Effective for dates of service on or after April 1, 2013, refer to:
https://www.bcbsal.org/providers/policies/careCore.cfm

Name of Policy:
Positron Emission Tomography (PET)-Cardiac Applications

Policy #: 134
Category: Radiology
Latest Review Date: February 2013
Policy Grade: A

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.
**Description of Procedure or Service:**

Positron emission tomography (PET) images biochemical reactions and physiological functions by measuring concentrations of radioactive chemicals that are partially metabolized in the body region of interest. Radiopharmaceuticals used for PET are generated in a cyclotron or nuclear generator and introduced into the body by intravenous injection or by respiration. A variety of tracers are used for PET scanning, including fluorine-18, rubidium-82, oxygen-15, nitrogen-13, and carbon-11. Because of their short half-life, tracers must be made locally. With the exception of fluorine and rubidium, all the tracers must be manufactured with an on-site cyclotron. The tracers may be coupled to a variety of physiologically active molecules. For example, fluorine-18 is often coupled with fluorodeoxyglucose as a means of detecting glucose metabolism, which in turn reflects the metabolic activity, and thus viability, of the target tissue.

The scanners used for PET imaging are very similar to those used for x-ray computed tomography, but PET requires more complicated technology and computerized mathematical models of physiologic functions and tracer kinetics for generation of images.

Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient permitting the simultaneous detection of the high-energy paired photons that are emitted at 180 degrees from one another.

PET using a gamma camera is a general term, which describes techniques in which a SPECT gamma camera is used to detect photons emitted from decaying positrons associated with the metabolism of radiolabeled FDG. It produces images similar to those produced by a PET scanner. This technique is also referred to as FDG-SPECT, metabolic SPECT, FDG-collimated SPECT, dual-heal coincidence SPECT (FDG-DHC-SPECT), or molecular coincidence detection (MCD).

FDG-collimated-SPECT screens out lower energy photons, thus only detecting the high-energy photons, however this approach decreases sensitivity and resolution compared to that associated with PET scanners. FDG-dual head coincidence-SPECT, operated in the “coincidence mode”, (the camera will only count those photons that are simultaneously detected at 180 degrees from one another) more closely resembles a PET scanner. However, the lower number of detectors in the SPECT approach compared to the full or partial ring of detectors used in Pet imaging will result in a relative loss of sensitivity and resolution. The clinical value of PET scans is related to both the ability to image the metabolic activity of target tissues and the resolution associated with the actual scanner.

In terms of cardiac applications, PET scanning has focused on two distinct clinical situations: 1) myocardial perfusion scanning as a technique of identifying perfusion defects, which in turn reflect coronary artery disease (CAD); and 2) assessment of myocardial viability in individuals with left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure.
effective for dates of service on or after April 1, 2013, refer to:
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Effective for dates of service on or after July 10, 2006 through March 31, 2013:
Metabolic Myocardial PET Imaging for cardiac involvement related to sarcoidosis meets
Blue Cross and Blue Shield of Alabama’s medical criteria for coverage.

Effective for dates of service on or after April 1, 2006 through March 31, 2013:
Metabolic Myocardial PET Imaging-Assessment of Myocardial Viability meets Blue Cross
and Blue Shield of Alabama’s medical criteria for coverage when ALL of the following criteria
are met:
- The patient has documented coronary artery disease; AND
- Coronary angiography indicates a correctable lesion; AND
- The nuclear stress test is discordant with the clinical data or is indeterminate; AND
- The patient is a revascularization candidate

Effective for dates of service from July 26, 2002 through March 31, 2006:
Metabolic Myocardial PET Imaging-Assessment of Myocardial Viability meets Blue Cross
and Blue Shield of Alabama’s medical criteria for coverage for dates of service on or after July
26, 2000 when:
- The patient has documented coronary artery disease; AND
- The left ventricular ejection fraction is equal to or less than 30%; AND
- The patient is being evaluated for cardiac revascularization/bypass or cardiac transplant

The metabolic PET imaging may be performed with a dedicated PET camera or using molecular
coincidence detection (i.e., FDG-SPECT or gamma cameras).

