Clinical Policy Title: Single photon emission computed tomography (SPECT) scans

Clinical Policy Number: 18.01.03

Effective Date: January 1, 2016
Initial Review Date: September 16, 2015
Most Recent Review Date: October 19 2016
Next Review Date: October 2017

Related policies:

None.

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of single photon emission computed tomography (SPECT scan) scans to be clinically proven and, therefore, medically necessary when the following criteria are met:

- Bone and joint conditions (e.g., stress fracture, osteoid osteoma, spondylosis, infection [e.g., discitis]).
  - Assessment of osteomyelitis, to distinguish bone from soft tissue infection.
  - Distinguishing spinal benign lesions from malignant lesions (e.g., SPECT scan to demonstrate a focal area of increased uptake at the site of the lesion and differentiate between a metabolically active or “hot” lesion and an inactive lesion).
- Brain tumors, to differentiate between lymphomas and infections such as toxoplasmosis, particularly in the immunosuppressed, or recurrent tumor versus radiation changes when PET is not available.
- Cardiovascular imaging, including:
- Myocardial perfusion imaging for the diagnosis and management of coronary artery disease (CAD) (such as detection of CAD, determination of myocardial viability, and assessment of efficacy of therapy).
- Myocardial infarction, to detect and localize necrosis.

- Liver hemangioma, using labeled red blood cells to further define lesions identified by other imaging modalities
- Localization of abscess/infection/inflammation in soft tissues or cases of fever of unknown origin.
- Neuroendocrine tumors (e.g., adenomas, carcinoid, pheochromocytomas, neuroblastoma, vasoactive intestinal peptide [VIP] secreting tumors, thyroid carcinoma, adrenal gland tumors), using a monoclonal antibody (OctreoScan™ [Covidien, Hazelwood, MO]) or I-131 meta-iodobenzyl-guanidine (MIBG).
- Parathyroid imaging.
- Renal dimercapsotussinic acid (DMSA) scan to assess the status of kidney for scarring and function.
- Diagnosing pulmonary embolism (by means of SPECT scan ventilation/perfusion scintigraphy).
- Localizing epileptic foci preoperatively (in place of positron emission tomography (PET)).

**Limitations:**

All other uses of SPECT scans are not medically necessary and are considered investigational for the following conditions:

- Attention deficit disorder, autism, and hyperactivity disorder.
- Chronic fatigue syndrome.
- Colorectal carcinoma (e.g., used with the monoclonal antibody or IMMU-4 and CEA-Scan® [Immunomedics Inc., Morris Plains, New Jersey]).
- Dopamine transporter (DaT) scans for all indications (e.g., Parkinsonism syndrome, essential tremor or dementia with Lewy bodies, or Alzheimer’s disease), and for the monitoring of disease progression.
- Malignancies other than those for which SPECT scans are listed as medically necessary.
- Neuropsychiatric disorders without evidence of cerebrovascular disease.
- Pervasive development disorders (PDD).
- Prostate carcinoma (e.g., used with the monoclonal antibody ProstaScint® [EUSA Pharma, Langhorne, PA], with or without fusion imaging with computed tomography or magnetic resonance imaging).
- Scintimammography for breast cancer.
- SPECT/SISCOM for the preoperative evaluation of individuals with intractable focal epilepsy to identify and localize area(s) of epileptiform activity when other techniques designed to localize a focus have indeterminate results.
**Frequency limitations:**

Medicare administrative contractor discretion.

In the case of myocardial viability, FDG positron emission tomography (PET) may be used following a SPECT scan that was inconclusive. However, SPECT scans may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.

**Alternative covered services:**

Approved radiologic studies appropriate for the member’s condition.

**Background**

Single photon emission computed tomography (SPECT) scan is a nuclear medicine tomographic imaging technique using gamma rays. It is very similar to conventional nuclear medicine planar imaging using a gamma camera. However, it is able to provide true 3D information. This information is typically presented as cross-sectional slices through the patient, but can be freely reformatted or manipulated, as required.

