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Clinical UM Guideline

Subject:	Single Photon Emission Computed Tomography Scans for Noncardiovascular Indications		
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Description

This document addresses the use of single photon emission computed tomography (SPECT) for non-cardiovascular indications. SPECT provides three-dimensional images of the concentration of a radiopharmaceutical within various tissues and organs, and is an established imaging modality for a number of different indications.

Note: Please see the following related documents for additional information:

- CG-MED-77 SPECT/CT Fusion Imaging

Clinical Indications

Medically Necessary:

SPECT scans are considered **medically necessary** for **any** of the following:

1. Bone and joint conditions—to differentiate between infectious, neoplastic, avascular or a traumatic process.
2. Brain tumors—to differentiate between lymphomas and infections such as toxoplasmosis particularly in the immunosuppressed, or recurrent tumor vs. radiation changes, when PET is not available.
3. Dopamine transporter (DaT) scan—when criteria (a) and (b) are met:
    a. To differentiate Parkinsonian syndromes associated with nigrostriatal degeneration from other disorders:
        i. To differentiate Parkinsonian syndrome from non-neurodegenerative disorders such as essential tremor or drug-induced tremor; **or**

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ii. In individuals with dementia, to differentiate between Alzheimer disease and dementia with Lewy bodies; **and**

b. The diagnosis is unclear and the results are likely to guide management.

4. Liver hemangioma—using labeled red blood cells to further define lesions identified by other imaging modalities.
5. Liver malignancies—to determine arterial hepatic perfusion as a component of selective internal radiation therapy (SIRT) or radioembolization treatment.
6. Localization of abscess/infection/inflammation in soft tissues or cases of fever of unknown origin.
7. Neuroendocrine tumors (for example, 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).
8. Parathyroid imaging.
9. Renal - Dimercaptosuccinic acid (DMSA) scan to assess the status of kidney for scarring and function.
10. 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 are indeterminate.

~~9.~~

Not Medically Necessary:

For noncardiovascular indications, SPECT scans are considered **not medically necessary** for all other purposes, including, but not limited to:

1. Attention Deficit and Hyperactivity Disorder.
2. Chronic fatigue syndrome.
3. Colorectal carcinoma (for example, used with the monoclonal antibody or IMMU-4 and CEA-Scan® [Immunomedics Inc., Morris Plains, New Jersey]).
4. Dopamine transporter (DaT) scan for all indications other than those listed as medically necessary.
5. Evaluation or management of cerebrovascular accident (CVA, stroke), subarachnoid hemorrhage, or transient ischemic attack.
6. Malignancies other than those listed as medically necessary.
7. Neuropsychiatric disorders without evidence of cerebrovascular disease.
8. Pervasive development disorders (PDD).

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9. Prostate carcinoma (for example, used with the monoclonal antibody ProstaScint® [EUSA Pharma, Langhorne, PA], with or without fusion imaging with computed tomography or magnetic resonance imaging).
10. Scintimammography for breast cancer.
11. ~~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 are indeterminate.~~

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. 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.

Parathyroid
When services are Medically Necessary:

CPT

78071	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT)

ICD-10 Diagnosis

All diagnoses

~~*Tumors, inflammatory processes*~~*Other body areas*
When services are Medically Necessary:

CPT

78803	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), single area (eg, head, neck, chest, pelvis), single day imaging

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78831	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (eg, pelvis and knees, abdomen and pelvis), single day imaging, or single area imaging over 2 or more days

ICD-10 Diagnosis

C40.00-C41.9	Malignant neoplasm of bone and articular cartilage of limbs, other and unspecified sites
C73	Malignant neoplasm of thyroid gland
C74.00-C74.92	Malignant neoplasm of adrenal gland
C75.0	Malignant neoplasm of parathyroid gland
C7A.00-C7A.8	Malignant neuroendocrine tumors
C7B.00-C7B.8	Secondary neuroendocrine tumors
C79.70-C79.72	Secondary malignant neoplasm of adrenal gland
C80.0	Disseminated malignant neoplasm, unspecified
D13.4	Benign neoplasm of liver
D18.03	Hemangioma of intra-abdominal structures
D18.09	Hemangioma of other sites
D35.00-D35.02	Benign neoplasm of adrenal gland
D35.1	Benign neoplasm of parathyroid gland
D3A.00-D3A.8	Benign neuroendocrine tumors
D37.6	Neoplasm of uncertain behavior of liver, gallbladder and bile ducts
D44.0	Neoplasm of uncertain behavior of thyroid gland
D44.10-D44.12	Neoplasm of uncertain behavior of adrenal gland
D44.2	Neoplasm of uncertain behavior of parathyroid gland
E20.0-E20.9	Hypoparathyroidism
E21.0-E21.5	Hyperparathyroidism and other disorders of parathyroid gland
E34.0	Carcinoid syndrome
M00.00-M02.9	Infectious arthropathies
M60.000-M60.9	Myositis
M65.00-M65.9	Synovitis and tenosynovitis

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M71.00-M71.9	Other bursopathies
M86.00-M86.9	Osteomyelitis
M87.00-M87.9	Osteonecrosis
N00.0-N08	Glomerular diseases
N10-N16	Renal tubulo-interstitial diseases
N17.0-N19	Acute kidney failure and chronic kidney disease
R10.0-R10.9	Abdominal and pelvic pain
R11.0-R11.2	Nausea and vomiting
R14.0-R14.3	Flatulence and related conditions
R16.0	Hepatomegaly, not elsewhere classified
R16.2	Hepatomegaly with splenomegaly, not elsewhere classified
R17	Unspecified jaundice
R18.0-R18.8	Ascites
R19.00-R19.8	Other symptoms and signs involving the digestive system and abdomen
R50.2-R50.9	Fever of other and unknown origin
R93.2	Abnormal findings on diagnostic imaging of liver and biliary tract
R93.3	Abnormal findings on diagnostic imaging of other parts of digestive tract
R93.5	Abnormal findings on diagnostic imaging of other abdominal regions, including retroperitoneum