Effective for dates of service on or after April 1, 2006 through March 31, 2013:
Perfusion PET imaging meets Blue Cross and Blue Shield of Alabama’s medical criteria for
coverage when:
- Perfusion stress imaging is non-diagnostic or inconsistent with the clinical state and the
  patient is being considered for heart catheterization
  OR
- Used in place of SPECT imaging for severely obese patients or patients who have breast
  implants

The following criteria are met:
- The individual is considered to be at high coronary artery disease (CAD) risk. (For
definition of this please see Key Points)
  OR
- The individual has EKG abnormalities with high-risk of CAD.
AND

- **One** of the following EKG abnormalities or drug is present:
  - Left ventricular hypertrophy (LVH)
  - Resting ST segment depression
  - Currently on Digoxin

OR

- When used to assess myocardial ischemia with culprit disease when the following criteria is met:
  - Stenosis > 50% by angiogram when the culprit lesion is amenable to percutaneous coronary intervention (PCI)

**Cardiac PET imaging does not meet** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage when used for indications not described above or a routine screening tool in asymptomatic individuals, even if the patient is at high risk for coronary artery disease (CAD).

**Effective for dates of service from July 23, 2003 through March 31, 2006:**

**Perfusion PET imaging meets** Blue Cross and Blue Shield of Alabama’s medical criteria for coverage for dates of service on or after July 23, 2003 when:

- The individual presenting with chest pain or symptoms suggestive of heart disease has a low-risk pretest assessment of CAD and the results of the other test(s) (e.g., exercise electrocardiography) are inconclusive; **OR**
- The individual presenting with chest pain or symptoms suggestive of heart disease has an intermediate (25-75%) risk of CAD **AND** the procedure is performed in place of SPECT **OR** when the SPECT is inconclusive

The perfusion PET will only be considered for coverage when performed on a dedicated PET scanner. There is no data to support the use of FDG-SPECT in the evaluation of coronary perfusion defects.

*Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

**Key Points:**
As a molecular diagnostic imaging modality, PET can detect rates of biological activity, as contrasted with other imaging modalities such as x-ray films, computed tomography (CT) and magnetic resonance imaging (MRI), which depict the anatomical location of both normal and abnormal structures in the body.
There are essentially three separate activities involved in a PET scan:

1. Manufacture of the radiopharmaceutical, which may be manufactured on site, or manufactured at a regional delivery center with delivery to the institution performing PET.
2. Actual performance of the PET scan.
3. Interpretation of the results.

Molecular Coincidence Detection: Clinical evidence suggests that PET using a gamma camera is clinically useful in improving health outcomes as a technique to evaluate myocardial viability in patients with known coronary artery disease. There are no data to suggest that the combination of FDG-SPECT is effective in the evaluation of coronary perfusion defects.

PET has been thoroughly researched, as a technique to assess myocardial viability in candidates to determine if a coronary revascularization procedure is appropriate. For example, a patient with a severe stenosis identified by coronary angiography may not benefit from revascularization if the surrounding myocardium is non-viable. A fixed perfusion defect imaged on the SPECT scanning or stress thallium echocardiography may suggest non-viable myocardium. However, a PET scan has the capability to reveal metabolically active myocardium, suggesting areas of hibernating myocardium that would indeed benefit from revascularization.

The most common PET technique for this application consists of N-13 ammonia as a perfusion tracer and fluorine-18 fluorodeoxyglucose (FDG) as a metabolic marker of the glucose utilization in the myocardium. The pattern FDG uptake in the areas of hypoperfusion suggest viable but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular dysfunction after revascularization of hibernating myocardium as identified by the PET scan.

The American College of Cardiology (ACC) and the American Heart Association have jointly published guidelines for the clinical use of cardiac radionuclide imaging including PET scans. These guidelines report that myocardial viability is associated with positive and negative predictive accuracy of 85% in identifying regions that are associated with clinical improvement after revascularization.

