Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 1/1/24**
(See policy history boxes for previous effective dates)

Title: SPECT/CT Fusion Imaging

Description/Background

Single Photon Emission Computed Tomography (SPECT)
Some SPECT procedures utilize whole body scanning (such as bone scans), SPECT studies typically focus on the function of specific organs, such as the thyroid, heart, lungs, gallbladder, liver and kidneys. SPECT agents(radiopharmaceuticals) incorporate antibody and peptide formulations that can be targeted to specific tissue receptors, allowing one to discriminate healthy from diseased tissue. SPECT agents can also be monitored for tissue changes overtime, allowing physicians to narrow down the characteristics of a specific disease process. Because SPECT tracers have very specific characteristics, more than one agent, each emitting a particular energy level, can be injected to track related processes simultaneously. The goal is to be able to pinpoint both the disease process and its ongoing response to treatments. However, because there are fewer landmarks using SPECT, the more specific the targeting agent is, the more difficult it is to interpret its anatomical position. This may make it difficult for physicians to accurately interpret certain SPECT images.

Computed Tomography (CT)
A CT scan is a painless, noninvasive diagnostic procedure that uses x-ray equipment to obtain cross-sectional images of the body. With the aid of a computer, each cross-sectional image of the body is added together to create a tomogram, (a 3-D image of the internal structures and organs in the body). CT scans are performed to analyze the internal structures of various parts of the body. For example, in the event of traumatic injuries, CT scans may be taken to identify blood clots or fractures. CT scans are also used to aid radiologists in performing procedures such as the biopsy of suspected cancers, the removal of internal body fluids for testing, and the draining of abscesses located deep within the body. With regards to cancer, CT scans are used to detect or confirm the presence of a tumor, its size, location, whether it has metastasized (spread) and to monitor the body's response to treatment.

SPECT/CT Fusion
SPECT/CT fusion refers to the imaging technique that combines the functional information from SPECT with the anatomical information from CT into one set of images. The SPECT and CT images are either "fused" by a software package that superimposes two digital images together or are processed simultaneously by combined SPECT/CT scanners. In either case, SPECT/CT fusion has been purported to allow for more accurate diagnosis and thus improved outcomes and treatment.

Regulatory Status

SPECT/CT fusion technologies have received FDA approval via the 510K process.

Medical Policy Statement

The safety and effectiveness of SPECT/CT fusion imaging have been established. It may be considered a useful imaging option when indicated.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Preoperative Evaluation: for preoperative evaluation to further localize a lesion identified on planar scintigraphy or SPECT when additional anatomic information is needed to direct surgery and that information has not already been provided by CT or MRI.
- Radiation Therapy
  - for planning of selective internal radiation therapy (SIRT).
  - For evaluation of administered dose activity and distribution following radioembolization.
- Bone Imaging
  - Avascular necrosis: when MRI cannot be performed or is nondiagnostic, in either of the following scenarios:
    - Diagnosis following negative or inconclusive radiographs
    - Preoperative planning for osteonecrosis with femoral head collapse
  - Fracture: including occult or stress fracture in any of the following scenarios:
    - Suspected spinal fracture when other imaging (radiographs, CT, or MRI) is nondiagnostic
    - Suspected skeletal injury in non-accidental trauma when MRI cannot be performed or is nondiagnostic
    - Suspected fracture, when MRI cannot be performed or is nondiagnostic, at the following high-risk/weight bearing sites:
      - Femoral neck; proximal femur
      - Tibia (anterior/lateral/plateau)
      - Great toe sesamoid
      - Patella
      - Scaphoid
      - Lunate
      - Talus

        - Navicular
        - Metatarsal base (second and fifth digits)
      - Bone Lesions: for further characterization of indeterminate bone lesions when MRI, CT, or planar scintigraphy is equivocal
      - Infection, not otherwise specified, in **either** of the following scenarios:
        - Diagnosis and management of osteomyelitis when MRI, CT, or planar scintigraphy is nondiagnostic
        - Evaluation of sternal wound infection or dehiscence when CT chest is nondiagnostic
      - Osseous Metastatic Disease: osseous metastatic disease, not otherwise specified in either of the following scenarios:
        - Diagnostic workup and management when **BOTH** of the following apply:
          - Patient has a documented malignancy and signs or symptoms concerning for bony metastatic disease
          - Suspicious findings on CT, MRI, or planar bone scintigraphy require further clarification
        - To determine bone invasion prior to surgical resection of head and neck malignancies when CT, PET/CT, or MRI is nondiagnostic
        - Postoperative joint or spine pain when other imaging (radiographs, CT, or MRI) is nondiagnostic
        - Spondylolysis/spondylolisthesis when other imaging studies are nondiagnostic
- Leukocyte scintigraphy is considered established in either of the following scenarios:
  - For diagnosis and management of osteomyelitis of the skull base or calvarium when CT, MRI, or planar scintigraphy is equivocal
  - For diagnosis and
  - management of osteomyelitis or septic arthritis at other sites (with or without bone marrow scintigraphy) when radiograph, ultrasound, or arthrocentesis is nondiagnostic or not sufficient to guide treatment and when CT, MRI, or planar scintigraphy is equivocal
- Sentinel Node Localization: when clinical evaluation is negative nodal involvement in the following scenarios:
  - Stage I-III invasive breast cancer
  - Cervical cancer that is stage IA1 with lymphovascular invasion (LVI), IA2, IB1, or IIA1
  - Head and neck cancer when decisions are being made regarding mandibular resection
  - Melanoma that is stage IA with adverse features, IB, stage II, in-transit, or locally recurrent
  - Penile cancer
  - Uterine cancer confined to the uterus
  - Vulvar cancer (T1 or T2)
- Neuroendocrine Cancer: diagnostic workup and management of documented neuroendocrine cancer in the following scenarios:
  - As clinically indicated for neuroblastoma or tumors of the autonomic nervous system (pheochromocytoma, paragaglioma, gaglioneuroma) in any of the following scenarios:
    - Suspected metastatic disease