When services may be Medically Necessary when criteria are met:
For the procedure codes listed above for the following diagnoses

ICD-10 Diagnosis	
C22.0-C22.9	Malignant neoplasm of liver and intrahepatic bile ducts
C70.0	Malignant neoplasm of cerebral meninges
C71.0-C71.9	Malignant neoplasm of brain
C72.20-C72.59	Malignant neoplasm of cranial nerves
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C79.31-C79.32	Secondary malignant neoplasm of brain and cerebral meninges
C81.00-C88.9	Lymphomas

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D01.5	Carcinoma in situ of liver, gallbladder and bile ducts
D32.0	Benign neoplasm of cerebral meninges
D33.0-D33.2	Benign neoplasm of brain
D33.3	Benign neoplasm of cranial nerves
D42.0	Neoplasm of uncertain behavior of cerebral meninges
D43.0-D43.2	Neoplasm of uncertain behavior of brain
D43.3	Neoplasm of uncertain behavior of cranial nerves
D49.6	Neoplasm of unspecified behavior of brain
G20	Parkinson's disease
G21.0-G21.9	Secondary parkinsonism
G30.0-G30.9	Alzheimer's disease
G31.01-G31.9	Other degenerative diseases of nervous system, not elsewhere classified
G40.011-G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable
G40.111-G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable
G40.211-G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable
G43.001-G43.919	Migraine
G44.001-G44.89	Other headache syndromes
G47.411-G47.429	Narcolepsy and cataplexy
G93.0-G93.9	Other disorders of brain
R22.0	Localized swelling, mass and lump, head
R51.0-R51.9	Headache
R56.00-R56.9	Convulsions, not elsewhere classified
Z76.82	Awaiting organ transplant status [specified as liver transplant]

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for all other diagnoses not listed; or when the code describes a procedure or situation designated in the Clinical Indications section as not medically necessary.

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Other

When services may be Medically Necessary when criteria are met:

CPT

78699	Unlisted nervous system procedure, diagnostic nuclear medicine [when specified as SPECT/SISCOM for the preoperative evaluation of individuals with intractable focal epilepsy]

ICD-10 Diagnosis

G40.011-G40.019	Localization-related (focal) (partial) idiopathic epilepsy and epileptic syndromes with seizures of localized onset, intractable
G40.111-G40.119	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with simple partial seizures, intractable
G40.211-G40.219	Localization-related (focal) (partial) symptomatic epilepsy and epileptic syndromes with complex partial seizures, intractable

When services are Not Medically Necessary:

For the procedure and diagnosis codes listed above when criteria are not met or for all other diagnoses not listed.

When services are also Not Medically Necessary:

For the following procedure codes; or when the code describes a procedure designated in the Clinical Indications section as not medically necessary.

~~**CPT**~~

~~78699~~	~~Unlisted nervous system procedure, diagnostic nuclear medicine [when specified as SPECT/SISCOM for the preoperative evaluation of individuals with intractable focal epilepsy]~~

HCPCS

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A9507	Indium In-111 capromab pendetide, diagnostic, per study dose, up to 10 millicuries [Prostascint]
S8080	Scintimammography (radioimmunoscintigraphy of the breast), unilateral, including supply of radiopharmaceutical

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

SPECT is an imaging method designed to provide information about the functional level of a specific part of the body. SPECT involves the injection of a low-level radioactive chemical, called a radiotracer, into the bloodstream. The images reflect the manner in which the tracer is processed by the body and thus this technology provides functional information, in contrast to the structural information provided by computed tomography (CT), magnetic resonance imaging (MRI) and ultrasound. Using various imaging protocols, scans are made with a device that can detect radioactivity in the body. Detailed information is generated by a SPECT camera, gamma camera, or tomograph. Each radiotracer used with SPECT is a radiation emitting substance that is used alone or attached to an element appropriate for obtaining specific information. For example, certain types of proteins called antibodies attach to specific types of tumors. Due to the radiotracer's ability to also attach to antibodies, the antibody facilitates coupling of the radiotracer to the tumor, enabling identification of the tumor's precise anatomical location.

SPECT can provide information about the level of chemical or cellular activity within an organ or system as well as provide structural information. For instance, areas of increased activity, such as inflammation in an abscess, are detectable via SPECT scan. Patterns of distribution of the radiotracer can be correlated with various diseases. SPECT has 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 evaluated. SPECT scans may be repeated to follow the course of a disease.

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SPECT is typically performed as an ambulatory (outpatient) procedure. 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 the body with little interference and is imaged. SPECT cameras can image large areas of the body, or the entire body.

Information acquired by SPECT frequently augments or confirms observations obtained by other testing. SPECT may also provide information not obtainable by means other than positron emission tomography (PET), which may provide additional information in some settings. The images obtained through PET are generally of higher quality than those provided by SPECT; however, the availability, sensitivity, specificity, and impact on clinical outcomes when using PET varies by clinical condition. For many conditions, SPECT has been found to be as useful as PET and it is generally more available.

Both PET and SPECT 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.

Currently, there is sufficient evidence in peer-reviewed medical literature in the form of randomized controlled clinical trials (RCTs) to support the use of SPECT in a variety of disease processes. The literature supports this imaging for the diagnosis and evaluation of selected malignancies; the evaluation of some specific central nervous system (CNS) disorders (for example, brain tumor, toxoplasmosis); and the evaluation of bone, joint and soft tissue disorders to distinguish between inflammation and infection. SPECT has been shown to be safe and effective for the monitoring of changes in these conditions over time, comparable to the gold standard of PET scanning. In addition, non-randomized controlled clinical trials have established the safety and efficacy of SPECT in identifying infections. Early identification of acute infection, such as in appendicitis, may be critical to facilitate early intervention and thus favorable outcomes.