SPECT scanning may also be used to assess myocardial viability. The initial myocardial uptake of thallium 201 reflects myocardial perfusion. Redistribution after prolonged periods can be used as a marker of myocardial viability. The initial protocols require redistribution imaging after 24-72 hours. While this technique was associated with a strong positive predictive value, there is a low negative predictive value, i.e., 40% of the patients without redistribution nevertheless showed clinical improvement after revascularization. The negative predictive value has improved with the practice of thallium re-injection. Twenty-four to seventy-two hours after initial mapping, patients receiving a re-injection of thallium can undergo redistribution imaging. The ACC/AHA guidelines note that PET imaging as a technique to identify viable myocardium is considered effective and acceptable.
The use of PET for myocardial perfusion imaging has been addressed in the peer-reviewed literature but not to the extent of which myocardial viability has been. In a patient with symptoms suggestive of coronary artery disease (CAD), a central clinical issue is to determine whether a coronary angiogram is necessary for further workup. A variety of non-invasive imaging studies including PET and SPECT scans have been investigated as a means of identifying reversible perfusion defects. By identifying these defects, patients can be identified who may benefit from further workup with an angiogram. The ACC/AHA guidelines on radionuclide imaging have summarized the studies comparing the two techniques.

There are several factors which can be used to identify an individual as being at high-risk for coronary artery disease. Risk factors for the development of heart disease include the following: hypertension, high cholesterol or lipid abnormalities, cigarette smoking or cocaine use or abuse, post-menopausal female, inactivity, obesity, current age (men older than 45, women older than 55) or diabetes. A family history of a first-degree relative developing heart disease or sudden cardiac death before the age of 60 may also be considered a risk factor.

There are specific EKG abnormalities or findings which may mask ischemic changes on the EKG. These include complete left bundle branch block, pre-excitation syndromes, left ventricular hypertrophy or the presence of resting or T-wave abnormalities related to pharmacologic therapies, ST segment depression, electronically paced ventricular rhythm, or Q waves.

Sarcoidosis is a systemic disorder of unknown etiology, which is characterized by its pathological hallmark, noncaseating granuloma. Cardiac involvement in patients with sarcoidosis is being increasingly recognized and is associated with poor prognosis. Clinical manifestations include advanced heart block, arrhythmias, and congestive heart failure. Cardiac involvement is clinically identified in only 5% of patients with sarcoidosis but as many as 25-78.8% on autopsy. Treatment with corticosteroids has long been the standard treatment, early and accurate diagnosis is important. In a study reported by Ishimaru et al, reported on 32 sarcoidosis patients and 30 control patients that underwent F-fluoro-2-deoxyglucose positron emission tomography (F-FDG PET). Their conclusions were that focally increased uptake of F-FDG indicates the presence of cardiac involvement of sarcoidosis and that F-FDG PET may have a novel role in the diagnosis and assessment of cardiac sarcoidosis. Focally enhanced accumulation of F-FDG suggests the presence of active inflammatory processes. Doughan and Williams also reported on the use of positive emission tomography as being very sensitive and findings seem to correlate with disease activity in cardiac imaging for sarcoidosis. Doughan and Williams recommend screening with 18F-FDG PET or contrast enhanced MRI (CMR) for cardiac sarcoidosis when the disease is suspected.

2010-2011 Update

Literature was reviewed through April 2011. No new publications were identified that compared SPECT to PET for cardiac conditions. Herzog, et al and Schindler, et al published two articles which describe the use of PET imaging to quantify both myocardial blood flow and flow reserve. However, as noted in an accompanying editorial, larger prospective clinical trials are needed to understand the clinical utility. Thus, the policy statements by Beanlands et al are unchanged.
**Key Words:**
PET, FDG-PET, F-18, positron emission, molecular coincidence detection (MCD), metabolic SPECT, FDG-collimated SPECT, dual-head-coincidence SPECT, FDG-DHC-SPECT, sarcoidosis

**Approved by Governing Bodies:**
The U.S. Food and Drug Administration (FDA) has approved the scanner and imaging hardware for PET as being substantially equivalent to x-ray computed tomography (CT). The FDA requires PET radiotracers to be approved through a new drug approval (NDA) process. Because PET radiotracers have an extremely short half-life, they must be produced in the clinical setting; the FDA also intends to regulate drug manufacturing processes in PET facilities. In 1991, the FDA approved the use of Rubidium 82 (Rb 82) in patients for the detection of coronary artery disease. The FDA has approved N-13 Ammonia for cardiac perfusion.