        - Suspected neuroblastoma or tumor of the autonomic nervous system based on CT, MRI or abnormal serum or urine metanephrine levels
    - For pheochromocytoma/paragaglioma prior to planned I131 iobenguane treatment
- Parathyroid/Thyroid Cancer: to identify tumor for surgical planning, localization of residual tissue in patients with recurrent or persistent disease following surgery and surveillance for intermediate or high-risk differentiated cancer 6 to 12 months after therapy has been completed
- Pulmonary Embolism: when CT/CTA cannot be performed or is nondiagnostic Infection/Inflammation: not otherwise specified, for functional anatomic mapping of infections
- Back pain when all other diagnostic workup is inconclusive.

Exclusions:
SPECT/CT fusion imaging for any other condition than listed above.

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:

78072 78830 78832

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

78999

Rationale

Bone Imaging
An article by Gotthardt in 2010 stated, "Three-phase bone scanning with 99mTc-hydroxymethylene diphosphonate or 99mTc-methylene diphosphonate has long been used as the standard method for the detection of osteomyelitis.[1] Bone scintigraphy has a high sensitivity exceeding 80% and a limited specificity reaching up to 50%. The limited specificity can be explained by uptake of the radiopharmaceutical at all sites of increased bone metabolism irrespective of the underlying cause. However, if combined SPECT/CT is performed, the specificity may increase considerably to above 80%."

In 2016, Hudyana et al[2] evaluate the accuracy of bone SPECT (single photon emission computed tomography)/CT (computed tomography) in diagnosing loosening of fixation material in patients with recurrent or persistent back pain that underwent lumbar arthrodesis with pedicle screws using surgery and clinical follow-up as gold standard. A total of 48 patients (median age 49 years, range 21-81 years; 17 men) who had undergone lumbar spinal arthrodesis were included in this retrospective analysis. SPECT/CT results were compared to the gold standard of surgical evaluation or clinical follow-up. Positive SPECT/CT results were considered true positives if findings were confirmed by surgery or if clinical and other examinations were completely consistent with the positive SPECT/CT finding. They were considered false positives if surgical evaluation did not find any loose pedicle screws or if symptoms subsided with non-surgical therapy. Negative SPECT/CT scans were considered true negatives if symptoms either improved without surgical intervention or remained stable over a minimum follow-up period of 6 months. Negative SPECT/CT scans were determined to be false negatives if surgery was still required and loosening of material was found. This retrospective analysis suggests that bone SPECT/CT bone is a highly sensitive and specific tool for the exclusion of screw loosening in patients who present with recurrent low back pain after having undergone lumbar arthrodesis. In addition, it can identify other potential causes of recurrent low back pain in this patient population.

Al-Riyami et al (2019)[3] assessed the diagnostic performance of ^{99m}Tc-HDP bone SPECT/CT in identifying potential pain generators in patients with persistent/recurrent lumbar pain after lumbar spine stabilization surgery (LSSS) but in whom conventional diagnostic imaging is inconclusive. In 160 of the 187 patients (85.6%), SPECT/CT showed positive mild or high tracer uptake in the LSSS region. More than half of the patients had abnormal tracer uptake in the stabilized segments (56.7%) and/or in the adjacent segments (55.6%). Although positive stabilized segment findings were commonly seen at <2 years (70.3%) and the rate decreased with time after LSSS, they were seen at >6 years after surgery in 38.2% of patients. In 51.4% of patients, abnormal activity was seen in the adjacent segments <2 years after LSSS, suggesting early/accelerated degeneration after surgery. The proportion of patients with abnormal activity in the adjacent segments increased to 67.3% at >6 years after LSSS ($p < 0.05$). Positive SPECT/CT findings in the stabilized segments were more frequent in patients with three or more stabilized segments ($p < 0.05$), but were not more frequent in the adjacent segments. Overall, positive SPECT/CT guided therapy in 64% of patients, which included facet joint/nerve root injections or re-do surgery at active sites and/or adjacent sites.

Brusko et al (2019)[4] described the largest series to date of patients with symptomatic spondylosis who underwent preoperative SPECT imaging for surgical planning. A total of 23 patients with an average age at surgery of 60.0 ± 11.0 years were included. Fifteen patients (65.2%) were male. A total of 53 spinal levels were treated, with an average of 2.30 levels treated per patient. All patients underwent fusion surgery, either lumbar (n = 14), with interbody fusion most commonly used (64.2%); or cervical (n = 9), with anterior cervical discectomy and fusion (66.6%) being the most common. The average length of hospital stay was 3.45 ± 2.32 days. One patient developed a wound infection postoperatively, requiring readmission. At the 3-month follow-up, 18 patients (78.3%) reported clinical improvement in pain. Eleven patients (47.8%) reported complete symptom resolution at the 6-month follow-up. At 1 year postoperatively, 19 patients (82.6%) reported significant relief of their symptoms following surgery. The results demonstrate that SPECT imaging could be a useful adjunct to guide surgical planning, resulting in substantial clinical improvement following surgery.