Renal

A DMSA renal scan using Technetium-99m labeled dimercaptosuccinic acid (DSMA) is a diagnostic imaging exam that evaluates the function, size, shape and position of the kidneys and detects scarring caused by frequent

infections. Mohkam and colleagues (2010) evaluated 1476 children with pyelonephritis who had renal ultrasound, voiding cystourethrography (VCUG) and DMSA scanning. A total of 79% of the children with pyelonephritis had evidence of pyelonephritis on DMSA scan. Renal ultrasound results were abnormal in 31.5% of children, VCUG showed vesicoureteral reflux in 25.9% of the children. The American Urological Association 2017 Clinical Practice Guideline recommends a DMSA scan for children with vesicoureteral reflux to detect new renal scarring when renal ultrasound is abnormal.

Cerebrovascular Disease

The use of SPECT for the evaluation and management of cerebrovascular disease, including cerebrovascular accidents (CVA, stroke), subarachnoid hemorrhages, and transient ischemic attacks (TIA) has been superseded by newer, more accurate imaging modalities. In recent years, the use of magnetic resonance angiography (MRA) and computed tomography angiography (CTA) has become the standard of care for these conditions and the use of SPECT has become obsolete in the presence of superior technologies. Perfusion MRI and CT perfusion are more akin to SPECT, which measures perfusion, not vessel anatomy. In addition, other advanced imaging modalities, such as PET, have replaced SPECT for evaluating certain types of cancer, including lymphoma.

Pervasive Development Disorder

The diagnosis of pervasive developmental disorder (PDD) can be complex and difficult due to the diversity of the presentation of symptoms and their severity. Due to the multitude of possible causes, and potential confusion with other conditions, many tests exist that may or may not be appropriate. It is vital that parents of children suspected of the disorder seek early diagnosis and care for their child to increase any potential benefits of treatment. The American Academy of Neurology Practice Guideline states the following: “There is no evidence to support a role for functional neuroimaging studies in the clinical diagnosis of autism at the present time” (Filipek, 2000).

Diagnosis of Brain Death

Early diagnosis of brain death allows for discontinuation of artificial ventilation and early organ transplants. Brain death is determined by clinical findings, such as no brainstem reflexes and no responses to external stimuli.

Diagnostic tests can also be used to assist in the diagnosis of brain death, including electroencephalography (EEG), evoked potentials, Doppler ultrasound, angiography, and SPECT. The typical SPECT finding of brain death is an empty skull appearance. The use of SPECT has been studied in helping to confirm the diagnosis of brain death. However, the current evidence is comprised of published studies with only small sample populations (Bertagna, 2009; Munari, 2005; Okuyaz, 2004).

Okuyaz and colleagues (2004) reported on 8 deeply comatose and clinically brain dead children who had SPECT and then observation for at least 24 hours following their SPECT. A total of 6 of the children showed lack of perfusion in the cerebrum and empty skull appearance. The 2 newborns had two consecutive SPECT scans. The first SPECT showed perfusion not consistent with brain death image. The second SPECT scans showed no perfusion. The authors concluded that while SPECT may confirm the diagnosis of brain death, clinical findings are still the mainstay for the diagnosis. Munari and colleagues (2005) compared SPECT with cerebral angiography in 20 clinically brain dead individuals. In order to avoid time lag, after SPECT, all individuals immediately underwent angiography before data analysis and map reconstruction. The results of the SPECT were interpreted by a specialist in nuclear medicine and the angiography results were interpreted by a neuroradiologist. Both were blinded to the results of the other evaluation. Both SPECT and angiography confirmed brain death, showing absence of brain perfusion in 19 of 20 individuals. Further studies with larger groups are necessary to determine if SPECT can accurately diagnose the absence of brain perfusion. Joffe and colleagues (2010) conducted a literature review to determine the usefulness of SPECT testing to confirm the diagnosis of brain death. Using clinically confirmed brain death as the gold standard of comparison, the sensitivity and specificity of SPECT was 90% and 100%, respectively. Using cerebral angiography as the gold standard of comparison, the sensitivity of SPECT was 100% and the specificity could not be determined as there were no individuals without clinical brain death undergoing the tests. The authors concluded that since SPECT is being used to diagnose the state of death, specificity of SPECT should be clarified.

Parkinsonian Syndromes

Dopamine transporter (DaT) scan injection (Ioflupane I 123) is a molecular imaging agent used during a SPECT scan to determine the location and concentration of dopamine transporters in the synapses of striatal dopaminergic neurons. It is becoming increasingly utilized as a tool for detecting the degeneration of the dopaminergic pathway,

distinguishing those individuals with Parkinsonian syndromes associated with nigrostriatal degeneration from those with other disorders (for example, non-neurodegenerative disorders such as essential tremor [ET] or drug-induced tremor, or in individuals with dementia, to differentiate between Alzheimer disease and dementia with Lewy bodies [DLB]).

Kupsch and colleagues (2012) reported on an RCT (non-blinded) that compared DaT scanning in 102 individuals with a control group of 112 individuals. The study authors evaluated the clinical management of Parkinson's, diagnosis, confidence of diagnosis, quality of life (QOL), health resource use, and the safety in those with uncertain diagnosis. Participants were evaluated at baseline, 4 weeks, 12 weeks, and 1 year. SPECT scans were performed at baseline and then evaluated for changes in clinical management plan and confidence of diagnosis. The most frequent change in clinical management at 12 weeks and 1 year was the initiation of medication not previously considered at baseline (50% in the imaging group compared with 21% in the control group). More participants in the imaging group had a change in their clinical management at 12 weeks and 1 year post-treatment when compared with the control group. Other changes in clinical management included more aggressive dopaminergic therapy and initiation of dopaminergic therapy. At 4 weeks, 45% of the DaT group had a change in diagnosis from baseline compared with 9% of the control group. At 12 weeks, 46% of the DaT group had a change in diagnosis from baseline compared with 12% in the control group. At 1 year, 54% of the DaT group had a change in diagnosis from baseline compared with 23% in the control group. All these reported changes were in the direction of better agreement between clinical diagnosis and imaging results. Confidence of diagnosis for participants suspected of Parkinson's or non-Parkinson's was higher at the 4 weeks, 12 weeks and 1 year with DaT imaging when compared with control group. QOL questionnaires and health resource use were similar between the imaging and control groups (no significant differences between the groups were observed).

