



Status: Revised
Doc ID: RBM10-0923.1

Effective Date: 09/10/2023

Last Review Date: 01/24/2023

Approval and implementation dates for specific health plans may vary. Please consult the applicable health plan for more details.

Clinical Appropriateness Guidelines

Advanced Imaging

Appropriate Use Criteria: SPECT Imaging

Proprietary

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Description and Application of the Guidelines

The Carelon Clinical Appropriateness Guidelines (hereinafter “the Carelon Clinical Appropriateness Guidelines” or the “Guidelines”) are designed to assist providers in making the most appropriate treatment decision for a specific clinical condition for an individual. As used by Carelon, the Guidelines establish objective and evidence-based criteria for medical necessity determinations where possible. In the process, multiple functions are accomplished:

- To establish criteria for when services are medically necessary (i.e., in general, shown to be effective in improving health outcomes and considered the most appropriate level of service)
- To assist the practitioner as an educational tool
- To encourage standardization of medical practice patterns
- To curtail the performance of inappropriate and/or duplicate services
- To advocate for patient safety concerns
- To enhance the quality of health care
- To promote the most efficient and cost-effective use of services

The Carelon guideline development process complies with applicable accreditation standards, including the requirement that the Guidelines be developed with involvement from appropriate providers with current clinical expertise relevant to the Guidelines under review and be based on the most up-to-date clinical principles and best practices. Relevant citations are included in the References section attached to each Guideline. Carelon reviews all of its Guidelines at least annually.

Carelon makes its Guidelines publicly available on its website twenty-four hours a day, seven days a week. Copies of the Carelon Clinical Appropriateness Guidelines are also available upon oral or written request. Although the Guidelines are publicly-available, Carelon considers the Guidelines to be important, proprietary information of Carelon, which cannot be sold, assigned, leased, licensed, reproduced or distributed without the written consent of Carelon.

Carelon applies objective and evidence-based criteria, and takes individual circumstances and the local delivery system into account when determining the medical appropriateness of health care services. The Carelon Guidelines are just guidelines for the provision of specialty health services. These criteria are designed to guide both providers and reviewers to the most appropriate services based on a patient’s unique circumstances. In all cases, clinical judgment consistent with the standards of good medical practice should be used when applying the Guidelines. Guideline determinations are made based on the information provided at the time of the request. It is expected that medical necessity decisions may change as new information is provided or based on unique aspects of the patient’s condition. The treating clinician has final authority and responsibility for treatment decisions regarding the care of the patient and for justifying and demonstrating the existence of medical necessity for the requested service. The Guidelines are not a substitute for the experience and judgment of a physician or other health care professionals. Any clinician seeking to apply or consult the Guidelines is expected to use independent medical judgment in the context of individual clinical circumstances to determine any patient’s care or treatment.

The Guidelines do not address coverage, benefit or other plan specific issues. Applicable federal and state coverage mandates take precedence over these clinical guidelines. If requested by a health plan, Carelon will review requests based on health plan medical policy/guidelines in lieu of the Carelon Guidelines. Pharmaceuticals, radiotracers, or medical devices used in any of the diagnostic or therapeutic interventions listed in the Guidelines must be FDA approved or conditionally approved for the intended use. However, use of an FDA approved or conditionally approved product does not constitute medical necessity or guarantee reimbursement by the respective health plan.

The Guidelines may also be used by the health plan or by Carelon for purposes of provider education, or to review the medical necessity of services by any provider who has been notified of the need for medical necessity review, due to billing practices or claims that are not consistent with other providers in terms of frequency or some other manner.

General Clinical Guideline

Clinical Appropriateness Framework

Critical to any finding of clinical appropriateness under the guidelines for a specific diagnostic or therapeutic intervention are the following elements:

- Prior to any intervention, it is essential that the clinician confirm the diagnosis or establish its pretest likelihood based on a complete evaluation of the patient. This includes a history and physical examination and, where applicable, a review of relevant laboratory studies, diagnostic testing, and response to prior therapeutic intervention.
- The anticipated benefit of the recommended intervention should outweigh any potential harms that may result (net benefit).
- Current literature and/or standards of medical practice should support that the recommended intervention offers the greatest net benefit among competing alternatives.
- Based on the clinical evaluation, current literature, and standards of medical practice, there exists a reasonable likelihood that the intervention will change management and/or lead to an improved outcome for the patient.

If these elements are not established with respect to a given request, the determination of appropriateness will most likely require a peer-to-peer conversation to understand the individual and unique facts that would supersede the requirements set forth above. During the peer-to-peer conversation, factors such as patient acuity and setting of service may also be taken into account.

Simultaneous Ordering of Multiple Diagnostic or Therapeutic Interventions

Requests for multiple diagnostic or therapeutic interventions at the same time will often require a peer-to-peer conversation to understand the individual circumstances that support the medical necessity of performing all interventions simultaneously. This is based on the fact that appropriateness of additional intervention is often dependent on the outcome of the initial intervention.

Additionally, either of the following may apply:

- Current literature and/or standards of medical practice support that one of the requested diagnostic or therapeutic interventions is more appropriate in the clinical situation presented; or
- One of the diagnostic or therapeutic interventions requested is more likely to improve patient outcomes based on current literature and/or standards of medical practice.

Repeat Diagnostic Intervention

In general, repeated testing of the same anatomic location for the same indication should be limited to evaluation following an intervention, or when there is a change in clinical status such that additional testing is required to determine next steps in management. At times, it may be necessary to repeat a test using different techniques or protocols to clarify a finding or result of the original study.

Repeated testing for the same indication using the same or similar technology may be subject to additional review or require peer-to-peer conversation in the following scenarios:

- Repeated diagnostic testing at the same facility due to technical issues
- Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study

- Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time

Repeat Therapeutic Intervention

In general, repeated therapeutic intervention in the same anatomic area is considered appropriate when the prior intervention proved effective or beneficial and the expected duration of relief has lapsed. A repeat intervention requested prior to the expected duration of relief is not appropriate unless it can be confirmed that the prior intervention was never administered.