Oncology Imaging

In 2010, Pandit-Taskar et al reported on a prospective nonrandomized study of sentinel lymph node (SNL) mapping in women with endometrial and cervical cancer.[5] The study compared SPECT/CT to planar LSG in endometrial and cervical cancer to assess its ability to localize the sentinel lymph nodes (SLN). Forty patients with endometrial cancer and 10 with cervical cancer underwent preoperative lymphoscintigraphy (LSG) with 1 or 4 mCi of 99mTc sulfur colloid administered as injections into the cervix. All patients were scanned immediately with planar LSG obtained in the anterior and lateral views. SPECT/CT imaging was obtained following the planar imaging. Planar LSG alone localized SLN in 30/40 (75%) of the endometrial cancer patients while SPECT/CT localized SLN in all 40 patients (100%). In the 10 cases where SLN was not identified with planar imaging, SPECT/CT localized nodes in the external iliac, internal iliac, common iliac and obturator groups. In cervical cancer, planar LSG alone localized sentinel lymph nodes in 8/10 patients (80%) as compared to SPECT/CT, which localized nodes in all 10 patients (100%). SPECT/CT imaging was especially useful in delineating external iliac versus internal iliac or obturator nodes and the parametrial nodal uptake. The conclusion was that SPECT/CT appears to improve sentinel lymph node detection and anatomic localization as compared to planar imaging in cervical and uterine cancer.

Stoffels et al (2012) reported findings from a nonrandomized, prospective study comparing metastatic node detection and disease-free survival using single-photon emission computed tomography/computed tomography (SPECT/CT)-aided sentinel lymph node excision versus standard sentinel lymph node excision in patients with melanoma.[6] Between March 2003 and October 2008, 254 patients had standard surgery for excision of sentinel lymph nodes. After November 2008, 149 patients had SPECT/CT performed prior to sentinel lymph node excision. In the SPECT/CT group, surgical approach was changed in 33 of 149 individuals based upon SPECT/CT findings. SPECT/CT allowed sentinel lymph node excision in the head and neck area more frequently and more sentinel lymph nodes per patient were detected. The number of positive sentinel lymph nodes per patient was significantly higher in the SPECT/CT group. False negative sentinel lymph node rate was 6.8% in the SPECT/CT group and 23.8% in the group that did not have SPECT/CT. Overall survival rates were 95.9% in the SPECT/CT group and 92.1% in the group without SPECT/CT.

Marcinow et al (2013) reported results of an ongoing phase III prospective, nonrandomized trial examining the use of a novel receptor-targeted (CD206) radiotracer, 99mTc-tilmanocept, and SPECT/CT for sentinel lymph node (SLN) detection in oral cavity squamous cell carcinoma.[7] In this study, compared with planar lymphoscintigraphy (LS), SPECT/CT identified additional SLNs in 11 of 20 cases (55%). The authors concluded that SPECT/CT improves preoperative localization of SLN, including identification of SLN locations near the primary tumor when compared with planar LS imaging.

Palmedo et al (2014)[8]assessed the additional value of SPECT/CT of the trunk used in conjunction with conventional nuclear imaging and its effects on patient management in a large patient series. In 353 patients, whole-body scintigraphy (WBS), SPECT, and SPECT/CT were prospectively performed for staging and restaging. SPECT/CT of the trunk was performed in all patients. In the 308 evaluable patients (211 with breast cancer, 97 with prostate cancer), clinical follow-up was used as the gold standard. Bone metastases were confirmed in 72 patients and excluded in 236. Multistep analyses per lesion and per patient were performed. Clinical relevance was expressed in terms of downstaging and upstaging rates on a per-patient basis. In the total patient group, sensitivities, specificities, and negative and positive predictive values on a per-patient basis were 93 %, 78 %, 95 % and 59 % for WBS, 94 %, 71 %, 97 % and 53 % for SPECT, and 97 %, 94 %, 97 % and 88 % for SPECT/CT, respectively. In all subgroups, specificity and positive predictive value were significantly ($p<0.01$) better with SPECT/CT. Downstaging of metastatic disease in the total, breast cancer and prostate cancer groups using SPECT/CT was possible in 32.1 %, 33.8 % and 29.5 % of patients, respectively. Upstaging in previously negative patients by additional SPECT/CT was observed in three breast cancer patients (2.1 %). Further diagnostic imaging procedures for unclear scintigraphic findings were necessary in only 2.5 % of patients. SPECT/CT improved diagnostic accuracy for defining the extent of multifocal metastatic disease in 34.6 % of these patients.

Jimenez-Heffernan et al (2015)[9] examined the additional value of SPECT/CT over planar lymphoscintigraphy (PI) in SLN detection in malignancies with different lymphatic drainage such as breast cancer, melanoma, and pelvic tumors. From 2010 to 2013, 1,508 patients were recruited in a multicenter study: 1,182 breast cancer, 262 melanoma, and 64 pelvic malignancies (prostate, cervix, penis, vulva). PI was followed by SPECT/CT 1-3 h after injection of (99m)Tc-colloid particles. Surgery was performed the same or next day. Significantly more SNs were detected by SPECT/CT for breast cancer (2,165 vs. 1,892), melanoma (602 vs. 532), and pelvic cancer (195 vs. 138), all P < 0.001. The drainage basin mismatch between PI and SPECT/CT was 16.5% for breast cancer, 11.1% for melanoma, and 51.6% for pelvic cancers. Surgical adjustment was 17% for breast cancer, 37% for melanoma, and 65.6% for pelvic cancer. SPECT/CT detected more SNs and changed the drainage territory, leading to surgical adjustments in a considerable number of patients in all malignancies studied but especially in the pelvic cancer group because of this group's deep lymphatic drainage.

Den Toom et al (2017)[10] assessed the role of single-photon emission computed tomography with computed tomography (SPECT-CT) for the identification of sentinel lymph nodes (SLNs) in patients with early stage (T1-T2) oral cancer and a clinically negative neck (cN0). In addition to planar lymphoscintigraphy, SPECT-CT was performed in 66 consecutive patients with early stage oral cancer and a clinically negative neck. The addition of SPECT-CT to planar images was retrospectively analyzed for the number of additional SLNs, more precise localization of SLNs, and importance of anatomical information by a team consisting of a nuclear physician, surgeon, and investigator. Identification rate for both imaging modalities combined was 98% (65/66). SPECT-CT identified 15 additional SLNs in 14 patients (22%). In 2/15 (13%) of these additional SLNs, the only metastasis was found, resulting in an upstaging rate of 3% (2/65). In 20% of the patients with at least one positive SLN, the only positive SLN was detected due to the addition of SPECT-CT. SPECT-CT was considered to add important anatomical information in two patients (3%). In 5/65 (8%) of the patients initially scored SLNs on planar lymphoscintigrams were scored as non-SLNs when SPECT-CT was added. There were four false-negative SLN biopsy procedures in this cohort.