Several other studies have been conducted evaluating the clinical utility of DaT scans in diagnosing and evaluating movement disorders, including Parkinson's disease similar to the study by Kupsch and colleagues (2012) (Bairactaris, 2009; Bajaj, 2014; Bega, 2015; Bhattacharjee, 2019; Catafau, 2004; Cerasa, 2016; Gayed, 2015; Marshall, 2009; Mirpour, 2018; O'Brien, 2014; Seibyl, 2014; Vlaar, 2008).

A randomized, open label, single-dose, multicenter trial assessed changes in clinical management, safety, and QOL related to DaT scan compared with a clinical diagnosis in 267 individuals with clinically uncertain Parkinsonian

syndrome (Kupsch, 2013). Individuals were randomized to either DaT scan (n=131) or a control group (n=136). The results showed a significant difference between the DaT scan group compared to the control group in clinical management after 12 weeks (p=0.004), and significantly more DaT scan participants had changes in diagnosis at 4 weeks and at 12 weeks (both p<0.001) compared to participants in the control group; however, there was no significant difference in the total score for QOL found between the two groups. There were no deaths or serious adverse events. While this study did not show a significant change in QOL, it did show that DaT scan is safe and impactful in the clinical management of individuals with clinically uncertain Parkinsonian syndrome.

Accurate differentiation of Parkinsonian syndromes from non-neurodegenerative disorders such as ET or drug-induced tremor may be pivotal to informed disease management decision-making, for example, in guiding cessation of therapy in individuals who have failed to respond unequivocally to levodopa; in individuals with suspected ET who are possible candidates for deep brain stimulation (DBT) and where an accurate diagnosis determines the target of DBT, and in drug-induced tremor, avoidance or discontinuation of causative drugs, or symptomatic treatment (when the causative agent cannot be discontinued, lowered, or switched to an alternative drug).

DaT imaging using SPECT is increasingly being incorporated into consensus diagnostic criteria for DLB. Accurate recognition of DLB is important for disease management (both nonpharmacologic, behavioral and drug treatment strategies), and is essential for the development of disease-modifying treatments. Correct diagnosis is imperative as optimal treatment choice – based on considerations of efficacy and limitation of significant side effects – are specific to DLB. A Cochrane Review (McCleery, 2015) evaluated the accuracy of DaT imaging for the diagnosis of DLB in individuals in secondary care who were suspected to have dementia or already diagnosed by clinical work-up. Systematic review of the literature through 2013 identified only a single study that used a neuropathological reference standard to assess the accuracy of DAT imaging for the diagnosis of DLB. A total of 22 participants in the study met consensus clinical criteria for DLB or National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA) criteria for Alzheimer's disease, or both. The study's results suggest that DaT imaging may be an accurate means of excluding the diagnosis of DLB.

A systematic review of the literature was conducted by Brigo and colleagues (2015) which similarly assessed the utility of DaT imaging in the differential diagnosis between DLB and other dementia syndromes. A total of eight

studies were included, and three studies used a neuropathological reference standard which yielded sensitivity and specificity values higher than those adopting a clinical diagnostic reference. The authors pointed out that, "… the clinical utility of these studies lacking neuropathological diagnosis at autopsy as the reference standard is limited by the fact that they are intrinsically unable to demonstrate an accuracy of DaT imaging above that of careful clinical diagnosis alone." The review concluded that the few studies that provided analysis of the correlation between DaT scans and a neuropathologic reference standard, versus clinical diagnosis, were each small but suggest that DaT imaging may be a more accurate method. Studies with neuropathological diagnosis at autopsy are warranted.

Thomas and colleagues (2017) conducted a validation study of DaT imaging in the clinical diagnosis of DLB with neuropathological diagnosis at autopsy. There were 55 individuals greater than 60 years of age, who underwent DaT imaging in prospective research studies, and donated their brain tissue in the study. DaT imaging was reviewed by blinded raters as either normal or abnormal. Due to the study time span being from the late 1990s through the 2000s, most individuals were assessed with the 1996 consensus criteria for DLB, while others were assessed with the 2005 criteria. After death, autopsy was performed and neuropathological diagnosis was applied using standard international criteria without the results of the DaT imaging. There were 33 individuals with DLB and 22 individuals with Alzheimer disease per clinical diagnosis. However, of the 33 individuals with a clinical diagnosis of DLB, neuropathological diagnosis at autopsy showed 23 (70%) individuals with pure Lewy body disease (LBD), 5 (15%) individuals with Alzheimer disease, 3 (9%) individuals with mixed LBD and Alzheimer disease, 1 (3%) individual with frontotemporal lobar degeneration, and 1 (1%) individual with corticobasal degeneration. Of the 22 individuals with a clinical diagnosis of Alzheimer disease, neuropathological diagnosis at autopsy showed 0 (0%) individuals with pure LBD, 16 (72%) individuals with Alzheimer disease, 4 (18%) individuals with mixed LBD and Alzheimer disease, 2 (9%) individuals with frontotemporal lobar degeneration, and 0 (0%) individuals with corticobasal degeneration. In assessing the validity of DaT imaging, all cases with either pure LBD or mixed LBD were considered proven LBD (n=30). All other cases were considered non-LBD (n=25). Of the LBD cases, 24 had abnormal DaT imaging (sensitivity 80%, 95% confidence interval [CI], 92–62), of the non-LBD cases, 23 had normal DaT imaging (specificity 92%, 95% CI, 99–74). The balanced diagnostic accuracy of DaT imaging was 86% (95% CI, 94–74). There were 3 (10%) individuals with DLB who met pathological criteria for LBD, but had normal DaT imaging. DaT imaging had a higher accuracy than clinical diagnosis, which had an accuracy of 79% (sensitivity 87%, specificity 72%, 95% CI, 89–66). While this study

needs to be replicated in larger, multicenter studies, the results support the use of DaT imaging in the diagnosis DLB.

