Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 7/1/12**
(See policy history boxes for previous effective dates)

Title: Positron Emission Tomography (PET Scans) for Cardiac Applications

Description / Background

Positron emission tomography (PET) scans are based on the use of positron-emitting radionuclide tracers, which simultaneously emit two high-energy photons in opposite directions. These photons can be simultaneously detected (referred to as coincidence detection) by a PET scanner, consisting of multiple stationary detectors that encircle the thorax. Compared to single photon emission computed tomography (SPECT) scans, coincidence detection offers greater spatial resolution.

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 (FDG) as a means of detecting glucose metabolism, which in turn reflects the metabolic activity, and thus viability, of the target tissue.

Cardiac PET scanning initially 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)
2. Assessment of myocardial viability in patients with left ventricular (LV) dysfunction as a technique to determine candidacy for a revascularization procedure.

A third potential clinical use related to CAD is being evaluated, use of cardiac PET in the measurement of myocardial blood flow and blood flow reserve. Cardiac PET is also being studied in the evaluation of coronary artery inflammation.

Regulatory Status:

The U.S. Food and Drug Administration (FDA) issued a Federal Register notice on March 10, 2000, summarizing the regulatory history of PET radiotracers and highlighting its decisions on safety and effectiveness uses of certain PET radiotracers. With regard to PET radiotracers used for cardiac indications, the FDA has approved the following uses:

- ^{18}F-FDG for evaluation of myocardial hibernation. The FDA concluded that "a 10-mCi dose (for adults) of FDG F 18 injection produced under conditions specified in an approved application can be found to be safe and effective in PET imaging of patients with CAD and left ventricular dysfunction, when used together with myocardial perfusion imaging, for the identification of left ventricular myocardium with residual glucose metabolism and reversible loss of systolic function."
- ^{13}N-ammonia for evaluation of myocardial blood flow/perfusion**.** The FDA concluded that "a 10-mCi dose (for adults) of ammonia N 13 injection produced under conditions specified in an approved application can be found to be safe and effective in PET imaging of the myocardium under rest or pharmacological stress conditions to evaluate myocardial perfusion in patients with suspected or existing CAD."
- In addition, 82-rubidium chloride injection for evaluation of myocardial perfusion (NDA-19-414) was previously approved in 1989 "for assessing regional myocardial perfusion in the diagnosis and localization of myocardial infarction."

Furthermore, the *Federal Register* notice stipulates that due to safety concerns stemming from various manufacturing practices, "the agency cannot conclude that these PET drugs are generally recognized as safe and effective for the above-noted indications and therefore needs to review information on how each drug product is formulated and produced at each manufacturing site. Because these PET drugs are not generally recognized as safe and effective, they are new drugs for which approved NDA's [New Drug Application] or ANDA's [Abbreviated New Drug Application] are required for marketing."

A draft guidance document for Current Good Manufacturing Practice (CGMP) requirements was issued on April 1, 2002; although, as of October 2003, regulatory procedures had not yet been finalized. Manufacturers are not required to submit NDAs or ANDAs for a period of 4 years after enactment of the FDA Modernization Act (FDAMA) or "2 years after the date that the agency adopts special approval procedures and CGMP requirements for PET drugs, whichever is longer." Nevertheless, many PET facilities operate without specific FDA approval. An FDA website page includes various PET-related documents: Available online at: http://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm085783.htm . Last accessed September 2011.

Therefore, as the new regulations are implemented and the FDA reviews the safety and effectiveness of radiotracers, implementation of Plan policies regarding PET scans may need to focus on the following:

- Whether or not the individual PET radiotracer manufacturer facility meets the current good manufacturing practices (CGMP) for PET scanning as established by FDA
- Whether or not the radiotracer is FDA-approved and is being used for a specific indication that has been FDA-approved
- Whether or not the clinical indication for individual patients meets medical necessity criteria.