KleinJan et al (2018)[11] evaluated if and how fluorescence-guidance can help realize improvements beyond the current state-of-the-art in sentinel node (SN) biopsy procedures, use of the hybrid tracer indocyanine green (ICG)-99mTc-nancolloid was evaluated in a large cohort of patients. A prospective trial was conducted (n = 501 procedures) in a heterogeneous cohort of 495 patients with different malignancies (skin malignancies, oral cavity cancer, penile cancer, prostate cancer and vulva cancer). A total of 1,327 SN-related hotspots were identified on 501 preoperative SPECT/CT scans. Intraoperatively, a total number of 1,643 SNs were identified based on the combination of gamma-tracing (>98%) and fluorescence-guidance (>95%). In patients wherein blue dye was used (n = 300) fluorescence-based SN detection was superior over visual blue dye-based detection (22-78%). No adverse effects related to the use of the hybrid tracer or the fluorescence-guidance procedure were found and outcome values were not negatively influenced.

Mestdaugh et al (2019)[12], in a one-armed, single-center prospective trial, intended to minimize the proportion of patient that undergo bilateral elective nodal irradiation (ENI), by using lymph drainage mapping by SPECT/CT to select patients with a minimal risk of contralateral nodal failure for unilateral ENI. Patients with primary T1-4 N0-2b HNSCC of the oral cavity, oropharynx, larynx (except T1 glottic) or hypopharynx, not extending beyond the midline and planned for primary (chemo) radiotherapy, were eligible. After 99mTc-nanocolloid tracer injection in and around the tumor, lymphatic drainage is visualized using SPECT/CT. In case of contralateral lymph drainage, a contralateral sentinel node procedure is performed on the same day. Patients without contralateral lymph drainage, and patients with contralateral drainage but without pathologic involvement of any removed contralateral sentinel nodes, receive unilateral ENI. Only when tumor cells are found in a contralateral sentinel node the patient will be treated with bilateral ENI. The primary endpoint is cumulative incidence of cRF at 1 and 2 years after treatment. Secondary endpoints are radiation-related toxicity and quality of life. The removed lymph nodes will be studied to determine the prevalence of occult metastatic disease in contralateral sentinel nodes. This single-center prospective trial aims to reduce the incidence and duration of radiation-related toxicities and improve quality of life of HNSCC patients, by using lymph drainage mapping by SPECT/CT to select patients with a minimal risk of contralateral nodal failure for unilateral elective nodal irradiation.

Giammarile et al (2019)[13] provided guidelines for nuclear medicine physicians performing lymphoscintigraphy for SLN detection in patients with early NO oral cavity squamous cell carcinoma. These practice guidelines were written and have been approved by the European Association of Nuclear Medicine (EANM) and the International Atomic Energy Agency (IAEA) to promote high-quality lymphoscintigraphy. The final result has been discussed by distinguished experts from the EANM Oncology Committee, and national nuclear medicine societies. The document has been endorsed by the Society of Nuclear Medicine and Molecular Imaging (SNMMI). These guidelines, together with another two focused on Surgery and Pathology (and published in specialised journals), are part of the synergistic efforts developed in preparation for the "2018 Sentinel Node Biopsy in Head and Neck Consensus Conference".

Kwak et al (2020)[14] investigated the use of SPECT/CT quantification in guiding surgical selection of positive sentinel lymph nodes in head and neck melanoma. The authors retrospectively reviewed data from patients with cutaneous head and neck melanoma who underwent lymphoscintigraphy with SPECT/CT prior to SLN biopsy (SLNB). Quantification of radiotracer uptake from SPECT/CT data was performed using in-house segmentation software. SLNs identified using SPECT/CT were compared to SLNs identified surgically using an intraoperative γ-probe. A radioactivity count threshold using SPECT/CT for detecting a positive SLN was calculated. One hundred and five patients were included. Median number of SLNs detected was 3/patient with SPECT/CT and 2/patient with intraoperative γ-probe. The hottest node identified by SPECT/CT and intraoperative γ-probe were identical in 85% of patients. All 20 histologically positive SLNs were identified by SPECT/CT and γ-probe. On follow-up, all nodal recurrences occurred at lymph node levels with the hottest node identified by SPECT/CT and either the hottest or second hottest node identified by γ-probe during SLNB. Using our data, a SPECT/CT radioactivity count threshold of 20% would eliminate the unnecessary removal of 11% of SPECT/CT identified nodes and 12% of intraoperatively detected nodes. The authors concluded that utilizing SPECT/CT quantification, a radioactivity count threshold can be developed to guide the selective removal of lymph nodes in head and neck SLNB. Furthermore, the nodal level containing the hottest node identified by SPECT/CT quantification must be thoroughly investigated for SLNs and undergo careful follow-up and surveillance for recurrence.