SPECT Imaging (including SPECT/CT)

General Information

Scope

These guidelines address nuclear medicine imaging in both adult and pediatric populations. For interpretation of the Guidelines, and where not otherwise noted, “adult” refers to persons age 19 and older, and “pediatric” refers to persons age 18 and younger. Where separate indications exist, they are specified as **Adult** or **Pediatric**. Where not specified, indications and prerequisite information apply to persons of all ages.

See the Code section for a list of modalities included in these guidelines.

Technology Considerations

Bone marrow scintigraphy is a nuclear medicine study which may be done in conjunction with other studies such as Gallium or leukocyte scintigraphy for evaluation of marrow involvement. This study is done using technetium 99m-labeled sulfur colloid, the normal biodistribution of which is the reticuloendothelial system (liver, spleen, bone marrow).

Bone scintigraphy is a nuclear medicine exam that uses a radiopharmaceutical (typically technetium 99m labeled methylene diphosphonate [MDP] or hydroxydiphosphonate [HDP]) to measure osteoblastic activity throughout the axial and appendicular skeleton. Bone scintigraphy can be limited or whole body and can be performed with planar scintigraphy or with SPECT.

Dacryoscintigraphy is a nuclear medicine exam in which a radiopharmaceutical (typically, technetium 99m pertechnetate) is administered via eye dropper or syringe to the surface of the eye. This test is used to evaluate the patency of the nasolacrimal duct.

Gallium scintigraphy is a nuclear medicine exam that uses a radiopharmaceutical (typically Gallium-67 citrate) to measure neoplastic, infectious and inflammatory activity involving osseous and soft tissue structures.

A **Gastric emptying study** is a nuclear medicine exam that uses a radiopharmaceutical (typically technetium 99m sulfur colloid) which is mixed into a standardized solid meal or liquid for oral administration. Multiple images are obtained of the abdomen, and the percentage of activity remaining in the stomach is calculated over time. For measurement of gastric emptying only, imaging is typically performed at hourly intervals until 4 hours after solid meal ingestion and for one hour after liquid administration. **Small bowel and whole-gut transit studies** may be performed in conjunction with a gastric emptying study, and typically involve administration of a second radiopharmaceutical, ¹¹¹In-DTPA, followed by additional delayed imaging.

Gastrointestinal blood loss scintigraphy refers to nuclear medicine evaluation for the source of an active site of gastrointestinal bleeding. This is generally used to evaluate a site of lower GI bleeding, though more proximal sites can also be detected. This test is done using the patient’s red blood cells, which are radiolabeled using technetium 99m either in vitro or in vivo. **GERD scintigraphy** is also known as a “reflux scan” or a “milk scan.” It is a nuclear medicine exam in which a radiopharmaceutical (typically technetium 99m labeled DTPA or sulfur colloid) is administered orally (or by nasogastric or gastrostomy tube) in a liquid meal such as water, juice, or milk. Dynamic imaging is then carried out, typically at 10 seconds per frame for one hour. The number of reflux episodes is determined, as well as the proximal extent of the reflux.

Hepatic scintigraphy refers to nuclear medicine imaging of the liver. Depending on the reason for imaging, there are several radiotracers which may be used. Radiolabeled autologous red blood cells may be used for characterization of a liver lesion when it is suspected to be a hemangioma. Radiolabeled sulfur colloid may be used for characterization of a liver lesion when it is suspected to represent focal nodular hyperplasia.

Hepatobiliary scintigraphy is a nuclear medicine exam that uses a radiopharmaceutical [a technetium 99m-labeled iminodiacetic acid (IDA) such as DISIDA, BrIDA, or PIPIDA] to evaluate the hepatobiliary system including

bile formation and transit through the biliary system into the intestine. Gallbladder ejection fraction (GBEF) can be calculated through the administration of a cholecystikinin analog. Also called HIDA scans after an early form of the primary radiopharmaceutical used in them, these studies are most commonly used in the evaluation of suspected acute cholecystitis, but may also be useful in evaluation of suspected biliary atresia or bile leak.

Leukocyte scintigraphy is a nuclear medicine exam that uses a radiopharmaceutical (typically technetium 99m or Indium-111 labeled autologous white blood cells [WBC]) to measure infectious and inflammatory activity involving osseous and soft tissue structures.

Lymphoscintigraphy is a nuclear medicine procedure in which a radiopharmaceutical (typically technetium 99m sulfur colloid, filtered to ensure a small particle size) is used to evaluate lymphatic flow and nodal drainage pathways. This test may be used for lymphedema, but is primarily used for sentinel lymph node detection in malignancies such as breast cancer or melanoma.

A **Meckel's scan** is a nuclear medicine examination in which technetium 99m pertechnetate is used to detect a Meckel's diverticulum. These often become clinically apparent because of gastrointestinal bleeding, which in the setting of Meckel's diverticulum almost always indicates the presence of ectopic gastric mucosa. Uptake of pertechnetate is dependent on the presence of gastric mucosa, so this radiopharmaceutical is generally useful in Meckel's diverticula that present with bleeding, but the test may be of less value in other presentations, where the presence of gastric mucosa in the diverticulum may be less likely.

Perfusion scintigraphy is a nuclear medicine examination performed with a gamma camera that measures cerebral blood flow using lipophilic radiopharmaceutical agents (typically technetium-99 labeled hexamethylpropylene amine oxide [HMPAO] or ethyl cysteinate dimer [ECD]) with high cerebral retention.