Stress echo and SPECT myocardial perfusion imaging (MPI) are considered equivalent diagnostic tests. However, in addition to myocardial ischemia, stress echo can provide additional information that is not obtainable with MPI, such as valve function, assessment of pulmonary pressure, and assessment of dynamic obstruction. The most commonly performed myocardial perfusion imaging tests are single (at rest or stress, CPT code 78451) and multiple (at rest and stress, CPT code 78452) tomographic SPECT scan studies. Evaluation of the individual’s left ventricular wall motion and ejection fractions are routinely performed during SPECT MPI and are included in the code’s definition. Attenuation correction, when performed, is included in the MPI service.

SPECT scans can provide information about the level of chemical or cellular activity within an organ or system, as well as provide structural information. This process may show areas of increased activity, such as the inflammation in an abscess. Patterns of distribution of the radiotracer can be correlated with various diseases. SPECT scans have been useful in early detection in brain and bone disorders, as well as some types of malignancies. The selection of a radiotracer and imaging protocol is specific to the disease process being investigated. SPECT scans may be repeated to follow the course of a disease.

SPECT scans are typically performed without the need a hospital stay. The individual is given a dose of a radiotracer, which circulates in the bloodstream and binds to specific target cells. The emitted radiation from the radiotracer travels through body with little interference and is imaged. SPECT scan cameras can image large areas of the body, or the entire body.
Information acquired by SPECT scans frequently adds or confirms observations obtained by other testing. SPECT scans may also provide information not obtainable by means other than PET, which is a newer technology and may provide additional information in some settings. The images obtained through PET are generally of higher quality than those provided by SPECT scans; however, the availability, sensitivity, specificity, and impact on clinical outcomes when using PET vary by clinical condition. For many conditions, SPECT scans have been found as useful as PET, and it is generally more available.

Both PET and SPECT scans may diagnose disease before any clinical symptoms or structural expressions of disease by providing information about the level of functioning within a body system. CT, MRI, and planar scintigraphy are alternatives for providing structural information. However, these techniques provide no information about functionality and are often inadequate to diagnose or evaluate disease.

Dopamine transporter imaging with single photon emission computed tomography (DAT-SPECT) scan is being evaluated to improve the differential diagnosis of Parkinson’s disease from non-Parkinsonian tremor and of dementia with Lewy bodies (DLB) from Alzheimer’s disease. Most of the available literature is from Europe, where a ligand has been available for over a decade. In terms of technical performance, the ligand is specific for the striatal dopamine transporter, and studies indicate reliability in assessment of the images when performed by experienced readers.

For diagnosing Parkinson’s disease in patients with parkinsonian symptoms, studies of diagnostic accuracy report good specificity for confirming nigrostriatal degeneration, with less sensitivity for ruling out disease. These findings are dependent, however, on a reference standard (clinical diagnosis) which may be flawed, and it is unknown whether DAT-SPECT scans would show greater sensitivity when compared with the criterion standard of histopathological diagnosis. Evidence on clinical utility scans includes a randomized controlled trial that showed more patients evaluated with DAT-SPECT have changes in diagnosis and management compared to controls without imaging; however, no improvement in quality of life was observed within the one-year follow-up. In other studies, DAT-SPECT scans findings are consistent with about 90 percent of diagnoses made by specialists in movement disorders and that in a relatively small proportion of patients, the diagnosis has been altered based on DAT-SPECT scans.

For discriminating between DLB and Alzheimer’s disease, the sensitivity and specificity of DAT-SPECT scans is somewhat lower than for PS, although the comparison standard used in the available studies may be flawed. One retrospective community-based study suggests DAT-SPECT scans may influence the clinical diagnosis and management of a large proportion of patients with possible DLB. Overall, the evidence available at this time is insufficient to determine with certainty the effect of this technology on health outcomes. Therefore, DAT-SPECT scans are considered investigational.

**Searches**

Keystone First searched PubMed and the databases of:
• UK National Health Services Centre for Reviews and Dissemination.
• Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
• The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on September 29, 2016. Search terms were: “SPECT/CT for imaging of adult and pediatric patients, nuclear medicine.”