Medical Policy Statement

The safety and effectiveness of cardiac PET scanning have been established. It may be considered a useful diagnostic option for patients meeting patient selection criteria.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

Cardiac PET scanning is established for the following indications:

- Assessing myocardial perfusion for diagnosing coronary artery disease in patients with indeterminate SPECT scan
- For patients for whom SPECT could be reasonably expected to be suboptimal in quality on the basis of body habitus. (e.g., BMI > 40), large breasts, breast implants, mastectomy, chest wall deformity, pleural or pericardial effusion)
- For assessing the myocardial viability in patients with severe left ventricular dysfunction as a technique to determine candidacy for a revascularization procedure
- For diagnosing cardiac sarcoidosis in patients who are unable to undergo magnetic resonance imaging (MRI) scanning. Examples of patients who are unable to undergo MRI include, but are not limited to, patients with pacemakers, automatic implanted cardioverter-defibrillators (AICDs), or other metal implants.

CPT / HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

78459 78491 78492

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

This policy was initially developed with a literature review in 1997. The policy has been updated regularly with subsequent literature reviews using MEDLINE. Most recently, the literature was searched from January 2009 to January 2011. Following is a summary of the literature to date:

In 2003, the American College of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. (2) Cardiac applications of positron emission tomography (PET) scanning were included in these guidelines. The ACC/AHA guidelines categorize specific indications for PET scanning to Class I, Class IIa, Class IIb, or Class III. Class I is defined as conditions for which there is evidence and/or

general agreement that a given procedure or treatment is useful and effective. Class IIa is defined as conditions for which there is conflicting evidence or a divergence of opinion, but the weight of evidence/opinion is in favor of usefulness/efficacy. Class IIb is similar to Class II except that the usefulness/efficacy is less well-established by evidence/opinion. The medically necessary indications for PET myocardial perfusion studies in this policy are consistent with Class I and Class IIa indications in the ACC guidelines.

Myocardial Viability

PET has perhaps been most thoroughly researched as a technique to assess myocardial viability to determine candidacy for a coronary revascularization procedure. 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, as imaged on single photon emission computed tomography (SPECT) scanning or stress thallium echocardiography, may suggest nonviable myocardium. However, a PET scan may 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 glucose utilization. A pattern FDG uptake in areas of hypoperfusion (referred to as FDG/blood flow mismatch) suggests viable, but hibernating myocardium. The ultimate clinical validation of this diagnostic test is the percentage of patients who experience improvement in left ventricular (LV) dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

SPECT scanning may also be used to assess myocardial viability. While initial myocardial uptake of thallium-201 reflects myocardial perfusion, redistribution after prolonged periods can be used as a marker of myocardial viability. Initial protocols required redistribution imaging after 24 to 72 hours. While this technique was associated with a strong positive predictive value (PPV), there was a low negative predictive value (NPV); i.e., 40% of patients without redistribution nevertheless showed clinical improvement after revascularization. The NPV has improved with the practice of thallium reinjection. Twenty-four to 72 hours after initial imaging, patients receive a reinjection of thallium and undergo redistribution imaging.

The ACC/AHA guidelines conclude that PET imaging “appears to have slightly better overall accuracy for predicting recovery of regional function after revascularization in patients with left ventricular (LV) dysfunction than single photon techniques (i.e., SPECT scans).” However, the ACC guidelines indicate that either PET or SPECT scans are Class I indications for predicting improvement in regional and global LV function and natural history after revascularization and thus do not indicate a clear preference for either PET or SPECT scans in this situation.

Further supporting the equivalency of these 2 testing modalities, Siebelink and colleagues performed a prospective randomized study comparing management decisions and outcomes based on either PET imaging or SPECT imaging in 103 patients with chronic coronary artery disease (CAD) and LV dysfunction who were being evaluated for myocardial viability. (3) Management decisions included drug therapy or revascularization with either angioplasty or coronary artery bypass grafting. This study is unique in that the diagnostic performance of the two studies was tied to the actual patient outcomes. No difference in patient management or cardiac event-free survival was demonstrated between management based on the two imaging techniques. The authors concluded that either technique could be used for management of patients considered for revascularization with suspicion of jeopardized myocardium.

