APPENDIX to Positron Emission Tomography (PET) Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Oncologic Indications

The oncology portion of this policy is based primarily on the April 2009 Centers for Medicare and Medicaid Services' (CMS) National Coverage Determination (NCD); the policy adopts the current two-part CMS framework differentiating positron emission tomography (PET) imaging that directs initial treatment strategies from PET imaging that guides subsequent treatment strategies. Practice Guidelines and publications from the National Comprehensive Cancer Network (NCCN), the National Cancer Institute (NCI), the Blue Cross Blue Shield Technology Evaluation Center (TEC), and the Agency for Healthcare Research and Quality (AHRQ) were also considered along with other relevant clinical research.

The Centers for Medicare and Medicaid Services began coverage for PET in 1998, adopting a limited cancer specific/indication specific approach, rather than broad coverage of the technology. By 2005, CMS coverage for PET included select indications for only nine types of cancer (Hillner et al., 2008). The Coverage with Evidence Development (CED) program was

developed to extend coverage of new technologies, such as PET and PET/CT, when existing evidence did not otherwise support coverage (CMS, 2006). The National Oncologic PET Registry (NOPR) was created to support data collection for "analysis of the effect of PET on referring physicians' plans of intended patient management" across a broad range of previously non-covered cancer types and indications. When the CED designation is applied, providers and facilities are required to complete timely pre- and post-PET assessments and submit the data to NOPR as a condition of coverage (Hillner et al., 2008).

The initial results from the NOPR published by Hillner and colleagues (2008) indicated physicians changed their intended patient management in 36.5% of cases following a PET study. This data included older patients with suspected and known cancers. A subsequent study by Hillner et al., (2008) demonstrated among the same cohort of patients with pathologically confirmed cancers, on average, physicians changed patient management in 39.8% of cases when PET was utilized for initial staging; 35.9% of cases when PET was utilized for restaging; and 38.5% of cases when PET was utilized to detect suspected recurrence. The results for these three indications were fairly consistent across 18 different types of cancer, with the noted exception of multiple myeloma which revealed a consistently higher rate of change in intended management (staging 52.2%; restaging 46.4%; recurrence 50.9%). A third study by Hillner et al. (2009) found when PET was utilized to monitor response to treatment, physicians changed their intended treatment strategy in approximately 50% of cases, most often when PET results showed disease progression.

The Centers for Medicare and Medicaid Services' NCD 100-03, entitled Positron Emission Tomography (PET) Scans, became effective in April 2009 with an implementation date of October 2009. This NCD included coverage positions for 17 specific cancers and solid tumors in general and superseded previous NCDs for all oncological indications. The decision to change the CMS coverage position for PET was based in part on the results of a 2008 AHRQ Technology Assessment Report entitled Positron Emission Tomography for Nine Cancers (Bladder, Brain, Cervical, Kidney, Ovarian, Pancreatic, Prostate, Small Cell Lung, Testicular) prepared by the University of Alberta Evidence-Based Practice Center and data collected through the NOPR. The newly revised coverage position for PET eliminated the four-part framework and adopted a two-part framework that included Initial Treatment Strategy (formerly diagnosis and staging) and Subsequent Treatment Strategy (formerly restaging and monitoring response to treatment). This NCD significantly expanded coverage for the initial treatment of solid tumors while maintaining the CED designation for subsequent treatment of many solid tumors and other types of cancer. Prostate cancer is a noted exception with PET not covered in the initial treatment phase.

The NCCN issued two task force reports on the clinical utility of PET/CT for oncological indications (Podoloff et al., 2007; Podoloff et al., 2009). While providing a good overview of the role of PET for 14 different types of cancer, the conclusions of the report were equivocal in some areas and based on lower-level evidence and panel consensus. The NCCN also published cancer-specific Practice Guidelines that frequently included imaging recommendations at various stages of the disease process. These guidelines were also based on lower-level evidence and consensus within the NCCN.

Unknown Primary

A 2002 TEC Assessment identified four reports totaling 47 patients referred for PET imaging with a single known metastatic site from an unknown primary cancer. In 13 (28%) of these patients, PET identified previously undetected metastases that were subsequently confirmed by biopsy. The assessment concluded PET imaging could provide useful detail on the extent of metastatic disease and therefore contribute to optimal decision-making regarding the appropriateness of local or regional therapy verses systemic therapy for these patients.

Surveillance

A review of the literature and specialty society guidelines did not support the routine use of PET or PET/CT for regular surveillance of asymptomatic patients.

For conditions and indications listed as investigational, there is not, as of yet, adequate evidence in the medical literature to support the use of PET, and/or CMS coverage requires continued evidence development.