Endocrine/Neuroendocrine Imaging

In 2007, a study done by Lavely and colleagues showed the following: Ninety-eight participants were diagnosed with primary hyperparathyroidism and a single adenoma.[15] Each participant had previously undergone planar imaging, SPECT scanning, and SPECT/CT fusion imaging and comparisons were made to compare the accuracy of parathyroid SPECT/CT imaging to a combination of SPECT and planar imaging for the localization of the parathyroid adenomas. The overall sensitivity for localization for all of the modalities was 60%, specificity was 99%, positive predictive value (PPV) was 80%, negative predictive value (NPV) was 97%, and area under the curve (AUC) was 80%. When SPECT/CT was compared to planar imaging, the single-phase SPECT/CT was not significantly superior to dual-phase imaging for sensitivity, AUC or PPV of localization. The dual-phase SPECT/CT did have a higher sensitivity, AUC and PPV than the dual-phase planar imaging. When SPECT/CT was compared to SPECT scan, the dual-phase SPECT/CT was superior to dual-phase SPECT sensitivity and AUC for localization. The most superior method found was early SPECT/CT in combination with any delayed imaging when compared to a single- or dual-phase planar or SPECT scan for localization of parathyroid adenoma.

A study done by Prommegger et al in 2009 looked at 116 participants with single parathyroid gland disease and primary hyperparathyroidism who had a SPECT scan and CT scan and compared to SPECT/CT scan to determine whether the SPECT/CT fusion scan was superior in detecting abnormalities in the parathyroid glands.[16] The CT scan alone predicted the position of the abnormal gland in only 75 participants. The SPECT scan alone predicted the position in 64 participants and the SPECT/CT fusion scan predicted the position of the abnormal gland in 102 participants. The sensitivity for CT scan was 70% and specificity was 94%. Sensitivity for SPECT scan was 59% with a specificity of 95%. The SPECT/CT scan showed sensitivity of 80% with a specificity of 99%. A total of 62 participants ultimately underwent surgery. The authors concluded that the use of SPECT/CT fusion imaging had a higher sensitivity and specificity than CT or SPECT imaging alone when used for preoperative localization of parathyroid glands in individuals with hyperthyroidism.

Guidelines on parathyroid imaging from the Parathyroid Task Group of the European Association of Nuclear Medicine (2009)[17] discussed dual-tracer and single-tracer parathyroid scintigraphy protocols as well as various modalities of image acquisition. Primary hyperparathyroidism is an endocrine disorder with high prevalence, typically caused by a solitary parathyroid adenoma, less frequently (about 15%) by multiple parathyroid gland disease (MGD) and rarely (1%) by parathyroid carcinoma. Patients with MGD may have a double adenoma or hyperplasia of three or all four parathyroid glands. Conventional surgery has consisted in routine bilateral neck exploration. The current trend is toward minimally invasive surgery. The success of targeted parathyroid surgery depends not only on an experienced surgeon, but also on a sensitive and accurate imaging technique. Recognizing MGD is the major challenge for pre-operative imaging, to not direct a patient towards inappropriate minimal surgery. Scintigraphy should also report on thyroid nodules that may cause confusion with a parathyroid adenoma or require concurrent surgical resection. The two main reasons for failed surgery are ectopic glands and undetected MGD. Imaging is mandatory before re-operation, and scintigraphy results should be confirmed with a second imaging technique (usually US for a neck focus, CT or MRI for a mediastinal focus). Hybrid SPECT/CT instruments should be most helpful in this setting. SPECT/CT has a major role for obtaining anatomical details on ectopic foci. However, its use as a routine procedure before target surgery is still investigational. Preliminary data suggest that SPECT/CT has lower sensitivity in the neck area compared to pinhole imaging. Additional radiation to the patient should also be considered. The guidelines also discuss aspects related to radio-guided surgery of hyperparathyroidism and imaging of chronic kidney disease patients with secondary hyperparathyroidism.

Wong et al (2015) performed a meta-analysis to determine the diagnostic utility of parathyroid scintigraphy with SPECT/CT fusion imaging for the localization of parathyroid adenoma when compared to older planar and SPECT scans.[18] Twenty-four articles were included in their analysis. Sensitivity of SPECT/CT was found to be 0.86 (confidence interval [CI] 0.81-0.90) compared to sensitivity of SPECT at (0.74; CI 0.66–0.82) and planar imaging at (0.70; CI 0.61–0.80). They concluded that using SPECT/CT imaging with parathyroid scintigraphy improves performance when compared to older planar and SPECT imaging.

In 2016 Treglia and colleagues reported on a review of 23 articles in which participants with primary hyperparathyroidism had SPECT/CT fusion imaging prior to undergoing surgery.[19] The pooled detection rate of SPECT/CT in preoperative planning of individuals with primary hyperparathyroidism was 88% (95% CI = 84% to 92%) on a per participant-based analysis and 88% (95% CI = 82% to 92%) on a per lesion-based analysis.

Touska et al (2019)[20] evaluated the accuracy of 1-stop (single patient-attendance) SPECT/CT guided ultrasound in the localization of parathyroid adenomata. The evaluation included patients with hyperparathyroidism who had undergone parathyroidectomy were identified over a 5-y period. Pathologic correlation with results from preoperative 99mTc-sestamibi SPECT/CT followed by targeted ultrasound of the neck was performed. The number of glands, the location, and the presence of concurrent thyroid disease were reviewed. The study included 146 patients (88% single gland, 7% multigland, and 5% negative explorations). The sensitivity and specificity of SPECT/CT-guided ultrasound were 83% and 96%, respectively. The sensitivity was higher for single gland (87%) than multigland disease (70%). The addition of ultrasound significantly increased the sensitivity of the technique ($P < 0.001$). The presence of concurrent thyroid disease (nodules/thyroiditis) did not adversely affect sensitivity (85% confidence interval, 74.2%-93.1%) compared with normal or atrophic glands (82% confidence interval, 72.3%-89.7%). The authors concluded that SPECT/CT-guided ultrasound represents a useful means of localizing parathyroid adenomata, thereby aiding the decision to undertake minimally invasive or exploratory surgery. The 1-stop approach offers patient convenience and enables the radiologist to use the additive benefits of both modalities to optimize localization.