Myocardial Perfusion

In a patient with symptoms suggestive of CAD, an important clinical decision point is to determine whether invasive coronary angiography is necessary. A variety of noninvasive imaging tests, including PET (using rubidium-82) and SPECT scans have been investigated as a means of identifying reversible perfusion defects, which may reflect CAD and thus identify patients appropriately referred for angiography. The following table summarizes the ACC guidelines for myocardial reperfusion for both SPECT and PET scans in patients with an intermediate risk of CAD. (2)

Indication	**SPECT Class**	**PET Class**
Identify extent, severity, and location of ischemia (SPECT protocols vary according to whether patient can exercise)	I	IIA
Repeat test after 3–5 years after revascularization in selected high-risk asymptomatic patients (SPECT protocols vary according to whether patients can exercise)	IIa	
As initial test in patients who are considered to be at high risk (i.e., patients with diabetes or those with a more than 20% 10-year risk of a coronary disease event) (SPECT protocols vary according to whether patients can exercise)	IIa	
Myocardial perfusion PET when prior SPECT study has been found to be equivocal for diagnostic or risk stratification purposes.	NA	I

The sensitivity and specificity of PET may be slightly better than SPECT. However, their diagnostic utilities are similar in terms of altering disease risk in a manner affecting subsequent decision making among patients with intermediate pretest probability of CAD. For example, a patient with a 50% pretest probability of CAD would have a 9% post-test probability of CAD following a negative PET scan compared to 13% after a negative SPECT. In either case, further testing would not likely be pursued.

Test Characteristics for PET and SPECT scanning based on the Canadian Joint Position Statement (4)

	PET	**SPECT**
Sensitivity	0.91	0.88
Specificity	0.89	0.77
Estimated likelihood ratio positive	8.27	3.83
Estimated likelihood ratio negative	0.10	0.16

Post-Test Probability				
Pretest Probability	**Positive Test**		**Negative Test**	
	PET	**SPECT**	**PET**	**SPECT**
30%	78%	62%	4%	6%
50%	89%	79%	9%	13%

70%	95%	90%	19%	27%

- Estimated positive likelihood ratio = Sensitivity/(1-Specificity)
- Estimated negative likelihood ratio = (1-Sensitivity)/Specificity)
- Post-test probability = post-test odds/(post-test odds + 1)
- Post-test odds = pre-test odds x Likelihood Ratio

Another consideration is that there are fewer indeterminate results with PET than SPECT. A retrospective study by Bateman et al. (5) matched 112 SPECT and 112 PET studies by gender, body mass index (BMI), and presence and extent of CAD and were compared for diagnostic accuracy and degree of interpretative certainty (age 65 years; 52% male; mean BMI: 32 kg/m2; 76% with CAD diagnosed on angiography). Eighteen of 112 (16%) SPECT studies were classified as indeterminate compared to 4 of 112 (4%) PET studies. Liver and bowel uptake were believed to affect 6 of 112 (5%) PET studies, compared to 46 of 112 (41%) SPECT studies. In obese patients (BMI>30), the accuracy of SPECT was 67% versus 85% for PET; accuracy in non-obese patients was reported to be 70% for SPECT and 87% for PET. (5) Therefore, for patients with intermediate pretest probability of CAD, one should start with SPECT testing and only proceed to PET in indeterminate cases. In addition, since obese patients are more prone to liver and bowel artifact, PET testing is advantageous over SPECT in severely obese patients.

A proposed diagnostic algorithm follows:
In 2005, a joint statement from the Canadian Cardiovascular Society, Canadian Association of Radiologists, Canadian Association of Nuclear Medicine, Canadian Nuclear Cardiology Society, Canadian Society of Cardiac Magnetic Resonance recommends (Class I recommendation, level B evidence) PET scanning for patients with intermediate pretest probability of CAD who have nondiagnostic noninvasive imaging tests or where such a test does not agree with clinical diagnosis, or may be prone to artifact that could lead to an equivocal other test, such as obese patients. (4)

2006 Update
A literature review was conducted in May 2006. No clinical trials or studies were found that would alter the policy statements or policy guidelines noted above. Studies continued to show the equivalence of SPECT and PET. As one example, Slart and colleagues (6) concluded that there was overall good agreement between SPECT and PET for the assessment of myocardial viability in patients with severe LV dysfunction. Comparative studies reported on test accuracy and did not address impact on clinical outcomes.