Peritoneal venous shunt scintigraphy is a nuclear medicine study in which a radiopharmaceutical (such as technetium 99m macroaggregated albumin [MAA]) is injected into the peritoneal cavity in order to evaluate the patency of a LeVeen or Denver shunt. In the presence of a patent shunt, macroaggregated albumin will travel to the lungs, generally within one hour of injection.

Planar scintigraphy refers to static, two-dimensional nuclear medicine imaging. While planar imaging may provide sufficient information in regions where the anatomy is less complex, it is often supplemented by SPECT imaging for improved anatomic localization.

Radionuclide cisternography is a minimally invasive procedure which uses a radiopharmaceutical (typically Indium-111 or Technetium 99m-labeled diethylenetriaminepentaacetic acid [DTPA]) injected into the cerebrospinal fluid (CSF) to measure CSF flow and identify sites of leakage.

Radiopharmaceuticals are drugs used for diagnosis and therapy which include an isotope (element with the same number of protons but a different number of neutrons and prone to measurable radioactive decay) often coupled to a ligand that binds to a molecule of interest. Examples include technetium 99m-methylene diphosphonate (TC-99 MDP) for bone scintigraphy, iodine 123 for thyroid scintigraphy, and ¹⁸F-fluorodeoxyglucose (FDG) for PET oncologic imaging.

Renal scintigraphy refers to several types of nuclear imaging performed to evaluate the structure and/or function of the kidneys: renal cortical scintigraphy uses the radiopharmaceutical technetium 99m-dimercaptosuccinic acid (DMSA) to assess the amount of functioning cortical tissue; renal perfusion/functional imaging uses radiopharmaceutical agents such as technetium 99m-mercaptoacetyltriglycine (MAG3) to assess blood flow to the kidneys as well as excretory function; diuretic renal scintigraphy, which uses MAG3 imaging before and after a diuretic in order to evaluate for the presence of upper urinary tract obstruction; and ACE-inhibitor renal scintigraphy, in which and ACE inhibitor is used alongside MAG3 to assess for renal artery stenosis.

Single photon emission computed tomography (SPECT) uses gamma decay from radiopharmaceutical agents captured by gamma cameras to create three-dimensional images of the body, in contrast to the two-dimensional images obtained with planar scintigraphy. SPECT has an improved signal-to-noise ratio relative to planar scintigraphy and is especially useful in regions with complex anatomy that makes localization difficult using two-dimensional imaging alone. **Dopaminergic SPECT** is a brain SPECT exam using a radiopharmaceutical that measures presynaptic dopamine to assess nigrostriatal dysfunction. Ioflupane (I-123) is an FDA approved ligand of dopamine transports used with SPECT (DaTscan)¹ to diagnose Parkinson's disease in select clinical scenarios.

Splenic scintigraphy is generally performed as part of a liver-spleen scan, in which a radiopharmaceutical (such as technetium 99m sulfur colloid or technetium 99m-labeled heat-denatured red blood cells) is administered. Splenic scintigraphy is typically used to evaluate for splenosis, accessory splenic tissue, splenic infarction, or wandering spleen.

Thallium scintigraphy has mainly been used in myocardial imaging, both for assessment of perfusion and viability. Thallium is a potassium analog and its intracellular uptake occurs by several pathways, including a co-transport mechanism in tumor cells. It is taken up by Gallium-avid tumors but, unlike Gallium, does not show significant accumulation in inflammatory or necrotic tissue.²

Thyroid scintigraphy is a nuclear medicine study in which a radiopharmaceutical (generally iodine-123 or iodine-131, though technetium 99m pertechnetate can also be used for thyroid evaluation, particularly in pediatric patients) is administered in order to evaluate the thyroid gland. This test can be used in the evaluation of thyrotoxicosis or to assist in characterization of thyroid nodules. When an iodine-based radiopharmaceutical is used, radioactive iodine uptake (RAIU) can be measured in conjunction with imaging.

VQ scintigraphy is a nuclear medicine study used to evaluate the lungs. This study may evaluate ventilation, perfusion, or both. Ventilation-perfusion scans are generally used in the evaluation of suspected pulmonary embolism. Quantitative lung perfusion scintigraphy is used to evaluate how blood flow is distributed within the lungs, and may be used prior to lung surgery or to evaluate congenital vascular anomalies. Perfusion imaging is performed using technetium 99m-labeled macro-aggregated albumin (MAA). There are several radiopharmaceuticals which may be used for ventilation imaging, including aerosols such as technetium 99m-diethylenetriaminepentaacetic acid (DTPA) or technetium 99m-sulfur colloid, or gases such as ¹³³Xe (Xenon).

Definitions

Phases of the care continuum are broadly defined as follows:

- **Screening** is testing in the absence of signs or symptoms of disease
- **Diagnosis** is testing based on a reasonable suspicion of a particular condition or disorder, usually due to the presence of signs or symptoms
- **Management** is testing to direct therapy of an established condition, which may include preoperative or postoperative imaging, or imaging performed to evaluate the response to nonsurgical intervention
- **Surveillance** is the periodic assessment following completion of therapy, or for monitoring known disease that is stable or asymptomatic

Statistical terminology

- **Confidence interval (CI)** is a range of values which is likely to contain the cited statistic. For example, 92% sensitivity (95% CI, 89%-95%) means that, while the sensitivity was calculated at 92% on the current study, there is a 95% chance that, if a study were to be repeated, the sensitivity on the repeat study would be in the range of 89%-95%.
- **Diagnostic accuracy** relates to the ability of a test to discriminate between the target condition and health. Diagnostic accuracy is quantified using sensitivity and specificity, predictive values, and likelihood ratios.
- **Hazard ratio** is the odds that an individual in the group with the higher hazard reaches the outcome first. Hazard ratio is analogous to odds ratio and is reported most commonly in time-to-event analysis or survival analysis. A hazard ratio of 1 means that the hazard rates of the 2 groups are equivalent. A hazard ratio of greater than 1 or less than 1 means that there are differences in the hazard rates between the 2 groups.
- **Likelihood ratio** is the ratio of an expected test result (positive or negative) in patients with the disease to an expected test result (positive or negative) in patients without the disease. Positive likelihood ratios, especially those greater than 10, help rule in a disease (i.e., they substantially raise the post-test probability of the disease, and hence make it very likely and the test very useful in identifying the disease). Negative likelihood ratios, especially those less than 0.1, help rule out a disease (i.e., they

substantially decrease the post-test probability of disease, and hence make it very unlikely and the test very useful in excluding the disease).