A study by Chen et al discussed the incremental value of ^{131}I SPECT/CT in the management of patients with differentiated thyroid carcinoma (DTC).[21] Planar imaging was performed on 66 consecutive DTC patients who were considered to have locally advanced or metastatic disease after total or nearly total thyroidectomy. SPECT/CT was added for patients whose planar findings were inconclusive. The planar images were interpreted by two experienced nuclear medicine physicians. Interpretation of the SPECT/CT images was a consensus opinion of one of the nuclear medicine physicians and an experienced radiologist.

Fusion images were considered to improve image interpretation when they better localized sites of increased ^{131}I uptake. The final diagnosis was verified by pathologic findings, other imaging modalities and clinical follow-up. Both site-based and patient-based analyses were performed, and the impact of SPECT/CT results on therapeutic strategy was assessed.

Spanu et al (2018)[22] evaluated the diagnostic role of ^{131}I SPECT/CT in detecting metastases in papillary thyroid microcarcinoma (PTMC) patients during long-term follow-up and whether the procedure should be included in the current diagnostic protocol. The authors retrospectively studied 351 consecutive PTMC patients who had undergone thyroidectomy and radioiodine therapy; 21 were at high risk, 94 at low risk, and 236 at very low risk. During follow-up, the patients underwent diagnostic ^{131}I whole-body scanning (WBS) followed by SPECT/CT. WBS found 248 radioiodine-avid foci in 126 patients, and SPECT/CT found 298 in 139 patients, confirming all foci found on WBS. SPECT/CT also correctly classified 76 of the avid foci as unclear or wrongly classified on WBS. Globally, SPECT/CT detected and correctly classified 64 neoplastic lesions in 27 of 30 patients with metastases, and WBS evidenced 39 of 64 lesions, 28 of which were unclear or wrongly classified, in 16 of the 30 patients. Nineteen of 27 patients, including 13 at very low risk, had only neck metastases, 9 of 19 being T1aN0M0 with an undetectable thyroglobulin level. Three of 27 patients, including 1 at very low risk, had only distant metastases with an undetectable or very low thyroglobulin level. Five of 27 patients had neck and distant metastases with a thyroglobulin level <2.5 ng/mL in 1 case, between 2.5 and 10 in 3 cases, and >10 in the remaining case. SPECT/CT also reduced WBS false-positive results in 15 of 139 patients (10.8%). SPECT/CT had an incremental value over WBS in 38.1% of patients with positive findings and changed the classification and therapeutic management in 21.6%. Metastases occurred in 8.5% of patients during long-term follow-up. SPECT/CT performed better than WBS, particularly in patients at very low risk with inconclusive WBS results, a TNM stage of T1aN0M0, and an undetectable or very low level of thyroglobulin. Prolonged surveillance is justified in PTMC patients, and wider use of ^{131}I SPECT/CT in the diagnostic protocol was suggested by the authors.

Bural et al (2012)[23] assessed the clinical utility of SPECT/CT in subjects with endocrine and neuroendocrine tumors compared to SPECT alone. Fourty-eight subjects (31 women;17 men; mean age 54±11) with clinical suspicion or diagnosis of endocrine and neuroendocrine tumor had 50 SPECT/CT scans (32 Tc-99m MIBI, 5 post treatment I-131, 8 In-111 Pentetreotide, and 5 I-123 MIBG). SPECT alone findings were compared to SPECT/CT and to pathology or radiological follow-up. From the 32 Tc-99m MIBI scans, SPECT accurately localized the lesion in 22 positive subjects while SPECT/CT did in 31 subjects. Parathyroid lesions not seen on SPECT alone were smaller than 10 mm. In five post treatment I-131 scans, SPECT alone neither characterized, nor localized any lesions accurately. SPECT/CT revealed 3 benign etiologies, a metastatic lymph node, and one equivocal lesion. In 8 In-111 Pentetreotide scans, SPECT alone could not localize primary or metastatic lesions in 6 subjects all of which were localized with SPECT/CT. In five I-123 MIBG scans, SPECT alone could not detect a 1.1 cm adrenal lesion or correctly characterize normal physiologic adrenal uptake in consecutive scans of the same patient with prior history of adrenelectomy, all of which were correctly localized and characterized with SPECT/CT. The authors concluded that SPECT/CT was superior to SPECT alone in the assessment of endocrine and neuroendocrine tumors. It is better in lesion localization and lesion characterization leading to a decrease in the number of equivocal findings.

Pulmonary Conditions

Mazurek et al (2015)[24] evaluated the utility of SPECT/CT scintigraphy in the diagnosis of PE compared to planar scintigraphy and SPECT methods. The study group consisted of 109 consecutive patients suspected of having PE referred for performing lung scintigraphy. The inclusion criteria were: performance of perfusion planar, SPECT and SPECT/CT scans; availability of clinical data covering a 6-month follow-up period, and D-dimer level testing. The number of eligible patients was 84. PE was reported in patients with at least 1 segmental or 2 subsegmental perfusion defects without parenchymal abnormalities on CT scans. PE was excluded when there was a normal perfusion pattern or perfusion defects were caused by lung parenchymal abnormalities or were not arranged in accordance with the pulmonary vasculature. Twenty-six patients (31%) had a final diagnosis of PE. The sensitivity and specificity values of each method were as follows: planar(Q) 73 and 43%, SPECT(Q) 88 and 47% and SPECT/CT(Q) 100 and 83%. SPECT/CT(Q) yielded a significantly higher diagnostic accuracy than planar(Q) ($p < 0.001$) and SPECT(Q) ($p < 0.001$) scans. The authors concluded that hybrid SPECT/CT imaging had a high diagnostic efficacy in the diagnosis of PE.