2007–2008 Update
The policy was updated with a literature review using MEDLINE in January 2008. While comparative studies were identified for SPECT compared to PET in the evaluation of CAD, the comparative data are still limited. Using a thorax-cardiac phantom, Knesaurek and Machac concluded that PET was better at detecting smaller defects. (7) In this study, a 1-cm insert was not detectable by SPECT, yet it was detectable using PET. Merhige and colleagues reported on outcomes of non-contemporaneous patients with similar probabilities of CAD that were evaluated by SPECT or PET. (8) In this study involving PET scans done at one center compared to those evaluated by SPECT, those receiving PET evaluations had lower rates of angiography (13% vs. 31%) and revascularization (6% and 11% - both respectively) with similar rates of death and myocardial infarction at 1-year follow-up. These results are viewed

as preliminary, and additional comparative studies showing impact on outcomes are needed. Another publication also described the PAREPET study that will determine whether the amount of viable dysfunctional myocardium and/or sympathetic dysinnervation is associated with the risk of sudden cardiac death. (9)

2009 Update

A literature review was conducted in September 2008. None of the articles identified would prompt a change in the policy statements above. A recent review by Di Carli and Hachamovitch (10) describes the current and potential diagnostic uses of cardiac PET and is in agreement with the policy statements. The Study of Perfusion and Anatomy's Role in CAD (SPARC) trial is recruiting patients to evaluate the role of cardiac PET/CT for the diagnosis of CAD. (11) To date, there are no articles from the PAREPET or SPARC trials.

2010-2011 Update

The policy was updated with a literature review through January 2011. No new publications were identified that compared SPECT to PET for cardiac conditions. Recent publications describe the use of PET imaging to quantify both myocardial blood flow and flow reserve. (12,13) However, as noted in an accompanying editorial, larger prospective clinical trials are needed to understand the clinical utility. (14) Thus, the policy statements are unchanged.

Based on clinical input received in 2011, an additional indication was added to the policy on the workup of cardiac sarcoidosis. Published evidence on the utility of PET scanning for cardiac sarcoidosis is limited due to the relatively small numbers of patients with this condition. A recent review article (15) concluded that imaging studies had incremental value when combined with clinical evaluation and/or myocardial biopsy in the diagnosis of cardiac sarcoidosis. This review reported that cardiac magnetic resonance imaging (MRI) was the more established imaging modality in diagnosing sarcoidosis, with an estimated sensitivity of 100% and specificity of 80%. There is limited evidence to define the sensitivity, specificity or predictive value of PET scanning for this purpose, but it appears to have reasonably good accuracy based on small series of patients.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.
Clinical input received in June 2011 was generally in agreement on the medical necessity of PET for myocardial viability or for patients with an indeterminate SPECT scan. However, input from reviewers disagreed on using a strict BMI cutoff to define patients in whom a SPECT scan would be expected to be suboptimal. Therefore, the language of the policy statement was changed to "Cardiac PET scanning may be considered medically necessary to assess myocardial perfusion and thus diagnose coronary artery disease in patients with indeterminate SPECT scan; or in patients for whom SPECT could be reasonably expected to be suboptimal in quality on the basis of body habitus."

Three reviewers responded to the question of whether PET scanning was medically necessary in the workup of patients with suspected cardiac sarcoidosis. All three were in agreement that PET scanning was medically necessary in this patient group. Two of the three reviewers

offered that MRI scanning was the preferred test in the workup of cardiac sarcoidosis but that PET scanning was medically necessary in patients who were unable to undergo MRI. As a result of this input, an additional indication was added to the policy statement for workup of cardiac sarcoidosis: "Cardiac PET scanning may be considered medically necessary for the diagnosis of cardiac sarcoidosis in patients who are unable to undergo MRI scanning. Examples of patients who are unable to undergo MRI include, but are not limited to, patients with pacemakers, automatic implanted cardioverter-defibrillators (AICDs) or other metal implants."