In 2017, The American College of Radiology (ACR) in collaboration with the American College of Nuclear Medicine published a practice parameter for the performance of DaT SPECT imaging for movement disorders. The practice parameter stated the following:

A. Clinical indications for DaT SPECT imaging include, but are not limited to: Differentiating Parkinsonian syndrome from essential tremor and drug-induced tremor in patients with:
    1. Worsening essential tremor
    2. Tremor who use neuroleptics
    3. Tremor "who want to know"
    4. Psychogenic features
    5. Dementia, to differentiate between Alzheimer disease and dementia with Lewy bodies (DLB)

In 2019, the ACR published ACR Appropriateness Criteria® for dementia that offers the following guidance for SPECT imaging:

> HMPAO SPECT or SPECT/CT Brain Regional cerebral blood flow determined using single-photon emission computed tomography (SPECT) imaging with Tc-99m hexamethylpropyleneamine oxime (HMPAO) shows bilateral temporoparietal or hippocampal hypoperfusion in patients with AD [advanced dementia]. Whether brain SPECT contributes substantially to diagnostic accuracy after a careful clinical examination using current diagnostic criteria is controversial. Although perfusion MRI is promising, SPECT remains superior in identifying pathologic perfusion. An evidence-based review performed by the AAN [American Academy of Neurology] concluded that SPECT imaging cannot be recommended for either the initial assessment or to clarify the differential diagnosis of suspected dementia because it has not demonstrated superiority to clinical criteria. When compared with FDG [fluorodeoxyglucose]-

> PET, SPECT has a lower diagnostic accuracy and is inferior in its ability to separate healthy controls from patients with true dementia.

Although HMPAO SPECT is not endorsed by the ACR for differentiating dementia from other conditions, the guideline states,

> I-123 Ioflupane [Ioflupane SPECT] striatal activity tends to be normal in AD and low in DLB and Parkinson disease; however, AD and DLB can coexist in the same patient, potentially confounding results. This is not a first-line imaging test but may be valuable after cross-sectional imaging to exclude other pathology.

In 2019, ~~T~~the ACR published Appropriateness Criteria for movement disorders and neurodegenerative diseases. The ACR categorized the discussion into 5 variants and the following are the recommendations for SPECT imaging:

> Variant 1: Rapidly progressive dementia; suspected Creutzfeldt-Jakob disease. Initial imaging.
> HMPAO SPECT or SPECT/CT Brain Tc-99m hexamethyl-propylamine-oxime (HMPAO) single-photon emission computed tomography (SPECT)/CT of the brain may be helpful in the evaluation of a patient with suspected CJD. Tc-99m HMPAO SPECT/CT demonstrates changes in regional cerebral blood flow that can be seen even before signal changes are apparent on MRI. Despite the increased sensitivity for early changes, the lack of specificity of the SPECT findings limits its utility as the initial imaging study.
> Variant 2: Chorea; suspected Huntington disease. Initial imaging.
> HMPAO SPECT or SPECT/CT Brain There is insufficient evidence to support the use of Tc-99m HMPAO SPECT/CT of the brain in the initial evaluation of a patient with chorea or suspected HD.
> Variant 3: Parkinsonian syndromes. Initial imaging.
> HMPAO SPECT or SPECT/CT Brain There is no relevant literature to support the use of Tc-99m HMPAO SPECT/CT of the brain in the initial imaging evaluation of a patient with Parkinsonian syndrome.

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Variant 4: Suspected neurodegeneration with brain iron accumulation. Initial imaging.
HMPAO SPECT or SPECT/CT Brain There is no relevant literature to support the use of Tc-99m HMPAO SPECT/CT of the brain in the initial imaging evaluation of a patient with suspected NBIA
Variant 5: Suspected motor neuron disease. Initial imaging.
HMPAO SPECT or SPECT/CT Brain There is no relevant literature to support the use of Tc-99m HMPAO SPECT/CT of the brain in the initial imaging evaluation of a patient with suspected motor neuron disease.

Although evidence is lacking to support the use of SPECT as an initial imaging modality in the evaluation of movement and neurodegenerative disorders, it may aid clinicians when the diagnosis remains unclear following initial assessment and the results are likely to guide disease management.

Prostate Cancer

ProstaScint, a monoclonal antibody (capromab pendetide) combined with radioactive indium-111, is used to detect prostate cancer. It is injected into the body and a gamma camera (designed to detect radioactivity) is then used to locate prostate cancer cells. ProstaScint may have a clinical benefit; however, there is a paucity of evidence demonstrating improved progression-free survival (PFS) following ProstaScint scans (including fusion with CT or MRI). In a study by Koontz (2008), 40 individuals, who had prostate specific antigen (PSA) recurrence after total prostatectomy, were scanned prior to salvage prostate bed radiotherapy. A total of 20 individuals had negative scans and 20 individuals had locally positive scans. The 2-year PFS rates were 60% for those individuals with a negative scan and 74% for those individuals with a positive scan. The researchers concluded that individuals "with locally positive scans did not have statistically different progression-free survival than those with a negative scan result."

Pucar and colleagues (2008) concluded that "ProstaScint has no added benefit over other imaging modalities in evaluating post-radical prostatectomy recurrence, due to its low sensitivity for detecting local recurrences and bone metastases." A prospective trial of 25 hormone-naive men with clinically localized prostate cancer, who received ProstaScint scanning, with blinded correlation by a radiologist and pathologist, found that sensitivity ranged from

37% to 87%, and specificity from 0% to 50%. According to the study authors, the scan seemed to have comparable affinity for both benign and malignant prostate tissue (Mouraviev, 2009).

