BlueCross BlueShield of Louisiana

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Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Positron Emission Tomography (PET) Miscellaneous Applications *is addressed separately in medical policy 00104.*

Note: Positron Emission Tomography (PET) Oncologic Applications *is addressed separately in medical policy 00105.*

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider the use of positron emission tomography (PET) scanning to assess myocardial perfusion and thus diagnose coronary artery disease (CAD) to be **eligible for coverage** when patient selection criteria are met.

Patient Selection Criteria
Coverage eligibility for the use of positron emission tomography (PET) scanning assessment of myocardial perfusion and diagnosis of coronary artery disease (CAD) will be considered when ANY of the following are met:

- Single photon emission computed tomography (SPECT) study is unavailable or inconclusive; OR Patients who may be prone to artifact, such as severely obese patients (body mass index [BMI] ≥ 35 kg/m^2); OR
- Patients who have had a breast implant; OR
- Conditions associated with high risk for morbidity (e.g., allergy to contrast medium, poor arterial access, renal dysfunction for which angiography increases the likelihood of renal failure).

Based on review of available data, the Company may consider the use of positron emission tomography (PET) scanning to assess the myocardial viability in patients with severe left ventricular (LV) dysfunction as a technique to determine candidacy for a revascularization procedure to be **eligible for coverage**.

Based on review of available data, the Company may consider the use of cardiac positron emission tomography (PET) scanning for the diagnosis of cardiac sarcoidosis in patients who are unable to undergo magnetic resonance imaging (MRI) scanning to be **eligible for coverage**. Examples of patients who are unable to undergo magnetic resonance imaging (MRI) include, but are not limited to, patients with pacemakers, automatic implanted cardioverter-defibrillators (AICDs), or other metal implants.

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

When Services Are Considered Not Medically Necessary
Based on review on available data, the Company considers the use of positron emission tomography (PET) scanning for cardiac application to be **not medically necessary**** when patient selection criteria are not met for conditions not indicated in the policy statement.

Background/Overview

Cardiac PET scanning is used in 2 key clinical situations: 1) myocardial perfusion scanning as a technique of identifying perfusion defects, which in turn reflect CAD; and 2) assessment of myocardial viability in patients with 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.

Positron emission tomography scans are based on the use of positron-emitting radionuclide tracers, which simultaneously emit 2 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 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. Most tracers have a short half-life and must be manufactured with an on-site cyclotron. Rubidium-82 is produced by a strontium-82/rubidium-82 generator. The half-life of fluorine-18 is long enough that it can be manufactured commercially at offsite locations and shipped to imaging centers. The radionuclides may be coupled to a variety of physiologically active molecules, including oxygen, water and ammonia. 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. Tracers that target the mitochondrial complex are also being developed.

Note: This policy only addresses the use of radiotracers detected with the use of dedicated PET scanners. Radiotracers such as fluorodeoxyglucose (FDG) may be detected using SPECT cameras, a hybrid PET/SPECT procedure that may be referred to as FDG-SPECT or molecular coincidence detection. This technique is not discussed in this document.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)
The 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 for certain 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 LV dysfunction, when used together with myocardial perfusion imaging, for the identification of LV myocardium with residual glucose metabolism and reversible loss of systolic function."

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

- **^{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.

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 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; and
- Whether or not the clinical indication for individual patients meets medical necessity criteria.

Centers for Medicare and Medicaid Services (CMS)
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.

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

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.

Rationale/Source

Myocardial Perfusion Imaging

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 sensitivity and specificity of PET may be slightly better than SPECT. For example, the performance characteristics for PET and SPECT based on the Canadian Joint Position Statement is shown in the table below.

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

	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

However, their diagnostic utilities may be 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.

	Post-Test Probability			
	Positive Test		**Negative Test**	
Pretest Probability	**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

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

In 2012, Jaarsma et al. reported a meta-analysis comparing the diagnostic performance of noninvasive myocardial perfusion imaging with SPECT, cardiac MRI or PET. The comparison standard was CAD identified with coronary angiography. A total of 166 articles (17,901 patients) met the inclusion criteria, with 114 articles on SPECT, 37 on cardiac MRI, and 15 on PET. Sensitivity with patient level analysis was similar for the 3 tests, with a pooled sensitivity of 88% for SPECT, 89% for MRI, and 84% for PET. Pooled specificity was lower for SPECT (61%), compared to MRI (76%), and PET (81%). The pooled diagnostic odds ratio was 15.31 for SPECT, 26.42 for MRI, and 36.47 for PET. Meta-regression indicated that MRI and PET have a significantly higher diagnostic accuracy than SPECT. Although this analysis is limited by potential publication bias for SPECT and significant heterogeneity in the MRI and SPECT studies, most subgroup analyses showed a relative superiority of MRI and PET over SPECT.