Cardiac Applications

Cardiac PET is a scanning technology used to non-invasively characterize cardiac blood flow and function. It involves injection of a positron-emitting radioisotope with follow-up imaging using a special camera that captures characteristic high-energy gamma rays produced after isotope administration. This highly quantitative technology generates images that are more accurate and less subject to attenuation artifacts than those produced by single-photon emission computed tomography (SPECT).

Cardiac PET imaging primarily focuses on the assessment of myocardial viability and myocardial perfusion. Studies comparing diagnostic accuracy have generally concluded that results obtained with PET imaging are comparable to SPECT results (Slart et al., 2005; Sawada, 2006).

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 non-viable myocardium. However, a PET scan may reveal metabolically active myocardium, suggesting areas of "hibernating" myocardium that would benefit from revascularization. The most common PET technique for this application is N-13 ammonia as a perfusion tracer and fluorine-18 fluorodeoxyglucose (FDG) as a metabolic marker of glucose utilization. A pattern of FDG uptake in areas of hypoperfusion (referred to as FDG/blood flow mismatch) suggests viable, but hibernating myocardium. Clinical validation of this diagnostic test is demonstrated by improvement in left ventricular function after revascularization of hibernating myocardium.

The joint American College of Cardiology/American Heart Association (ACC/AHA) 2009 Appropriate Use Criteria for Cardiac Radionuclide Imaging consider cardiac radionuclide imaging (SPECT or PET) appropriate in the assessment of myocardial viability for patients with

severe left ventricular dysfunction who are viable candidates for revascularization (Hendel, 2009.

Myocardial Perfusion

In a patient with symptoms suggestive of coronary artery disease (CAD), it is important to determine whether coronary angiography is necessary for further workup. A variety of non-invasive imaging tests, including PET (using rubidium-82) and SPECT scans have been investigated as a means of identifying reversible perfusion defects, which may reflect coronary artery disease, and thus identify patients who may benefit from further workup with an angiogram.

The ACC/AHA 2009 Appropriate Use Criteria consider cardiac radionuclide imaging (SPECT or PET) appropriate in the detection of coronary artery disease in symptomatic patients, except when there is low risk of CAD, along with interpretable electrocardiogram results and the ability to exercise, and when there is definite acute coronary syndrome (Hendel, 2009).

Central Nervous System Applications

Seizures

Positron emission tomography is an established functional imaging modality in the evaluation of surgical candidates with complex partial, medically refractory seizures (Willmann, et al., 2007; Knowlton, 2006). Presurgical PET studies are typically performed in the interictal state to detect areas of decreased metabolism presumed to represent epileptogenic foci. Positron emission tomography is also used to localize and minimize the placement of intracranial electrodes potentially reducing the morbidity associated with intracranial monitoring, even if invasive monitoring was not avoided altogether (Henry & Van Heertum, 2003).

Alzheimer's Disease and Dementia

Dementia is the loss of intellectual ability. Alzheimer's disease is the most common cause of dementia. The National Institute of Neurologic, Communicative Disorders and Stroke-Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) or the Diagnostic and Statistical Manual (DSM) diagnostic criterion are routinely used to diagnose dementia.

Although PET is frequently used in the research setting in the study of Alzheimer's disease and dementia, there is not yet sufficient evidence to support its routine use in the clinical setting. The American Academy of Neurology (AAN) Practice Parameter entitled Diagnosis of Dementia, stated, "at this time, there is not enough evidence to support or refute the use of PET" (Knopman, et al., 2001, reaffirmed 2004). The AAN Practice Parameter entitled Early Detection of Dementia: Mild Cognitive Impairment (Petersen, et al., 2001, reaffirmed 2003) did not address PET and brain imaging was noted under future research.

The American Psychiatric Association (APA) 2007 Practice Guideline for the Treatment of Patients with Alzheimer's disease and Other Dementias, stated "Functional neuroimaging may contribute to diagnostic specificity in certain instances" and noted the use of PET to differentiate Alzheimer's disease from frontotemporal dementia (FTD) was recently approved by CMS (Rabins et al., 2007). The guideline also indicated “The development of additional imaging tools

for improved diagnosis, early recognition, and more precise assessment of disease progression is a focus of current study" (Rabins et al., 2007).