El-Zawahry (2010) reported on a study using capromab pendetide (ProstaScint) with SPECT images to detect and localize prostate cancer in 69 participants with prostate cancer who had undergone radiation therapy. The goal of this study was to select appropriate individuals with biochemical recurrence of prostate cancer following radiation therapy and then offer cryosurgical ablation of the prostate and avoid premature androgen deprivation therapy. A total of 6 participants had metastatic signal on SPECT scanning and were not considered candidates for cryosurgical ablation. A total of 63 participants had prostate biopsy; of these, 6 had negative biopsy and were excluded from cryosurgical ablation. A total of 59 participants underwent cryosurgical ablation. Use of the SPECT in combination with prostate biopsy spared 2 participants from cryosurgical ablation and spared 44 participants from premature androgen deprivation therapy. While the use of SPECT imaging shows promise, this study is limited by a small group size and per the authors "more patients will be needed to confirm our results" (El-Zawahry, 2010).

Ellis and colleagues (2011) evaluated the use of capromab pendetide imaging with SPECT in primary prostate cancer for pretreatment staging and localization for radiotherapy dose escalation. The authors hypothesized that SPECT with ProstaScint could improve pretreatment prostate cancer staging. A total of 239 participants were evaluated for tumor stage using conventional staging and SPECT. Distant metastatic disease was identified in 22 participants, but this could not be clinically confirmed. A total of 7 participants had uptake in the pelvic lymphatic chain and 15 participants had uptake in other sites suspicious of metastatic disease. In 65 participants, neither conventional imaging, nor any other staging method could confirm the presence of distant metastatic uptake suggested by SPECT. These findings were thought to represent false positive results. While a 10-year follow-up showed overall survival was 85%, this study was characterized by several weaknesses, since it was not randomized and did not have a control group.

Shen and colleagues (2014) conducted a meta-analysis comparing the diagnostic performance of PET/CT, MRI, bone SPECT and bone scintigraphy (BS) in detecting metastases in individuals with prostate cancer. A total of 16 articles were chosen for inclusion, which reported on 27 different studies evaluating 1102 individuals. Four of the

studies were retrospective and ten were prospective. Pooled sensitivity, specificity and the diagnostic odds ratio were reported on an individual and per-lesion basis. The authors concluded,

> …PET/ CT was a better imaging modality than BS and bone SPECT on either a per-patient basis or a per-lesion basis. Moreover, PET/CT has several additional advantages: evaluation of osteolytic lesions in weight-bearing bones and particularly in the spine and pelvis…

The ACR states the following: "The reliability and usefulness of indium-111 radiolabeled capromab pendetide (a first-generation monoclonal antibody against prostate-specific membrane antigen [PSMA]) scan as a method to stage prostate cancer remain unproven." In the ACR 2017 Appropriateness Criteria for Post-treatment Follow-up of Prostate Cancer they state "ProstaScint shows very limited performance and is challenging to interpret. It is unlikely to provide benefit and is not routinely used in the evaluation of prostate cancer recurrence." The National Comprehensive Cancer Network (NCCN, 2020) does not address ProstaScint.

Breast Cancer

Scintimammography, also known as breast scintigraphy, involves the use of monoclonal antibodies to target specific tissue types that are then analyzed with planar techniques or SPECT as a diagnostic tool for breast abnormalities. It has not been shown to improve health outcomes in individuals with breast cancer, populations being screened for breast cancer, or as an adjunct for diagnostic or surgical treatment planning. The evidence in the peer-reviewed literature is limited to small, uncontrolled studies that do not document outcome improvement (Ching, 2018; Ozulker, 2010). Another assessment on scintimammography reported the following conclusions (Sampalis, 2003):

- As a second-line diagnostic test after mammography, the sensitivity and corresponding negative predictive value of scintimammography are not high enough to influence treatment decisions. Specifically, even at the low end of the intermediate range of prevalence for malignancy, if a negative scintimammogram were to be used to recommend against doing biopsy, the risk of undetected malignancy would be 4.3%. This was considered too high given the relatively low morbidity of breast biopsy, which is the gold standard.

- There were inadequate data to permit conclusions regarding the use of scintimammography for staging of axillary lymph nodes.
- For other populations, including but not limited to: women with a breast lesion who have been referred for biopsy but who have a low probability of malignancy; women who have a probable benign finding on mammography and who are recommended for close follow-up; and women with dense breast tissue, the available evidence is insufficient to permit conclusion regarding the effectiveness of scintimammography.

Pan and colleagues (2010) reported on a meta-analysis of five types of non-invasive imaging methods (ultrasound, CT, MRI, scintimammography, and PET) for the evaluation of breast cancer recurrence and metastases. Ultrasound showed a sensitivity of 86% and specificity of 96%. CT sensitivity was 85% with specificity of 75%. MRI sensitivity was 95% and specificity 92%. Scintimammography had a sensitivity of 90%, specificity of 80%. PET was 95% with a specificity of 86%. Ultrasound had the highest specificity and PET had the highest sensitivity. This meta-analysis revealed that scintimammography does not have the highest specificity or sensitivity when compared with other modalities.

A 2012 retrospective study by Weigert and colleagues reported on 1042 individuals who underwent pathological analysis or follow-up imaging after having had at least 1 of the following: equivocal or negative mammogram or sonogram and an unresolved clinical concern; personal history of breast cancer or current cancer diagnosis; palpable masses negative on mammographic and sonographic examination; radiodense breast tissue; or high risk for breast cancer. Pathological analysis or follow-up imaging resulted in 250 positive findings and 792 negative findings. Individuals who had breast-specific gamma imaging were found to have positive results in 408 individuals and negative results in 634 individuals. While the authors concluded that "breast-specific gamma imaging significantly contributed to the detection of malignant or high-risk lesions in patients with negative or indeterminate mammographic findings," there is no data showing improved clinical outcomes.