We included:
• Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
• Guidelines based on systematic reviews.
• Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

Findings

Data suggest SPECT scan is a relatively safe and effective technique for assessing myocardial viability in patients with coronary artery disease (CAD) and left ventricular (LV) dysfunction and may be as accurate as dobutamine stress echocardiography (DbE) and, depending on the SPECT scan protocol, as accurate or less accurate than PET in this setting. However, accuracy varies with the SPECT scan protocol, has not been proven for each SPECT scan protocol, and is unacceptably low for frontol-temporal dementia (FTDF-FDG coincidence gamma camera [CGC]). While numerous techniques to improve SPECT scan accuracy have been tested, the value of each of these techniques requires additional confirmation (Hayes 2007).

Per the Society of Nuclear Medicine (SNM 2006), SPECT scan and CT are proven diagnostic procedures. The integration of these two procedures into a single device has resulted in the development of this technology. An SNM procedure guideline states that indications for SPECT/CT include imaging of skeletal disorders and tumors.

The conclusion of a study by Sudoh et al. (2006) showed that integrated breath-hold single-photon emission tomography and computed tomography images allow the accurate prediction of postoperative pulmonary function but without statistical superiority over the simple segment-counting technique. Further study of the usefulness of single-photon emission tomography and computed tomography in patients with severe emphysema and borderline lung function should prove valuable because the segment-counting technique underestimates pulmonary functional reserve in these patients.
The American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR) collaborated on the practice parameter’s goal of SPECT brain perfusion imaging to detect abnormalities in regional cerebral perfusion by producing images of diagnostic quality. They further state that SPECT brain perfusion imaging using lipophilic radiopharmaceuticals that cross the blood-brain barrier and localize in normal brain tissue is a proven and useful procedure to define the regional distribution of brain perfusion, evaluate a variety of brain abnormalities, and corroborate the clinical impression of brain death in appropriate situations.

**Policy updates:**

2016 — Added new information in findings section related to brain perfusion imaging. Added another indication for SPECT under coverage policy.

**Summary of clinical evidence:**

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods and Recommendations</th>
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| Patel RA, Beller GA. (2006) | **Key points:**  
  - SPECT-based myocardial viability testing is an important diagnostic modality due to widespread availability and reasonably good sensitivity and specificity for detecting viable myocardium and predicting clinical and functional responses to revascularization.  
  - In the future, single-photon emission computed tomography viability techniques may have a prognostic role in predicting responses to cardiac resynchronization therapy and evaluating myocardial stem-cell transplantation. |
| Schillaci O., et. al./PubMed/(1999) | **Key points:**  
  - Somatostatin receptor scintigraphy with In-111 pentetreotide has proved to be useful in detecting gastro-enteropancreatic tumors; however, the role of abdominal single photon emission computed tomography has not yet been definitively established.  
  - In-111 pentetreotide single photon emission computed tomography was the only imaging method able to localize tumoral lesions in 13 patients; all these localizations were then histologically verified.  
  - The scintigraphic positivity did not depend on the site or on the presence of hormonal hypersecretions. Results indicate that single photon emission computed tomography is more sensitive than planar images and computed tomography/magnetic resonance imaging in detecting abdominal gastro-enteropancreatic tumors and their metastases; it is able to increase both the number of visualized lesions and that of patients with positive findings.  
  - SPECT is particularly useful in patients in whom tumoral lesions have not been already localized; it should be the first imaging modality in patients with gastro-enteropancreatic tumors: its initial use will result in more information and proper management. |
| Godbe D., et. al./PubMed/(1992) | **Key points:**  
  - Prior studies from our institution have shown that SPECT is sensitive (100%) in predicting patients at risk for serious arrhythmias. However, the positive predictive value is low (15% to 20%). |
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<th>Citation</th>
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| analysis of single photon emission computed tomographic scans. | • The purpose of this study was to determine if quantitative analysis of SPECT defects could improve predictive value. One hundred seventy-five patients with positive SPECT scans were studied. One hundred two patients developed arrhythmias, 42 of which were ventricular. Arrhythmias were associated with all defect loci and all defect sizes.  
• The incidence of arrhythmias did increase with increasing size. Patients were at risk for arrhythmias up to 72 hours after trauma. The value of single photon emission computed tomography is its ability to predict patients at risk for arrhythmias. This study shows that any single photon emission computed tomographic defect, regardless of location or size, is a significant predictor of arrhythmias. |