Summary

Evidence from the medical literature supports the use of PET scanning to assess myocardial viability in patients with severe LV dysfunction who are being considered for revascularization. Results of primary studies and recommendations from specialty societies conclude that PET scanning is at least as good as, and likely superior, to SPECT scanning for this purpose. For assessing myocardial perfusion in patients with suspected coronary artery disease, PET scanning is less likely than SPECT scanning to provide indeterminate results. Therefore, PET scanning is also useful in patients with an indeterminate SPECT scan, as well as in patients whose body habitus is likely to result in indeterminate SPECT scans, for example patients with moderate to severe obesity. For patients who are undergoing a workup for cardiac sarcoidosis, MRI is the preferred initial test. However, for patients who are unable to undergo MRI, such as patients with a metal implant, PET scanning is the preferred test.

Government Regulations

National:

Beginning October 1, 2002, Medicare will cover FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization and will continue to cover FDG PET when used as a follow-up to an inconclusive SPECT. However, if a patient received a FDG PET with inconclusive results, a follow-up SPECT is not covered. FDA-approved or FDA-cleared full and partial ring PET scanners are covered.

Limitations: In the event that a patient receives a SPECT with inconclusive results, a PET scan may be performed and covered by Medicare. However, a SPECT is not covered following a FDG PET with inconclusive results.

Frequency: In the absence of national frequency limitations, contractors can, if necessary, develop reasonable frequency limitations for myocardial viability.

Local:

No LCD on this topic.

Michigan Department of Community Health:

No Medicaid policy on this topic. Codes are payable.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Positron Emission Tomography (PET) Scans for Miscellaneous Applications
- Positron Emission Tomography (PET) Scans for Oncologic Applications

References

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2. Klocke FJ, Baird MG, Gateman TM et al. ACC/AHA/ASNC guidelines for clinical use of cardiac radionuclide imaging: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (ACC/AHA/ASNC Committee to Revise the 1995 Guidelines for the Clinical Use of Radionuclide Imaging). 2003 American College of Cardiology Web site. Available online at: http://www.acc.org/qualityandscience/clinical/guidelines/radio/index.pdf . Last accessed September 2011.
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10. Di Carli MF, Hachamovitch R. New technology for noninvasive evaluation of coronary artery disease. Circulation 2007; 115(11):1464-80. Available online at: http://www.clinicaltrials.gov/ct2/show/NCT00321399?term=cardiac+sparc&rank=2 . Last accessed September 2011.

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12. Schindler TH, Schelbert HR, Quercioli A et al. Cardiac PET imaging for the detection and monitoring of coronary artery disease and microvascular health. JACC Cardiovasc Imaging 2010; 3(6):623-40.
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16. Medicare Policy: Program Memorandum, Coverage and Related Claims Processing Requirements for Positron Emission Tomography (PET) Scans –for Breast Cancer and Revised Coverage Conditions for Myocardial Viability, Transmittal AB-02-065, May 2, 2002. Available online at: http://www.cms.hhs.gov/Transmittals/Downloads/ab02065.pdf . Last accessed December 2008.
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 3/12/12, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
1/1/12	10/11/11	11/9/11	Joint policy established; PET scans for cardiac applications was separated out of the consolidated PET scan policy.
7/1/12	4/10/12	5/18/12	Clarified inclusionary criteria; changed criteria to read, “For patients for whom SPECT could be reasonably expected to be suboptimal in quality on the basis of body habitus. (e.g., BMI > 40), large breasts, breast implants, mastectomy, chest wall deformity, pleural or pericardial effusion)”.

Next Review Date: 2nd Qtr, 2013

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: PET SCANS FOR CARDIAC APPLICATION

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Covered; criteria apply.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.
Blue Cross Complete of Michigan	Covered; criteria apply.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.