Milia et al (2017)[25] compared diagnostic accuracy of V/P SPECT combine with simultaneous CT with a hybrid SPECT/CT scanner versus V/P SPECT and CTA in patients with acute pulmonary embolism. A total of 314 patients were available during the study period, with the diagnosis of PE confirmed in 70 (22.29%) of them. The overall population sensitivity and specificity was 90.91% and 92.44%, respectively for V/P SPECT, 80% and 99.15%, respectively, for CTA, and 95.52% and 97.08% for V/P SPECT/CT. SPECT/CT performed better than V/P SPECT (AUC differences=0.0419, P=0.0043, 95% CI; 0.0131-0.0706) and CTA (AUC differences=0.0681, P=0.0208, 95% CI; 0.0103-0.1259)). Comparing imaging modalities when contrast agent could be administered, sensitivity and specificity increased and V/P SPECT/CT was significantly better than CTA (AUC differences=0.0681, P=0.0208, 95% CI; 0.0103-0.1259) and V/P SPECT (AUC differences=0.0659, P=0.0052, 95% CI; 0.0197-0.1121). In case of non-contrast enhancement, there was non-significant increase of specificity. Secondary findings on CT impacted patient management in 14.65% of cases. The authors concluded that combined V/P SPECT/CT scanning had a higher diagnostic accuracy for detecting acute PE than V/P SPECT and CTA alone.

Thanuja et al (2020)[26] assessed the incremental value of V/Q SPECT/CT over conventional V/Q planar scintigraphy and V/Q SPECT to determine if Q only SPECT/CT without the conventional ventilation component could replace the current imaging protocol in diagnosing pulmonary embolism. A total of 66 patients fulfilled the initial inclusion and exclusion criteria, with 23 patients as positive for PE and 43 patients ruled out of having PE based on the reference standard. Sensitivity and specificity for V/P planar scintigraphy, V/Q SPECT, and V/Q SPECT-CT were 86.9% and 39.5%, 91.3% and 55.8%, and 100% and 97.6% respectively. Overall, SPECT/CT resulted in significantly higher diagnostic accuracy than planar and SPECT imaging respectively ($p<0.05$). Q-only SPECT/CT significantly over diagnosed pulmonary embolism in 12 patients ($p<0.05$).

Das et al (2021)[27] reviewed the clinical utility of V/Q SPECT/CT for diagnosing PE in patients hospitalized with severe acute respiratory syndrome coronavirus 2 (SARS-CoV2). Of the 33 patients imaged with Q-SPECT/CT, 6 patients (3 men, 3 women) had a laboratory confirmed diagnosis of COVID-19 (mean age, 55, +/- 11.4 years, range 33-68). All patients had a current diagnosis of malignancy and had a moderate or high pre-test probability for PE (mean Wells score 2.8, range 2-4). Q-SPECT/CT was positive in 4/6 (67%) of patients. Distribution of pulmonary emboli was bilateral and segmental in 75% of patients. Ancillary acute findings on SPECT/CT included bilateral parenchymal ground glass opacities (n = 5), pleural effusions (n = 2), and pneumomediastinum (n = 1). The authors concluded that V/Q SPECT/CT does have clinical utility for the diagnoses of PE in patients with COVID-19 when there is a contraindication for iodinated contrast media and a moderate or high pre-test probability for PE.

Farr et al (2015)[28] evaluated the ability of baseline perfusion defect score (DS) on SPECT to predict the development of severe symptomatic radiation pneumonitis (RP) and to evaluate changes in perfusion on SPECT as a method of lung perfusion function assessment after curative radiotherapy for non-small-cell lung cancer (NSCLC). Perfusion SPECT/CT and global pulmonary function tests (PFT) were performed before RT and four times during follow-up. A total of 71 consecutive patients were included in the study. Baseline DS was associated with chronic obstructive pulmonary disease. A significant inverse correlation was found between baseline DS and forced expiratory volume in 1 s and diffusing capacity of the lung for carbon monoxide. Patients with severe RP had significantly higher baseline total lung DS (mean 5.43) than those with no or mild symptoms (mean DS 3.96, $p < 0.01$). PFT results were not different between these two groups. The odds ratio for total lung DS was 7.8 (95% CI 1.9 - 31) demonstrating the ability of this parameter to predict severe RP. Adjustment for other potential confounders known to be associated with increased risk of RP was performed and did not change the odds ratio. The median follow-up time after RT was 8.4 months. The largest DS increase of 13.3% was associated with severe RP at 3 months of follow-up ($p < 0.01$). The development of severe RP during follow-up was not associated with changes in PFT results. The authors concluded that perfusion SPECT/CT was a valuable method for predicting severe RP and for assessing changes in regional functional perfusion after curative RT comparable with global PFT.

Infections/Inflammatory Conditions
Filippi and Schillaci (2006)[29] reported on a prospective study evaluating the usefulness of SPECT/CT hybrid imaging for the functional anatomic mapping of bone and joint infections. (99m)Tc-HMPAO scintigraphy was performed on 28 consecutive patients. (99m)Tc-HMPAO scintigraphy was true-positive for infection in 18 of 28 patients (for a total of 21 sites of uptake) and true-negative in 10 of 28 subjects. SPECT/CT provided an accurate anatomic localization of all positive foci. With regard to the final diagnosis, SPECT/CT added a significant clinical contribution in 10 of 28 patients (35.7%). In fact, SPECT/CT differentiated soft-tissue from bone involvement both in patients with osteomyelitis and in patients with orthopedic implants, allowed correct diagnosis of osteomyelitis in patients with structural alterations after trauma, and identified synovial infection without prosthesis involvement in patients with a knee implant.