Psychiatric Disorders

Although differences in radiotracer uptake between patients with mood and other psychiatric disorders and healthy controls have been found, PET imaging does not currently play a role in the diagnosis and treatment of psychiatric disorders and remains a research tool. The American Psychiatric Association (APA) Practice Guideline for the Psychiatric Evaluation of Adults stated "In patients with schizophrenia and mood and anxiety disorders, structural and functional neuroimaging studies have reported differences between patients and healthy control persons as well as differences in some patient subgroups and in responders and non-responders to some treatments (Velgare, 2006). Nevertheless, the clinical utility of neuroimaging techniques for planning of individualized treatment has not yet been shown." The guideline further noted additional research is required to establish the clinical utility of structural and functional neuroimaging in the diagnosis, monitoring and prediction of psychiatric disorders.

Chronic Osteomyelitis

Termatt and colleagues (2005) conducted a systematic review and meta-analysis of the literature to evaluate the diagnostic accuracy of various imaging modalities for the assessment of chronic osteomyelitis. Based on pooled sensitivity and specificity data from 23 studies, the authors concluded PET had "the highest diagnostic accuracy for confirming or excluding the diagnosis of chronic osteomyelitis." Leukocyte scintigraphy was sufficiently accurate in detecting chronic osteomyelitis of the peripheral skeleton, but PET was superior in the axial skeleton.

Summary

Positron emission tomography imaging for selected oncologic indications is supported in the peer reviewed scientific literature. Also supported by current research is the use of PET in patients with refractory seizures, certain cardiac indications and chronic osteomyelitis. There is insufficient evidence in the peer reviewed scientific literature to support the use of PET in patients with suspected or known Alzheimer's disease, dementia (including FTD), psychiatric disorders, and infection. Additional research is needed to identify optimal radiotracers as well as to clearly define the diagnostic utility of PET in comparison to other established imaging techniques.

2011 Update

An additional indication was added to the policy for 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 review article concluded imaging studies had incremental value when combined with clinical evaluation and/or myocardial biopsy in the diagnosis of cardiac sarcoidosis (Sharma, 2009). This review reported cardiac magnetic resonance imaging was the more established imaging modality in diagnosing sarcoidosis, with an estimated sensitivity of 100% and specificity of 80%. There was limited evidence to define the sensitivity, specificity or predictive value of PET scanning for this purpose, but it appeared to have reasonably good accuracy based on small series of patients.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement Policy

Type	Number	Description
CPT	78459	Myocardial imaging, positron emission tomography (PET), metabolic evaluation
	78491	Myocardial imaging, positron emission tomography (PET), perfusion; single study at rest or stress
	78492	Myocardial imaging, positron emission tomography (PET), perfusion; multiple studies at rest and/or stress
	78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
	78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
	78811	Positron emission tomography (PET) imaging; limited area (eg, chest, head/neck)
	78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
	78813	Positron emission tomography (PET) imaging; whole body
	78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (eg, chest, head/neck)

Type	Number	Description
	78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
	78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
HCPC	A9526	Nitrogen N-13 ammonia, diagnostic, per study dose, up to 40 millicuries
	A9552	Fluorodeoxyglucose F-18 FDG, diagnostic, per study dose, up to 45 millicuries
	A9555	Rubidium Rb-82, diagnostic, per study dose, up to 60 millicuries
	G0219	PET imaging whole body; melanoma for noncovered indications
	G0235	PET imaging, any site, not otherwise specified
	G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)
	S8085	Fluorine-18 fluorodeoxyglucose (F-18 FDG) imaging using dual-head coincidence detection system (nondedicated PET scan)
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Definitions

N/A

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

N/A

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Cardiology, the American College of Radiology, the American Heart Association, the American Society of Echocardiography, the Society of Cardiovascular Computed Tomography, the Society for Cardiovascular Magnetic Resonance, and the Society of Nuclear Medicine. Endorsed by the American College of Emergency Physicians. J Am Coll Cardiol. 2009 Jun 9; 53(23):2201-29.

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
1/26/2009	Policy revision with position change Policy Title Revision, criteria revised. Combined Polices: • Positron Emission Tomography(PET) Indications for Diagnosis Evaluation and Staging for Breast Cancer; • Positron Emission Tomography(PET) Indications - Excluding PET for Breast • Positron Emission Tomography(PET) in the Evaluation of (suspected) Alzheimers/Dementia Positron Emission Tomography(PET) Coronary Artery Disease Indication	Medical Policy Committee
4/3/2009	Policy revision with position change	Medical Policy Committee
6/24/2009	Policy revision with position change	Medical Policy Committee

Effective Date	Action	Reason
4/2/2010	Policy revision with position change Coding update	Medical Policy Committee
1/7/2011	Policy revision with position change	Medical Policy Committee
10/7/2011	Policy revision with position change	Medical Policy Committee

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These Policies are subject to change as new information becomes available.

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