A second 2012 meta-analysis by Parker et al. compared SPECT and PET stress myocardial perfusion imaging, using coronary angiography as the reference standard. A total of 117 articles met selection criteria. Single photon emission computed tomography was addressed by 113 studies (11,212 patients), while PET was examined in 9 studies (650 patients). Patient-level diagnostic accuracy data were pooled in a bivariate meta-analysis, showing significantly better sensitivity for PET (92.6%) compared with SPECT (88.3%). There was no significant difference in specificity between PET (81.3%) and SPECT (76.0%). The pattern of higher sensitivity for PET over SPECT and similar specificity was also found among higher quality studies.

Another consideration is that there are fewer indeterminate results with PET than SPECT. A retrospective study by Bateman et al. matched 112 SPECT and 112 PET studies by gender, BMI, and presence and extent of CAD and 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 nonobese patients was reported to be 70% for SPECT and 87% for PET. 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.

Merhige and colleagues reported on outcomes of non-contemporaneous patients with similar probabilities of CAD that were evaluated by SPECT or PET. 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.

Conclusions

Evidence on the diagnostic accuracy of PET for myocardial perfusion imaging establishes that PET is at least as good as SPECT in terms of sensitivity and specificity. However, the modest difference in accuracy may not translate to clinically meaningful differences in diagnosis or management, and SPECT remains the

first line test in most instances. There are some patients in which SPECT is indeterminate due to body habitus or other anatomic factors, PET can be performed successfully in most of these patients.

Myocardial Viability
Positron emission tomography 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 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 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 LV dysfunction after revascularization of hibernating myocardium, as identified by PET scanning.

Single photon emission computed tomography 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 positive 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.

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 CAD and LV dysfunction who were being evaluated for myocardial viability. 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 2 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 2 imaging techniques. The authors concluded that either technique could be used for management of patients considered for revascularization with suspicion of jeopardized myocardium.

Studies identified in literature updates continue to show the equivalence of SPECT and PET. The comparative studies reported on test accuracy and did not address impact on clinical outcomes. As one example, Slart and colleagues concluded that there was overall good agreement between SPECT and PET for the assessment of myocardial viability in patients with severe LV dysfunction. Using a thorax-cardiac phantom, Knesaurek and Machac concluded that PET was better at detecting smaller defects. In this study, a 1-cm insert was not detectable by SPECT, yet it was detectable using PET.

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

Conclusions
Positron emission tomography and SPECT can both be used to assess myocardial viability. The available evidence supports that both have roughly similar accuracy for this purpose. Positrom emission tomography may be more sensitive for small defects, but the clinical significance of identifying small defects is uncertain.

Myocardial Blood Flow Reserve
In 2011, Ziadi and colleagues reported a prospective study of the prognostic value of myocardial flow reserve (MFR) with ^{82}Rb PET in 704 consecutive patients. Follow-up at a median of 387 days was conducted for 677 patients (96%), the majority (90%) were by phone. The hypothesis was that patients with reduced flow reserve would have higher cardiac event rates and that ^{82}Rb MFR would be an independent predictor of adverse outcomes. The primary outcome was the prevalence of hard cardiac events (myocardial infarction and cardiac death), the secondary outcome was prevalence of a major adverse cardiac event (MACE: cardiac death, myocardial infarction, later revascularization, and cardiac hospitalization). For patients with a normal summed stress score (SSS) and impaired MFR, there was a significantly higher incidence of hard events (2% vs. 1.3%) and MACE (9% vs. 3.8%) compared to patients with a preserved MFR. Patients with an abnormal SSS and MFR less than 2 had a higher incidence of hard events (11.4% vs. 1.1%) and MACE (24% vs. 9%) compared to patients with a preserved MFR. ^{82}Rb MFR was an independent predictor of cardiac hard events (hazard ratio: 3.3) and MACE (hazard ratio: 2.4) over the SSS. Three patients (0.4%) were classified up and 0 classified down with MFR in the multivariate model ($p = 0.092$).

A retrospective study published in 2011 by Murthy et al. examined the prognostic value of ^{82}Rb PET coronary flow reserve (CFR) in a series of 2,783 patients referred for rest/stress PET myocardial perfusion imaging. Coronary flow reserve was calculated as the ratio of stress to rest myocardial blood flow using semi-quantitative PET interpretation. The primary outcome was cardiac death over a median follow-up of 1.4 years. Prognostic modeling was done with the Cox proportional hazards model. Adding CFR to a multivariate model significantly improved model fit and improved the c index, a measure of discrimination performance, from 0.82 to 0.84 ($p = 0.02$). Coronary flow reserve was a significant independent predictor of cardiac mortality and resulted in improved risk reclassification. A 2012 article by these authors found that the added value of PET CFR was observed in both diabetic and nondiabetic patients.