| Key points: | Marwick TH, et al.  
/NIH/(1992)  
Identification of recurrent ischemia after coronary artery bypass surgery: a comparison of positron emission tomography and single photon emission computed tomography | • Current techniques for the detection of recurrent coronary stenosis following bypass grafting have shown disappointing diagnostic accuracy. This study used the same dipyridamole-handgrip stress to compare the accuracy of rubidium-82 PET and thallium-201 SPECT, in 50 consecutive post-bypass patients undergoing coronary arteriography at a mean interval of 6.5 years after surgery. Significant stenosis in native coronary vessels (greater than 50% diameter) or grafts (greater than 70% diameter) were defined by quantitative angiography.  
• Four patients were fully revascularized, without significant recurrent coronary disease; normal perfusion was present in three (75%) by PET, and four (100%) by SPECT. |

**Glossary**

**Abscess** — A collection of pus often caused by the body's response to an infection.

**Adenoma** — A benign tumor that arises in or resembles glandular tissue.

**Carcinoid syndrome** — A syndrome due to carcinoid tumors that secrete large amounts of the hormone serotonin. Carcinoid tumors usually arise in the gastrointestinal tract, anywhere between the stomach and the rectum, and may metastasize (spread) to the liver.

**Colorectal carcinoma** — A cancer of the colon and rectum which is a malignant tumor arising from the inner wall of the large intestine.

**Liver hemangioma** — The most common benign tumor of the liver. It is made up of small blood vessels and is 4 – 6 times more common in women than men.

**Neuroendocrine tumors** — A diverse group of tumors, such as carcinoid, islet cell tumors, neuroblastoma and small cell carcinomas of the lung. All have dense granules and produce polypeptides that can be identified by immunochemical methods.

**Parkinsonian syndromes** — A group of diseases that share similar cardinal signs of parkinsonism characterized by bradykinesia, rigidity, tremor at rest and postural instability.
**Pervasive developmental disorders** — A group of disorders characterized by delays in the development of socialization and communication skills, which are often accompanied by cognitive and language delays.

**Pyelonephritis** — A type of urinary tract infection that can affect one or both kidneys.

**Subarachnoid hemorrhage** — Bleeding in the space between the two membranes that surround the brain.

**SPECT/CT scanner** — An integrated device containing both a CT scanner and a SPECT g-camera with a single patient table and therefore capable of obtaining a CT scan, a SPECT scan or both. If the patient does not move on the bed between the scans, the reconstructed SPECT and CT images will be spatially registered.

**SPECT/CT registration** — The process of aligning SPECT scans and CT images for the purposes of combined image display (fusion) and image analysis.

**SPECT/CT fusion** — The combined display of registered SPECT scan and CT image sets. Superimposed data typically are displayed with the SPECT scan data color coded to the CT data in gray scale.

**SPECT/CT acquisitions** — Can include the whole body, a limited portion of the body or an organ.

**Transient ischemic attack (TIA)** — A neurological event with the signs and symptoms of a stroke, but which go away within a short period of time. Also called a mini-stroke, a TIA is due to a temporary lack of adequate blood and oxygen (ischemia) to the brain.

**References**

**Professional society guidelines/other:**


Food and Drug Administration (FDA) [website]. Drugs @ FDA. FDA Approved Drug Products. Updated February 23, 2007. Available at:


**Peer-reviewed references:**


Clinical trials:


CMS National Coverage Determinations (NCDs):

National Coverage Determination (NCD) for Single Photon Emission Computed Tomography (SPECT SCANS) (220.12) Effective date 10 one 2002. Available at: https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=271&ncdver=1&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&KeyWord=Single+Photon+Emission+Computed+Tomography&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAAACAAAAAAA%3d%3d&. Accessed September 29, 2016.

Local Coverage Determinations (LCDs):
Cardiology— non-emergent outpatient testing: exercise stress test, stress echo, MPI SPECT SCANS, and cardiac PET (L35933). Revision effective date: October 01, 2015. Available at. https://www.cms.gov/medicarecoveragedatabase/details/lcddetails.aspx?LCDId=36209&ver=9&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7cCAL%7cNCD%7cMEDCAC%7cTA%7cMCD&ArticleType=SAD%7cEd&PolicyType=Both&s=All&KeyWord=Single+Photon+Emission+Computed+Tomography&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAACAAAAAAA%3d%3d Accessed September 29, 2016.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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