The ACR Appropriateness Criteria for breast cancer (2017) concludes that there is insufficient evidence to support the use of scintimammography breast cancer screening, citing that radiation dose from scintimammography is higher than the dose of a digital mammogram, and it is not indicated for screening in its present form. The NCCN (2020) guideline for breast cancer screening and diagnosis states "breast scintigraphy and contrast enhanced

mammography may improve detection of early breast cancers among women with mammographically dense breasts; current evidence does *not* support their routine use as alternative screening procedures." The NCCN does not mention scintimammography within the breast cancer clinical practice guideline (2021).

Cutaneous Melanoma

Sentinel lymph node biopsy (SLNB) is a procedure that is performed to risk-stratify certain individuals with cutaneous melanoma in whom there is a significant risk of regional node metastasis (Wong, 2018). As described by the NCCN (2020), "the technique for SLNB consists of preoperative dynamic lymphoscintigraphy, intraoperative identification using isosulfan blue or methylene blue dye, and a gamma probe to detect radiolabeled lymph nodes." SPECT/CT has been evaluated as an adjunct to lymphoscintigraphy to enhance the accuracy; however, there is a lack of peer-reviewed studies evaluating SPECT alone as an adjunct (NCCN, 2020). Furthermore, major authoritative organizations have not published recommendations on the use of SPECT for this indication.

Epilepsy

SPECT has also been studied for its application in the preoperative evaluation for those individuals with focal intractable epilepsy. A specialized type of SPECT scan, subtraction peri-ictal SPECT coregistered to MRI (SISCOM), is a ~~recently developed~~ neuroimaging modality that ~~has been proposed to~~ guides localization of seizure foci prior to epileptic surgery by measuring the differences in cerebral blood flow caused by changes in neuronal activity across the interictal, ictal and postictal states. Early studies regarding the use of SPECT and SISCOM published results that were equivalent in surgical outcomes when compared to other imaging modalities (Ahnlide, 2007; Kaiboriboon, 2002; Knowlton, 2008; Matsuda, 2009; O'Brien, 2000; O'Brien, 2004; Tan, 2008). Studies published more recently continue to show that SPECT/SISCOM, when used as a preoperative tool, results in ~~a~~favorable postoperative outcomes (Kudr, 2013; Perissinotti, 2014; Schneider, 2013; Seo, 2011; von Oertzen, 2011).

Chen and Guo (2016) reported on a meta-analysis evaluating the role of SISCOM in the preoperative evaluation of 320 individuals with epilepsy. A total of 11 articles were analyzed to determine the relationship of SISCOM and surgical outcomes. Due to identified publication bias, the results were unweighted; ~~and~~ the unweighted positive rate

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of SISCOM was 85.9% (275/320). MRI-negative results were reported for 142 individuals but 119 (83.8%) of these individuals had SISCOM-positive results. A total of 275 individuals underwent epilepsy surgery and of those, 175 had SISCOM localizations that were comparable to the gold standard. The authors concluded that SISCOM does show a slightly high sensitivity rate of seizure localization and is an option when MRI results are negative or indeterminate. Publication bias was found throughout the included small studies and this analysis shows that further studies of a larger population of individuals is necessary.

~~Tan (2008) reported on 50 individuals with focal epilepsy who had SPECT/SISCOM imaging prior to surgery. The authors evaluated if the results of SPECT/SISCOM alter surgery decisions. A consensus decision was made after presentation of data from a noninvasive evaluation (SPECT/SISCOM data was not provided initially). Consensus decisions were documented again following the presentation of SPECT/SISCOM data. For those individuals with localizing SPECT/SISCOM results, consensus decisions changed in 10 of 32 individuals. For those individuals with nonlocalizing SPECT/SISCOM results, consensus decisions changed in 1 of 18 individuals.~~

~~Seo and colleagues (2011) conducted a retrospective review of 14 children with intractable focal epilepsy, who all subsequently underwent respective epilepsy surgery. The authors studied individual medical records for clinical characteristics, surgical outcome, and localizing features on three preoperative diagnostic tests: SPECT/SISCOM; PET; and magnetoencephalography (MEG). Each test was localized by comparing the concordance with intracranial electroencephalogram (iEEG). MEG and SPECT/SISCOM showed the most concordance with iEEG at 79% (11 of 14 children). PET showed a 13% concordance with iEEG (3 of 14 children). While using a multiple modality approach may enhance the ability to localize the epileptogenic zone in focal epilepsy, the use of iEEG cannot be completely excluded because the extent of curative resection may not be accurately determined without proper iEEG monitoring. The authors concluded that larger prospective trials are necessary to clearly define the role of multiple imaging modalities.~~

~~An observational study (von Oertzen, 2011) reported on the use of SISCOM in the presurgical evaluation of epilepsy in 175 individuals with drug-resistant epilepsy. The individuals had either nonlesional MRI or discordant results with the standard set of presurgical tests. The authors concluded that while the study had large numbers, it may have been insufficiently powered and "logistic regression analysis did not show any influencing factors with regard to the gold standard comparison" (von Oertzen, 2011).~~

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In 2019, the ACR published Appropriateness Criteria for Seizures and Epilepsy. The ACR categorized the discussion into 6 variants and the following are the recommendations for HMPAO SPECT or SPET/CT brain ictal and interictal:

Variant 1: New-onset seizure. Unrelated to trauma. Initial imaging.
There is no relevant literature regarding the use of single-photon emission computed tomography (SPECT) or SPECT/CT as an initial imaging study in the evaluation of new-onset seizure unrelated to trauma.
Variant 2: New-onset seizure. History of trauma. Initial imaging.
There is no relevant literature regarding the use of SPECT or SPECT/CT as an initial imaging study in the evaluation of new-onset seizure with history of trauma.
Variant 3: Known seizure disorder. Unchanged seizure semiology.
There is no relevant literature regarding the use of SPECT or SPECT/CT in the evaluation of known seizure disorder with unchanged seizure semiology.
Variant 4: Known seizure disorder. Change in seizure semiology or new neurologic deficit or no return to previous neurologic baseline.
There is no relevant literature regarding the use of SPECT or SPECT/CT in the evaluation of known seizure disorder with changes in seizure semiology unless it is in the setting of presurgical planning.
Variant 5: Known seizure disorder. History of tumor.
There is no relevant literature regarding the use of SPECT or SPECT/CT in the evaluation of known seizure disorder with history of tumor unless in the setting of presurgical planning.
Variant 6: Known seizure disorder. Surgical candidate or surgical planning.
SPECT that uses perfusion agents like Tc-99m-HMPAO (hexamethyl-propylamine-oxime) or Tc-99m-neurolite provides an assessment of regional cerebral blood flow rather than brain metabolism. A seizure focus is typically demonstrated as an area of hypoperfusion on interictal examinations and hyperperfusion on ictal examinations. The utility of isolated interictal cerebral perfusion assessment in patients without an anatomic imaging abnormality is limited, with one study finding that of all patients with seizures only 60% of interictal cerebral perfusion imaging was abnormal. However, perfusion SPECT is complementary to structural imaging in presurgical

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planning. Statistical ictal SPECT co-registered to MRI was noted to identify a hyperperfusion focus in 84% of patients compared with 66% using subtraction ictal SPECT co-registered to MRI for seizure localization before TLE surgery and may be indicated for these cases.

Although evidence is lacking to support the use of SPECT as an initial imaging modality in the evaluation of seizures and epilepsy, it may aid clinicians with the preoperative evaluation to determine the location of the hyperperfusion focus when other techniques are indeterminate.

Other Indications

The efficacy of SPECT for other applications has not been firmly established due to the lack of published clinical studies for each application. Specifically, there is a lack of evidence regarding the use of SPECT in attention deficit and hyperactivity disorder (ADHD), autism spectrum disorders (ASDs), chronic fatigue syndrome, thyroid cancer, other malignant carcinomas, and neuropsychiatric disorders (Kan, 2015; Kashyup, 2011; Seckin, 2020; Wei, 2016).

Definitions

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.

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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 conditions that share similar cardinal signs of Parkinsonism characterized by bradykinesia, rigidity, tremor at rest, and postural instability, including but not limited to Parkinson's disease, idiopathic Parkinson's disease, progressive supranuclear palsy, dementia with Lewy bodies, multiple system atrophy, drug-induced parkinsonism, and corticobasal degeneration.

Pervasive developmental disorders: Refers to 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.

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.

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1. ACR–ACNM Practice parameter for the performance of dopamine (DaT) transporter single photon emission computed tomography (SPECT) imaging for movement disorders. (Resolution 25). Adopted 2017. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DaT_SPECT-Imaging.pdf?la=en. Accessed on ~~September 14, 2020~~January 15, 2021.
2. ACR–ACNM-SNMMI-SPR Practice parameter for the performance of neuroendocrine tumor scintigraphy. (Resolution 14). Revised 2020. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/TumorScint.pdf?la=en. Accessed on ~~September 14, 2020~~January 15, 2021.
3. ACR-SPR Practice parameter for the performance of parathyroid scintigraphy. (Resolution 38). Revised 2019. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/ParaThyroidScint.pdf. Accessed on ~~September 14, 2020~~January 15, 2021.
4. ACR–SPR Practice parameter for the performance single photon emission computed tomography (SPECT) brain perfusion imaging, including brain death examinations. (Resolution 26). Revised 2016. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/BrainPerf-SPECT.pdf. Accessed on ~~September 14, 2020.~~ January 15, 2021.

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~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~

5. ACR-ABS-ACNM-ASTRO-SIR-SNMMI Practice parameter for selective internal radiation therapy (SIRT) or radioembolization for treatment of liver malignancies. (Resolution 21). Revised 2019. Available at: https://www.acr.org/-/media/ACR/Files/Practice-Parameters/RMBD.pdf. Accessed on ~~September 14, 2020~~January 15, 2021.
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    - Breast Cancer (~~V6.2020~~V1.2021); Revised ~~September 8, 2020~~January 15, 2021.
    - Breast Cancer Screening and Diagnosis (V1.2020); Revised September 17, 2020
    - Cutaneous Melanoma (~~V4.2020~~V1.2021); Revised ~~September 1, 2020~~November 25, 2020.
    - Hepatobiliary Cancers (V5.2020); Revised August 4, 2020
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Index

DaT Scan
DMSA
Prostascint
Scintimammography
SISCOM
SPECT Scans

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	02/11/2021	Medical Policy & Technology Assessment Committee (MPTAC) review. Added SPECT/SISCOM for preoperative evaluation to Medically Necessary Position Statement from the Not Medically Necessary Position Statement. Updated Coding, Discussion/General Information and References sections.
Revised	11/05/2020	~~Medical Policy & Technology Assessment Committee (~~MPTAC~~)~~ review. Added liver malignancies to Medically Necessary Position Statement. Updated Discussion/General Information and References. Reformatted Coding section and updated with additional ICD-10-CM diagnosis codes for liver malignancies.
	10/01/2020	Updated Coding section with 10/01/2020 ICD-10-CM changes; added R51.0-R51.9 replacing R51 deleted 09/30/2020.

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New	11/07/2019	MPTAC review. Initial document development. Moved content of RAD.00023 to new clinical utilization management guideline document with the same title.

This Clinical UM Guideline is intended to provide assistance in interpreting Healthy Blue's standard Medicaid benefit plan. When evaluating insurance coverage for the provision of medical care, federal, state and/or contractual requirements must be referenced, since these may limit or differ from the standard benefit plan. In the event of a conflict, the federal, state and/or contractual requirements for the applicable benefit plan coverage will govern. Healthy Blue reserves the right to modify its Policies and Guidelines as necessary and in accordance with legal and contractual requirements. This Clinical UM Guideline is provided for informational purposes. It does not constitute medical advice. Healthy Blue may also use tools and criteria developed by third parties, to assist us in administering health benefits. Healthy Blue's Policies and Guidelines are intended to be used in accordance with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

~~Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to implement a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.~~

~~Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan's or line of business's members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.~~