Other publications describe the use of PET imaging to quantify both myocardial blood flow and MFR. However, as noted in an accompanying editorial, larger prospective clinical trials are needed to understand the clinical utility.

Cardiac Sarcoidosis
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 2009 review article 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 MRI was the more established imaging modality in diagnosing sarcoidosis, with an estimated sensitivity of 100% and specificity of 80%. A meta-analysis published in 2012 by Youssef et al. identified 7 studies with 164 patients. Studies were selected if

they used FDG PET for diagnosis of cardiac sarcoidosis and used the criteria of the Ministry of Health, Labor and Welfare (MHLW) of Japan as the reference standard. Pooled sensitivity of PET by random effects meta-analysis was 89% and pooled specificity was 78%. Area under the summary receiver operating characteristic curve was 93%, suggesting a good level of diagnostic discrimination.

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 CAD 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, AICDs or other metal implants."

Practice Guidelines and Position Statements
In 2003, the American College of Cardiology (ACC) and the American Heart Association (AHA) published updated guidelines for cardiac radionuclide imaging. Cardiac applications of PET scanning were included in these guidelines. The following table summarizes the guidelines for myocardial reperfusion for both SPECT and PET scans in patients with an intermediate risk of CAD. 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.

Indication	SPECT Class	PET Class
Identify extent, severity, and location of ischemia (SPECT protocols vary according to whether patient can exercise)	I	IIa

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

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

These guidelines also conclude that PET imaging "appears to have slightly better overall accuracy for predicting recovery of regional function after revascularization in patients with LV dysfunction than single photon techniques (i.e., SPECT scans)." However, the 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.

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.

2011 Appropriateness Criteria from the American College of Radiology (ACR) considers both SPECT and PET to be appropriate for the evaluation of patients with a high probability of CAD. American College of Radiology states that PET perfusion imaging has advantages over SPECT, including higher spatial and temporal resolution. Routine performance of both PET and SPECT are not necessary.

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 CAD, 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. It is also useful 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.

Ongoing Clinical Trials
A search of online site ClinicalTrials.gov revealed an ongoing randomized controlled trial under identifier NCT01288560. This study is expected to be completed in March 2015. It includes patients with CAD and

heart failure with a LV ejection fraction ≤ 45%. Patients were randomized to management algorithms guided either by SPECT or PET/MRI.

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Positron Emission Tomography (PET) Cardiac Applications

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Coding

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Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	78459, 78491, 78492
HCPCS	A9526, A9552, A9555, G0235, S8085
ICD-9 Diagnosis	All relative diagnoses
ICD-9 Procedure	92.05

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10/18/2005	Medical Policy Committee review. Format revision. FDA approval information added. Coverage eligibility unchanged.
10/27/2005	Quality Care Advisory Council approval
10/04/2006	Medical Director review
10/18/2006	Medical Policy Committee approval. FDA information updated. Coverage eligibility unchanged. Updated with additional references.
02/13/2008	Medical Director review
02/20/2008	Medical Policy Committee approval. Revised patient selection criteria changing obesity to severe obesity (BMI $\geq$ 40)
05/07/2009	Medical Director review

Positron Emission Tomography (PET) Cardiac Applications

Policy # 00103
Original Effective Date: 11/12/2001
Current Effective Date: 05/05/2014

05/20/2009	Medical Policy Committee approval. No change to coverage eligibility.
01/01/2010	Coding revision
06/03/2010	Medical Policy Committee review
06/16/2010	Medical Policy Implementation Committee approval. No change to coverage eligibility.
02/03/2011	Medical Policy Committee review
05/02/2011	Medical Policy Implementation Committee approval. Patient selection criteria revised. Denial reason when patient selection criteria not met was changed from investigational to not medically necessary.
02/02/2012	Medical Policy Committee review
02/15/2012	Medical Policy Implementation Committee approval. An additional indication for PET scanning was added "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." Policy effective date 3/5/2012 to allow for AIM implementation of policy revisions.
10/2/2012	Revised to correct original effective date and notation added to history as of 3/5/2012 effective date.
02/07/2013	Medical Policy Committee review
02/20/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/06/2014	Medical Policy Committee review
02/19/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2015

*****Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
    2. credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and 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.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.