- **Odds ratio** represents the odds that an outcome will occur given a particular exposure, compared to the odds of the outcome occurring in the absence of that exposure. An odds ratio of 1 means that the exposure does not affect the odds of the outcome. An odds ratio greater than 1 means that the exposure is associated with higher odds of the outcome. An odds ratio less than 1 means that the exposure is associated with lower odds of the outcome.
- **Predictive value** is the likelihood that a given test result correlates with the presence or absence of disease. Positive predictive value is defined as the number of true positives divided by the number of test positives. Negative predictive value is defined as the number of true negatives divided by the number of test negative patients. Predictive value is dependent on the prevalence of the condition.
- **Pretest probability** is the probability that a given patient has a disease prior to testing. May be divided into very low (less than 5%), low (less than 20%), moderate (20%-75%), and high (greater than 75%) although these numbers may vary by condition.
- **Relative risk** is the probability of an outcome when an exposure is present relative to the probability of the outcome occurring when the exposure is absent. Relative risk is analogous to odds ratio; however, relative risk is calculated by using percentages instead of odds. A relative risk of 1 means that there is no difference in risk between the 2 groups. A relative risk of greater than 1 means that the outcome is more likely to happen in the exposed group compared to the control group. A relative risk less than 1 means that the outcome is less likely to happen in the exposed group compared to the control group.
- **Sensitivity** is the conditional probability that the test is positive, given that the patient has the disease. Defined as the true positive rate (number of true positives divided by the number of patients with disease). Excellent or high sensitivity is usually greater than 90%.
- **Specificity** is the conditional probability that the test is negative, given that the patient does not have the disease. Defined as the true negative rate (number of true negatives divided by the number of patients without the disease). Excellent or high specificity is usually greater than 90%.

Clinical Indications

The following section includes indications for which SPECT imaging is considered medically necessary, along with prerequisite information and supporting evidence where available. Indications, diagnoses, or imaging modalities not specifically addressed are considered not medically necessary.

It is recognized that imaging often detects abnormalities unrelated to the condition being evaluated. Such findings must be considered within the context of the clinical situation when determining whether additional imaging is required.

SPECT Imaging – General (SPECT or SPECT/CT)

These indications apply only to scenarios not addressed elsewhere in the SPECT imaging guidelines.

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.

Selective internal radiation therapy (SIRT)

- For planning of selective internal radiation therapy (SIRT)
- For evaluation of administered dose activity and distribution following radioembolization

SPECT Bone Imaging (SPECT or SPECT/CT)

Avascular necrosis

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

Fracture (including occult or stress fractures) 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)

Indeterminate bone lesions

For further characterization of indeterminate bone lesions when MRI, CT, or planar scintigraphy is equivocal

Infection, not otherwise specified

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, not otherwise specified

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

Postoperative joint or spine pain when other imaging (radiographs, CT, or MRI) is nondiagnostic.

Spondylolysis (pars defect)

When other imaging studies are nondiagnostic.

SPECT Brain

Dopaminergic SPECT (SPECT only)

Movement disorders (Adult only)

Dopaminergic SPECT is considered medically necessary to distinguish between Parkinson's disease and essential tremor when diagnostic uncertainty persists after **ALL** of the following:

- Independent evaluation by at least one physician experienced in movement disorders
- Structural imaging (CT or MRI)
- Results of the test will determine whether medication is initiated or withdrawn, or whether deep brain stimulation is performed

Rationale

While clinical evaluation is usually sufficient to establish the diagnosis of Parkinson's disease, functional imaging with dopaminergic SPECT may be useful in select clinical scenarios where diagnostic uncertainty persists following specialist clinical evaluation³ and structural imaging. Dopaminergic SPECT has a high odds ratio (OR 210; 95% CI, 79-562) for distinguishing Parkinson's disease from essential tremor⁴, although the vast majority of articles used clinical consensus/follow up rather than histopathology as the criterion standard. Dopaminergic SPECT may impact management by changing prescribed medication including the initiation or withdrawal of dopaminergic treatment. This is especially true when the differential includes essential tremor since medical management differs substantially.⁵

Neurocognitive disorders (Adult only)

Includes mild cognitive impairment, dementia, and variants (e.g., vascular, Alzheimer's, frontotemporal degeneration spectrum, diffuse Lewy body).

Dopaminergic SPECT is considered medically necessary as a one-time study to differentiate between diffuse Lewy body dementia and Alzheimer's disease when substantial diagnostic uncertainty remains after **ALL** of the following:

- Neuropsychological testing
- Independent evaluation by at least one physician experienced in neurodegenerative disease
- Structural imaging (CT or MRI)
- Results of the test will determine whether a sustained course of medication is initiated or withdrawn

Rationale

Diffuse Lewy body dementia is a neurocognitive disorder characterized histopathologically by lewy body deposition, especially in the brainstem and nigrostriatal regions, progressing to the limbic system and cortex. Diffuse Lewy body dementia presents clinically with neurocognitive dysfunction and at least two additional clinical symptoms including delirium, visual hallucinations, REM sleep behavior disorder, or Parkinsonism.⁶ Clinical features of Lewy body dementia can overlap with Alzheimer's disease and Parkinson's in the early stages, and advanced imaging is a biomarker to aid the diagnosis when clinical symptoms are insufficient and symptomatic treatment for the condition may differ. Structural imaging shows relative preservation of the mesial temporal lobe in diffuse Lewy body dementia when compared to Alzheimer's.⁷ A positive

dopaminergic SPECT has a good positive predictive value for Lewy body dementia in this scenario and may be appropriate, as it is recommended by multiple evidence-based guidelines.⁷⁻⁹

Thallium Scintigraphy (SPECT only)

Intracranial mass

Thallium scintigraphy is considered medically necessary for evaluation of HIV-positive patients with an intracranial mass.