**Benefit Application:**
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational. Will be reviewed for medical necessity.

**Pre-certification requirements:**
**Effective for dates of service on or after November 1, 2007:**
A pre-cert is required when ordered by a provider in a Blue Cross and Blue Shield of Alabama’s Preferred or Participating Network for a patient covered by Blue Cross and Blue Shield of Alabama who will receive outpatient imaging services(s) from a Preferred Medical Doctor (PMD) or Preferred Radiology Participating (PRP) provider.

**Exceptions to the Alabama PMD and PRP pre-certification requirement:** NASCO, Wal-Mart, Blue Advantage, Flowers Foods, Inc., FEP.

In addition to the above Blue Cross and Blue Shield of Alabama PMD/PRP Network requirement, some self-insured national account groups may require pre-certification for all MRIs effective for dates of service on or after January 1, 2009. Please confirm during your benefit verification process if a pre-certification is required.

**Current Coding:**
CPT codes: 78459  Myocardial imaging, positron emission tomography (PET), metabolic evaluation 78491  Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress
Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress

HCPCS:

A9526  Nitrogen n-13 ammonia, diagnostic, per study dose, up to 40 millicuries
A9555  Rubidium RB-82, diagnostic, per study dose, up to 60 millicuries

(Effective January 1, 2006)

G0235  PET imaging, any site, not otherwise specified (Effective January 1, 2006)

Previous Coding:

G0030  PET myocardial perfusion imaging, (following previous PET, G0030-G0047); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0031  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0032  PET myocardial perfusion imaging, (following rest SPECT, 78464); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0033  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0034  PET myocardial perfusion imaging, (following stress SPECT, 78465); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0035  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0036  PET myocardial perfusion imaging, (following coronary angiography, 93510-93529); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0037  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0038  PET myocardial perfusion imaging, (following stress planar myocardial perfusion, 78460); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0039  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0040  PET myocardial perfusion imaging, (following stress echocardiogram, 93350); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0041  ;multiple studies, rest or stress (exercise and/or pharmacologic)
(Deleted effective January 1, 2006)
G0042  PET myocardial perfusion imaging, (following stress nuclear ventriculogram, 78481 or 78483); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)
G0043; multiple studies, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)

G0044 PET myocardial perfusion imaging (following rest ECG, 93000); single study rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)

G0045; multiple studies, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)

G0046 PET myocardial perfusion imaging, (following stress ECG, 93015); single study, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)

G0047; multiple studies, rest or stress (exercise and/or pharmacologic) (Deleted effective January 1, 2006)

G0230 PET imaging; metabolic assessment for myocardial viability following inconclusive SPECT study (Deleted effective January 1, 2006)

Q3000 Supply radiopharmaceutical diagnostic imaging agent, Rubidium RB-82, per dose (Deleted effective January 1, 2006)

References:
6. Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (DHHS). Expanded coverage of positron emission tomography (PET) scans and related claims processing requirements—for thyroid cancer and perfusion of the heart using ammonia N-13, June 20, 2003, Transmittal AB-03-092.


Policy History:
Metabolic PET, Medical Review Committee, July 2000
Medical Policy Group, July 2003
Cardiac Perfusion PET, Medical Review Committee, July 2003
Medical Policy Administration Committee, March 2004
Available for comment March 22-May 5, 2004
Medical Policy Group, March 2006 (3)
Medical Policy Administration Committee, April 2006
Available for comment April 3-May 17, 2006
Medical Policy Group, July 2006 (1)
Medical Policy Administration Committee, July 2006
Available for comment July 18-August 31, 2006
Medical Policy Group, December 2008 (2)
Medical Policy Group, April 2011 (3): Updated Key Points and References
Medical Policy Group, February 2013 (2) Updated policy with link to CareCore National©
medical policies effective April 1, 2013
Medical Policy Administration Committee, March 2013
Available for comment February 15 through March 31, 2013
Medical Policy Group, November 2013 (2): Updated link to CareCore National©

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member’s plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield’s administration of plan contracts.