity of services performed for each date of service submitted on a claim, and documentation must be available on request.

The medical record must document when significant resting ECG abnormalities are present, or a medication is being used and cannot be withdrawn, that would interfere with interpretation of a stress ECG, resulting in the selection of myocardial perfusion study.

The rationale for selecting pharmacologic stress rather than exercise stress must be indicated in the medical record.

Claims submitted for stress tests performed as preoperative evaluation of patients without symptoms of CAD who are deemed to be at moderate risk must document one of the following at-risk conditions in the medical record: diabetes mellitus with complications, peripheral vascular disease, aortic ancurysm, or cerebrovascular disease.

NOTE:

This policy is designed to address medical guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances may warrant individual consideration, based on review of applicable medical records.

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| Procedure Codes | Procedure Codes | | | | | |
|-----------------|-----------------|-------|--------|-------|-------|--|
| 78460 | 78461 | 78464 | 7846.5 | 78472 | 78473 | |
| 78478 | 78480 | 78481 | 78483 | 78491 | 78492 | |
| 78494 | 78496 | A4641 | A9500 | A9501 | A9502 | |
| A9505 | A9526 | A9555 | | | | |

Coding Guidelines

Use code 78478 with codes 78460, 78461, 78464, 78465.

Use code 78480 with codes 78460, 78461, 78464, 78465.

Use code 78496 in conjunction with code 78472.

Codes indicating multiple studies (Codes 78461, 78465, 78473) must be submitted with a quantity of one regardless of whether a one or two day protocol was used.

Code 78461 includes code 78460.

The radiopharmac eutical must be submitted under the appropriate code. The number of doses for codes A9500 and A9502 or the number of millicuries for code A9505 must be indicated as the quantity billed. If the quantity billed is submitted inappropriately, the service will be rejected.

Code A9505 – Thallous chloride, T1-201 (aka Thallium) per mci. - This may also be used to determine myocardial viability. An initial does of 2-4 mCi is given at peak exercise, with immediate imaging followed by repeat imaging after redistribution 4-6 hours later. Reinjection and further delayed imaging may be obtained when myocardial viability is of interest.

Code A9500 - Technetium Tc-99m Sestimibi (aka Cardiolite) per dose or code A9502 - Technetium TC99m

Tetrofodmin (aka Myoview) per unit dose. - These agents clear more slowly, allowing imaging up to 4-6 hours postinjection. There is little or no redistribution. These agents are primarily used in the diagnosis of CAD, acute myocardial infarction, and unstable angina. In a one-day stress protocol, an initial does of 5-8 mci is given at peak exercise, and a second dose of 15-24 mci is given at rest approximately four hours later.

Code A4641 must not be used when a specific code exists. When it is necessary to use code A4641, the name and dosage of the imaging agent must be indicated on the claim.

Administration/injection of drugs and fluids is included in the procedure and not separately allowed.

References

Title XVIII of the Social Security Act, Section 1862(a)(7). This section excludes routine physical examinations. Title XVIII of the Social Security Act, Section 1862(a)(1)(A) states that no payment shall be made for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury.

Title XVIII of the Social Security Act, Section 1833(e) states that no payment shall be made to any provider for any claim that lacks the necessary information to process the claim.