Rationale

In a systematic review comparing the diagnostic accuracy of thallium scintigraphy, FDG-PET, and MR spectroscopy in distinguishing CNS lymphoma from toxoplasmosis in HIV positive patients, Yang et al. found high (> 90%) diagnostic accuracy with moderate samples sizes for scintigraphy and PET. Limited data for MR spectroscopy suggests lower and widely ranging diagnostic accuracy.¹⁰

SPECT Gallium Scintigraphy (SPECT only)

Lymphoma

For diagnosis and management of lymphoma when PET imaging cannot be performed and when standard imaging (CT or MRI) does not provide sufficient information to guide management.

Osteomyelitis of the skull base or calvarium, when CT or MRI cannot be performed or is nondiagnostic

Gallium scintigraphy is considered medically necessary for diagnosis.

Perioperative evaluation, not otherwise specified, including delayed hardware failure

Also see Bone Marrow Scintigraphy.

Gallium scintigraphy, with or without bone marrow scintigraphy, is considered medically necessary for diagnosis and management of periprosthetic infection.

Rationale

For periprosthetic infections in the spine, a variety of structural and functional imaging modalities may help define the presence or extent of disease. CT and MRI are commonly performed but evaluation of the surgical bed may be limited by beam hardening/susceptibility artifact. Gallium and bone scintigraphy are functional imaging alternatives that have a higher diagnostic accuracy than leukocyte scintigraphy in the spine.^{11, 12}

Spinal infection, when MRI cannot be performed or is nondiagnostic

Gallium scintigraphy is considered medically necessary for diagnosis and management of spinal infection, including but not limited to epidural abscess, arachnoiditis, discitis, and osteomyelitis.

Rationale

MRI has high diagnostic accuracy for spondylodiscitis, is widely available, nonionizing, and is recommended as the initial modality by multiple clinical guidelines.¹³⁻¹⁵ When MRI cannot be performed or is nondiagnostic, functional imaging with bone scintigraphy with or without gallium scintigraphy is suggested as a weak recommendation based on low quality evidence from the Infectious Disease Society of America (IDSA). While gallium/bone scintigraphy may have moderate-to-high sensitivity for spondylodiscitis¹⁶, leukocyte scintigraphy has limited sensitivity in the axial skeleton and is not recommended.¹³ Functional imaging also offers the advantage of a wider field of view than MRI and can be useful to assess for multifocal or chronic forms

of osteomyelitis such as chronic recurrent multifocal osteomyelitis and the Synovitis, Acne, Pustulosis, Hyperostosis and Osteitis (SAPHO) syndrome.

SPECT Hepatic Scintigraphy (SPECT only)

Indeterminate liver lesion

For evaluation of an indeterminate liver lesion > 1 cm in size to evaluate for focal nodular hyperplasia or hemangioma.

Rationale

Cavernous hemangiomas are common; autopsy studies have shown that they occur in up to 7% of the population.^{17, 18} Hemangiomas appear as a homogenous hyperechoic mass, usually less than 3 cm in diameter with acoustic enhancement and sharp margins and are important to identify because they are benign lesions with a characteristic imaging appearance. Confident diagnosis of hemangioma can therefore avoid further biopsy and intervention. Triphasic CT and MRI are usually sufficient to establish the diagnosis.¹⁹ Hemangiomas usually show radiotracer uptake on RBC scintigraphy with high positive likelihood ratios and good interobserver agreement.^{20, 21} However, this is a historical technique that offers less information about alternative diagnosis and is typically reserved in situations where ultrasound is nondiagnostic and neither triphasic MRI or CT can be performed. Similarly, sulfur colloid scintigraphy has been used to further characterize suspected focal nodular hyperplasia²² but is rarely performed as both MRI and CT are usually diagnostic.

SPECT Leukocyte Scintigraphy

Fever of unknown origin, when contrast-enhanced CT cannot be performed or is nondiagnostic (SPECT only)

Leukocyte scintigraphy is considered medically necessary in **EITHER** of the following scenarios:

- Fever of duration greater than 3 weeks which is unexplained following a standard diagnostic evaluation to identify the source
- Unexplained fever in immunocompromised patient

Rationale

CT is usually the first line advanced imaging modality performed in the evaluation of fever of unknown origin (FUO).²³ When a source remains unidentified following a comprehensive clinical and laboratory evaluation and CT, nuclear medicine imaging may be an option. Leukocyte scintigraphy has historically been used in the work up of FUO. It is specific (83%; 95% CI, 61%-94%) but not sensitive (33%; 95% CI, 24%-44%) for FUO, because it is limited to the identification of infectious sources.²⁴ However, leukocyte scintigraphy may play a role in further characterizing abnormalities on CT, or when CT is negative and an infectious source is suspected.