Erba et al (2012)[30] assessed the value of (99m)Tc-HMPAO-WBC scintigraphy including SPECT/CT acquisitions in a series of 131 consecutive patients with suspected infectious endocarditis (IE). Patients with permanent cardiac devices were excluded. (99m)Tc-HMPAO-WBC scintigraphy results were correlated with transthoracic or transesophageal echocardiography, blood cultures, and the Duke Endocarditis Service criteria. Scintigraphy was true-positive in 46 of 51 and false-negative in 5 of 51 cases (90% sensitivity, 94% negative predictive value, and 100% specificity and positive predictive value). No false-positive results were found, even in patients with early IE evaluated within the first 2 mo from the surgical procedure. In 24 of 51 patients with IE, we also found extracardiac uptake, indicating septic embolism in 21 of 24. Despite the fact that septic embolism was found in 11 of 18 cases of Duke-definite IE, most of the added value from the (99m)Tc-HMPAO-WBC scan for decision making was seen in patients in whom the Duke criteria yielded possible IE. The scan was particularly valuable in patients with negative or difficult-to-interpret echocardiographic findings because it correctly classified 11 of 88 of these patients as having IE. Furthermore, 3 patients were falsely positive at echocardiography but correctly negative at (99m)Tc-HMPAO-WBC scintigraphy: these patients had marantic vegetations.

Erba et al (2014)[31] evaluated the diagnostic performance of (99m)Tc-HMPAO-leucocyte ((99m)Tc-HMPAO-WBC) scintigraphy in a consecutive series of 55 patients (46 men and 9 women, mean age 71 +/- 9 years, range 50 - 88 years) with a suspected late or a low-grade late vascular prosthesis infection (VPI), also comparing the diagnostic accuracy of WBC with that of other radiological imaging methods. All patients suspected of having VPI underwent clinical examination, blood tests, microbiology, US and CT, and were classified according to the Fitzgerald criteria. (99m)Tc-HMPAO-WBC planar, SPECT and SPECT/CT imaging identified VPI in 43 of 47 patients (20 of these also showed infection at extra-prosthetic sites). In the remaining eight patients without VPI, different sites of infections were found. The use of SPECT/CT images led to a significant reduction in the number of false-positive findings in 37% of patients (sensitivity and specificity 100 %, versus 85.1% and 62.5% for stand-alone SPECT). Sensitivity and specificity were 34% and 75% for US, 48.9% and 83.3% for CT, and 68.1% and 62.5% for the FitzGerald classification. Perioperative mortality was 5.5%, mid-term mortality 12%, and long-term mortality 27%. Survival rates were similar in patients treated with surgery and antimicrobial therapy compared to patients treated with antimicrobial therapy alone (61% versus 63%, respectively), while infection eradication at 12 months was significantly higher following surgery (83.3% versus 45.5%). SPECT/CT is useful for detecting, localizing and defining the extent of graft infection in patients with late and low-grade late VPI with inconclusive radiological findings.

SUMMARY OF EVIDENCE

Based on the above literature, SPECT/CT fusion imaging may be useful in providing precise localization of abnormal uptake and “next best step” for a procedure, a reduction in inaccurate or equivocal interpretations, improved timing of correlative functional and anatomic findings, eliminates unnecessary separate imaging further expediting correct clinical diagnosis and is more expedient for the patient and clinician in the appropriate circumstances.

SUPPLEMENTAL INFORMATION

The Society of Nuclear Medicine and Molecular Imaging (SNMMI)[32]

SNMMI Procedure Guideline for SPECT/CT Imaging (November 2012) states that indications for SPECT/CT might include but are not limited to imaging of the following:

- Tumors
- Thyroid disorders
- Parathyroid disorders
- Skeletal disorders
- Inflammation or infection
- Lymphatic system
- Heart disorders
- Brain disorders

The American Society of Nuclear Cardiology (ASNC)[33]

ASNC guideline for cardiac SPECT/CT and PET/CT states (2013) states “the clinical applications of hybrid cardiac imaging include but are not limited to attenuation-corrected MPI, coronary artery calcium scoring, coronary CTA, fusion imaging and localization, cardiac viability, and imaging of inflammatory cardiac conditions”.

Government Regulations

National or Local Coverage Determinations:

There are no national or local coverage determinations on this topic. Medicare has a fee for 78072.
Medicare has facility fees and work RVUs attached to codes 78830 and 78832.

(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

- PET/CT Fusion
- Positron Emission Tomography (PET) Scans -Cardiac Applications
- Positron Emission Tomography (PET) Scans -Miscellaneous Applications
- Positron Emission Tomography (PET) Scans-Oncologic Applications

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2023, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
7/1/12	5/15/12	5/15/12	Joint policy established
1/1/14	10/17/13	10/25/13	Routine review of non-covered service. No change in policy status.
5/1/15	2/17/15	2/27/15	Routine review; updated references and rationale.
7/1/16	4/19/16	4/19/16	Routine policy maintenance, no change in policy status
7/1/17	5/4/17	5/3/17	Policy status changed to reflect coverage of SPECT/CT fusion imaging for parathyroid tumors for patients meeting specific criteria. Added CPT code 78072 to policy. Other indications remain experimental/ investigational.
7/1/18	4/17/18	4/17/18	Routine policy maintenance, deleted several outdated references. No change in policy status.
7/1/19	4/16/19		Routine policy maintenance, no change in policy status.
7/1/20	4/14/20		Routine policy maintenance, added codes 78830 and 78832 as E/I effective 1/1/20. No change in policy status.
7/1/21	4/20/21		Routine policy maintenance, no change in status.
1/1/22	10/19/21		Established indications expanded with criteria aligning with vendor.
1/1/23	10/18/22		Routine policy maintenance, no change in policy status.
1/1/24	10/17/23		Routine policy maintenance, no change in policy status. Vendor managed: Carelon (ds)

Next Review Date: 4th Qtr. 2024

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: SPECT/CT FUSION IMAGING

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered for imaging of the parathyroid glands when used for anatomic localization prior to parathyroid surgery.
BCNA (Medicare Advantage)	Refer to government regulatory section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- 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.