Inflammatory bowel disease, including Crohn's disease and ulcerative colitis, when CT or MRI is nondiagnostic (SPECT only)

Leukocyte scintigraphy is considered medically necessary in **EITHER** of the following scenarios:

- Diagnosis of suspected Crohn's disease following nondiagnostic colonoscopy in **ANY** of the following clinical scenarios when a patient:
 - Meets criteria for irritable bowel syndrome with a normal colonoscopy and an elevated fecal calprotectin OR C-reactive protein (CRP) level
 - Has concurrent upper gastrointestinal signs or symptoms with a nondiagnostic upper endoscopy
 - Does not meet criteria for irritable bowel syndrome and does not have concurrent upper gastrointestinal signs or symptoms

- Management of new or worsening symptoms to confirm exacerbation or evaluate for complications, including stricture, abscess, toxic megacolon, or fistula

Rationale

Leukocyte scintigraphy also has the advantage of full gastrointestinal visualization and can detect sites of inflammatory bowel disease with the small and large bowel.^{25, 26} Relative to CT/MRI, leukocyte scintigraphy has lower spatial resolution, higher radiation doses, and is less widely available; hence, it is typically reserved as an add-on test when CT or MR enterography are nondiagnostic.

Osteomyelitis and septic arthritis (SPECT or SPECT/CT)

Also see Bone Marrow Scintigraphy.

Leukocyte scintigraphy is considered medically necessary 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

Rationale

Functional imaging with bone scintigraphy has historically been used to evaluate for osteomyelitis when radiographs are nondiagnostic. Greater accuracy and the lack of ionizing radiation for MRI have largely made scintigraphy an add-on test when MRI cannot be performed or is nondiagnostic²⁷⁻²⁹, although bone scintigraphy offers a wider field of view and hence can localize multifocal disease. Similarly, leukocyte scintigraphy is usually not appropriate in the initial evaluation of osteomyelitis²⁷ but may play a complementary role to bone scintigraphy in specific scenarios such as multifocal disease.

Perioperative evaluation, not otherwise specified, including delayed hardware failure (SPECT only)

Also see Bone Marrow Scintigraphy.

Leukocyte scintigraphy (with or without bone marrow scintigraphy) is considered medically necessary in **EITHER** of the following scenarios:

- For diagnosis and management of periprosthetic infection
- For evaluation of clinically suspected vascular graft or endograft infection (VGEI)

Rationale

EXTREMITY

Leukocyte scintigraphy is an option in patients with suspected periprosthetic infection³⁰ and has a high diagnostic accuracy (greater than 90%) for periprosthetic infections of the hip and knee; bone scintigraphy is highly sensitive for infection but is less specific.^{31, 32}

SPINE

For periprosthetic infections in the spine, a variety of structural and functional imaging modalities may help define the presence or extent of disease. CT and MRI are commonly performed but evaluation of the surgical bed may be limited by beam hardening/susceptibility artifact. Gallium and bone scintigraphy are functional imaging alternatives that have a higher diagnostic accuracy than leukocyte scintigraphy in the spine.^{11, 12}

Infectious and inflammatory conditions, not otherwise referenced (SPECT only)

Leukocyte scintigraphy is considered medically necessary for diagnosis and management in **EITHER** of the following scenarios:

- To evaluate for sternal wound infection or dehiscence when CT chest is nondiagnostic
- To evaluate sites of intra-abdominal infection suspected by CT or MRI

Rationale

CHEST

CT chest is usually sufficient for evaluating for sternal wound dehiscence or other forms of chest infection and has the advantage of simultaneous visualization of the mediastinum and lung parenchyma.³³ Historically and in rare circumstances, bone or leukocyte scintigraphy has been used to differentiate superficial and deep infections, although evidence for diagnostic accuracy is limited.³⁴

ABDOMEN AND PELVIS

CT or MRI is usually sufficient to evaluate for complications of intra-abdominal infection such as abscess and are widely available and commonly performed. However, factors such as distorted anatomy, ileus, ascites, and healing wounds can complicate the structural assessment of infection.²⁶ When diagnostic uncertainty remains following CT and/or MRI, leukocyte scintigraphy may be helpful as an add-on test to further characterize suspected sites of infection such as infected surgical material including vascular grafts, shunts, or abscess.^{25,26}

SPECT Lymphoscintigraphy (SPECT or SPECT/CT)

For sentinel node localization when clinical evaluation is negative for nodal involvement, in the following scenarios:

- Stage I-III invasive breast cancer
- Ductal carcinoma in situ (DCIS) when mastectomy is planned
- 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)

SPECT Metaiodobenzylguanidine (MIBG) Scintigraphy (SPECT or SPECT/CT)

Neuroendocrine cancer

Diagnostic workup and management of documented neuroendocrine cancer in the following scenarios:

Diagnostic workup

As clinically indicated for neuroblastoma or tumors of the autonomic nervous system (pheochromocytoma, paraganglioma, ganglioneuroma) in **ANY** of the following scenarios:

- Suspected metastatic disease
- Suspected neuroblastoma or tumors of the autonomic nervous system (pheochromocytoma, paraganglioma, ganglioneuroma) based on CT, MRI or abnormal serum or urine metanephrine levels
- For pheochromocytoma/paraganglioma prior to planned I131 iobenguane treatment

Management

As clinically indicated for pheochromocytoma/paraganglioma prior to planned I131 iobenguane treatment.

SPECT Parathyroid Imaging (SPECT or SPECT/CT)

Parathyroid adenoma

To identify a parathyroid adenoma for surgical planning in patients with primary hyperparathyroidism.

Localization of residual parathyroid tissue in patients with recurrent or persistent disease following parathyroidectomy.

Rationale

Ultrasound and sestamibi scintigraphy are the most common initial imaging tests used to evaluate suspected parathyroid adenoma and have a diagnostic accuracy of above 80%.³⁵ A meta-analysis of 12 diagnostic accuracy studies with over 500 patients found comparable sensitivity for ultrasound (80%, CI 77%-83%) and planar sestamibi scintigraphy (84%, CI 80%-87%) and slightly higher specificity for sestamibi (87%, CI 83%-91%) vs ultrasound (77%, CI 71%-82%).³⁶ When ultrasound and sestamibi exams are not diagnostic, 4-dimensional CT, including dynamic contrast enhancement, has high sensitivity (94%) and specificity (96%).³⁷ This is consistent with clinical practice/consensus-based guidelines on parathyroid scintigraphy.^{38, 39}

SPECT Pyrophosphate Imaging

Amyloidosis

For evaluation of cardiac amyloidosis in **ANY** of the following scenarios:

- Patient who is a carrier of the TTR gene mutation in **ANY** of the following scenarios:
 - Baseline screening for cardiac amyloidosis in asymptomatic carrier
 - Surveillance at two (2) yearly intervals in asymptomatic carrier
 - New or worsening symptoms suggestive of amyloidosis (cardiac or extracardiac)
- New onset symptomatic heart failure when **ANY** of the following apply:
 - African-American patient > 60 years old with **EITHER** of the following:
 - Heart failure of unknown etiology
 - Mean left ventricular wall thickness > 12 mm on echocardiography
 - Non-African-American patient > 60 years old with **BOTH** of the following:
 - Heart failure of unknown etiology
 - Mean left ventricular wall thickness > 12 mm on echocardiography
 - Patient with known or suspected familial amyloidosis
 - Patient with unexplained peripheral sensorimotor neuropathy
 - Patient > 60 years old with low-flow, low-gradient aortic stenosis
 - Patient > 60 years old with unexplained biceps tendon rupture
- Established extracardiac transthyretin amyloidosis (ATTR) with new or worsening cardiac symptoms
- Bilateral carpal tunnel syndrome (with or without heart failure) in patients who are > 60 years old
- Other testing suggestive of cardiac amyloidosis in patients - **EITHER** of the following:
 - Echocardiogram consistent with amyloidosis
 - Cardiac MRI consistent with amyloidosis

Rationale

Cardiac amyloidosis results from the deposition of an abnormal protein in the extracellular matrix of the myocardium. The most common types of cardiac amyloidosis which manifest clinically are transthyretin amyloidosis (ATTR) and light chain amyloidosis (AL). The clinical presentation of cardiac amyloidosis is variable does not differentiate ATTR from AL. Echocardiography and Cardiac MR imaging provide suggestive evidence of cardiac amyloidosis but are not diagnostic and cannot differentiate between AL and ATTR. However, this differentiation is important in selection of optimal treatment, prognostication, and genetic counseling.

99mTc-PYP imaging can lead to a diagnosis of ATTR without the need for biopsy when there are Echo or Cardiac MRI findings consistent with amyloidosis and laboratory markers of AL (serum and urine immunofixation electrophoresis and serum kappa/lambda ratio) are absent. False positive 99mTc-PYP imaging studies can occur in the setting of AL.⁴⁰⁻⁵³

SPECT Renal Scintigraphy (Pediatric only) (SPECT only)

Renal scarring

To evaluate for renal scarring at least 4 months following urinary tract infection in **EITHER** of the following scenarios:

- Age less than 3 years with atypical urinary tract infection
- Recurrent urinary tract infection

Rationale

Renal scintigraphy using dimercaptosuccinic acid (DMSA) is sensitive for the detection of renal scarring following urinary tract infection or pyelonephritis. Renal scintigraphy is not routinely indicated in initial evaluation of a urinary tract infection (UTI), but may be used to help direct management including use of prophylactic antibiotics in children under 3 years of age with atypical UTIs (including features such as septicemia, infection with non Escherichia coli organisms, and other markers of serious illness) or in patients with recurrent UTI.^{54, 55}

SPECT Somatostatin Receptor Imaging (SPECT or SPECT/CT)

Neuroendocrine cancer

Diagnostic workup and management of documented well-differentiated neuroendocrine cancer in **EITHER** of the following scenarios:

- Diagnostic workup in **EITHER** of the following scenarios:
 - Biopsy-proven well-differentiated neuroendocrine tumor
 - Suspected well-differentiated neuroendocrine tumor based on endoscopy, conventional imaging, or biochemical markers when not amenable to biopsy
- Management in **EITHER** of the following scenarios:
 - Prior to planned peptide receptor radioligand therapy (PRRT) for well-differentiated neuroendocrine tumor
 - When identification of more extensive disease will change management and **ANY** of the following criteria are met:
 - Equivocal findings of disease progression on conventional imaging
 - Clinical or biochemical progression with negative conventional imaging
 - When the original disease was only detectable by somatostatin receptor-based imaging

SPECT Thyroid Scintigraphy (SPECT or SPECT/CT)

Thyroid cancer

Diagnostic workup, management, and surveillance of documented thyroid cancer.

Diagnostic workup

As clinically indicated for differentiated thyroid cancer in **ANY** of the following scenarios:

- Prior to planned definitive radioactive iodine therapy in low risk patients
- Post thyroidectomy when radioactive iodine therapy is planned (except in low risk patients)
- For known or suspected metastatic disease when radioactive iodine therapy is planned

Management

As clinically indicated for differentiated thyroid cancer in **ANY** of the following scenarios:

- Immediately following radioactive iodine therapy
- Evaluation of persistent disease found on post radioactive iodine therapy imaging
- Evaluation for suspected recurrent thyroid cancer found during surveillance (i.e., elevated Tg, stable or rising antithyroglobulin antibodies, abnormal ultrasound during surveillance)

Surveillance

As clinically indicated for intermediate or high risk differentiated thyroid cancer 6 to 12 months after therapy has been completed.

Note: Low risk papillary thyroid cancer

- *Classic papillary thyroid cancer*
- *Largest primary tumor < 2 cm*
- *Intrathyroidal*
- *Unifocal or multifocal (all foci ≤ 1 cm)*
- *No detectable anti-Tg antibodies*
- *Postoperative unstimulated Tg < 1 ng/mL*

Note: Low risk follicular and Hurthle cell thyroid cancer

- *Largest primary tumor < 2 cm*
- *Intrathyroidal*
- *No vascular invasion*
- *Clinical N0*
- *Postoperative unstimulated Tg < 1 ng/mL*

Rationale

DIAGNOSTIC WORKUP

High quality evidence and medical society recommendations support the use of thyroid scintigraphy after thyroidectomy in patients with intermediate to high-risk differentiated thyroid cancer and in whom radioactive iodine treatment is planned. In a large systematic review, no clear improvement in overall survival or disease free survival was seen in low risk patients treated with radioactive iodine.⁵⁶ In a retrospective review of 1298 patients with low-risk differentiated thyroid cancer, radioactive iodine resulted in a 10-year overall survival of 95.8% while patients not treated with radioactive iodine after surgery had a 10-year overall survival of 94.6%.⁵⁷ Conversely, a review of the NCI database of 21,870 patients with intermediate-risk differentiated thyroid cancer who underwent total thyroidectomy with or without radioactive iodine showed improved overall

survival ($P < .001$). After a multivariate adjustment for demographic and clinical factors, radioactive iodine was associated with a 29% reduction in the risk of death, with a hazard risk 0.71 (95% CI, 0.62-0.82; $P < .001$).⁵⁸ In a 2015 NTCTCS Registry analysis of 4941 patients, improved overall survival was seen in stage III patients who received radioactive iodine (risk ratio, 0.66; $P = .04$) and stage IV patients who received both total/near-total thyroidectomy and radioactive iodine (risk ratio, 0.66 and 0.70; combined $P = .049$).⁵⁹

MANAGEMENT

Relatively weak evidence and medical society recommendations support the use of thyroid scintigraphy after radioactive iodine treatment evaluation. Up to 25% of images show lesions that may be clinically important but which were not originally detected on diagnostic imaging. In a retrospective study comparing whole body scans obtained before and after radioactive iodine in patients ($N = 93$) with thyroid carcinoma, in 27% of treatment cycles, the results of posttreatment and pretreatment scans differed. Only 10% of post-treatment scans detected new locations of metastatic disease.

SCREENING AND SURVEILLANCE

Biochemical monitoring remains the most vital component for surveillance of differentiated thyroid cancer, although conventional imaging may also be considered when clinically indicated. High quality evidence and medical society recommendations do not support the use of thyroid scintigraphy for asymptomatic surveillance of patients without evidence of disease. Both the American Thyroid Association and NCCN give consideration to a single exam after completion of therapy in intermediate-risk and high-risk differentiated thyroid cancer patients. The value of continued monitoring if no evidence of disease is seen is controversial.^{60, 61}

SPECT VQ Scintigraphy (SPECT only)

Pulmonary embolism, in the following scenarios:

Adult: In pregnant patients or when CT/CTA cannot be performed or is nondiagnostic

VQ scintigraphy is considered medically necessary in **ANY** of the following scenarios:

- Pulmonary embolism *likely* based on modified Wells criteria⁶² (> 4 points)
- Pulmonary embolism *unlikely* based on modified Wells criteria⁶² (≤ 4 points) with a positive D-dimer
- Suspected pulmonary embolism in pregnancy

Pediatric

VQ scintigraphy is considered medically necessary in **EITHER** of the following scenarios:

- Moderate or high clinical suspicion of pulmonary embolism
- Concern for recurrent embolism in patients on adequate medical therapy

Rationale

For patients with suspected pulmonary embolism of moderate-to-high pretest probability, the majority of high-quality evidence-based guidelines recommend the use of VQ scintigraphy as an add-on test when CTA is nondiagnostic or cannot be performed due to contrast allergy or nephrotoxicity.^{6, 63} While systematic reviews of comparative diagnostic accuracy are mixed^{64, 65}, many cited studies used earlier generations of CT technology, limiting the applicability of this literature to contemporary clinical practice. CT has fewer nondiagnostic studies⁶⁶ and is widely available. Comparative effective radiation dose between VQ scintigraphy and CT is also controversial, but a normal VQ or Q scan may offer a lower radiation dose than CT and confidently exclude pulmonary embolism when negative (negative likelihood ratio 0.05).⁶⁴ Scintigraphy is also recommended by consensus-based guidelines as an alternative test in pregnant patients.⁶⁷

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Codes

The following code list is not meant to be all-inclusive. Authorization requirements will vary by health plan. Please consult the applicable health plan for guidance on specific procedure codes.

Specific CPT codes for services should be used when available. Nonspecific or not otherwise classified codes may be subject to additional documentation requirements and review.

CPT/HCPCS

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78071	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT)
78072	Parathyroid planar imaging (including subtraction, when performed); with tomographic (SPECT), and concurrently acquired computed tomography (CT) for anatomical localization
78803	Radiopharmaceutical localization of tumor or distribution of radiopharmaceutical agent(s); tomographic (SPECT)
78830	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, single area (eg, head, neck, chest, pelvis), single day imaging
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
78832	Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT) with concurrently acquired computed tomography (CT) transmission scan for anatomical review, localization and determination/detection of pathology, 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

Refer to the ICD-10 CM manual

History

Status	Review Date	Effective Date	Action
Revised	01/24/2023	09/10/2023	Independent Multispecialty Physician Panel (IMPP) review. Revised indications for SPECT Bone Imaging and SPECT Leukocyte Scintigraphy.
Revised	11/11/2021	09/11/2022	IMPP review. Revised indications for SPECT Imaging – General and SPECT Bone Imaging.
Revised	11/11/2021	06/12/2022	IMPP review. Added and/or revised indications for SPECT Imaging – General, SPECT Lymphoscintigraphy, and SPECT Pyrophosphate Imaging.
Updated	-	09/12/2021	Added codes 78071 and 78072.
Created	07/08/2020	01/01/2021	Original effective date. IMPP review.