Medica.

UTILIZATION MANAGEMENT POLICY

TITLE: POSITRON EMISSION TOMOGRAPHY (PET) SCAN – MAYO MEDICAL PLAN ONLY

EFFECTIVE DATE: May 01, 2024

THIS POLICY APPLIES TO MAYO MEDICAL PLAN (MMP) MEMBERS.

NOTE: Medica is using clinical criteria developed by Carelon, a utilization management (UM) program third-party vendor, to assist in administering medical necessity criteria.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage. With respect to Medicare, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between utilization management reviewers by providing the criteria that determines the medical necessity.

BACKGROUND

- I. Definitions
 - A. **Cardiac sarcoidosis** is a rare inflammatory disease in which clusters of white blood cells, called granulomas, form in the tissue of the heart. Any part of the heart can be affected, though these cell clusters most often form in the heart muscle where they can interfere with the heart's electrical system and cause arrhythmias. Most individuals with cardiac sarcoidosis also have granulomas in other organs of the body, most commonly in the lungs. **Extracardiac** disease activity can be found in the lung, lymph nodes, liver, spleen, kidneys, and bones.
 - B. **Coronary Artery Disease (CAD)** refers to any one of the abnormal conditions that may affect the arteries of the heart and produce various pathologic effects, especially the reduced flow of oxygen and nutrients to the myocardium. The major complications of CAD are angina, myocardial infarction, and sudden cardiac death due to arrhythmias.
 - C. **Neurocognitive disorder** (previously known as dementia) is an umbrella term for a group of symptoms associated with a decline in memory, executive, and/or other cognitive functions. Alzheimer's disease is the most common, neurocognitive disorder.30,31 Two kinds of advanced imaging, structural and functional, are available for further characterization of dementia. Structural imaging includes MRI and CT and evaluates for masses and for morphologic changes in the brain parenchyma. Functional imaging includes PET/CT with FDG or Amyvid.
 - D. Myocardial perfusion imaging is a non-invasive imaging test that shows how well blood flows through (perfuses) the heart muscle. It shows areas of the heart muscle that are not getting enough blood flow. This test is often called a nuclear stress test. There are two techniques for this imaging: single photon emission computed tomography (SPECT) and positron emission tomography (PET).
 - E. **Positron emission tomography (PET)** is a three-dimensional diagnostic imaging technique that uses a radioactive substance (tracer) to look for disease in the body. The test involves either an intravenous injection or inhalation of the tracer which travels through the body and is absorbed by the organs and

tissues. Once the tracer is absorbed, the individual will proceed with the scan. The PET scanner detects and records the energy given off by the tracer and, with the aid of a computer, this energy is converted into three-dimensional pictures. The physician can view cross-sectional images of the body organ from any angle in order to detect any functional problems. A PET scan shows how the organs and tissues are functioning and can measure blood flow, oxygen use, neurotransmitter dynamics, and metabolic changes.

- F. **Positron emission tomography/computed tomography (PET/CT)** is a diagnostic imaging technique that combines the functional information from the PET with the anatomical information from the CT into one set of images. Both scans are performed at the same time. The results are merged and form highly-defined, three-dimensional images that provide detailed functional information about metabolic activity. The PET/CT is primarily used in oncology for cancer diagnosis and staging, but it can also be used in the management of neurologic conditions (e.g., to localize epileptic seizures), and cardiologic conditions (e.g., evaluation of myocardial viability).
- G. **Radiotracers (radiopharmaceuticals)** are radioactive substances used in the diagnostic or therapeutic interventions in advance imaging like PET scan to create three-dimensional images. Radioactive tracers are administered via intravenous injection, inhalation, oral ingestion, or by direct injection into an organ. The mode of tracer administration will depend on the disease process that is to be studied. Tracers accumulate in areas of high metabolic activity such as tumor cells allowing the detection of cancer, monitor its progression, response to treatment, and to detect metastases.
- H. **Refractory epilepsy** is when medications do not successfully control the epileptic seizures. Epilepsy is a neurological disorder characterized by unpredictable seizures.
- I. **Solid tumor** is an abnormal mass of tissue that usually does not contain cysts or liquid areas. Solid tumors may be benign (not cancer), or malignant (cancer). Different types of solid tumors are named for the type of cells that form them. Examples of solid tumors are sarcomas, melanomas, and carcinomas. Leukemias (cancers of the blood) generally do not form solid tumors.
- J. **Surveillance** is done for the purpose of detecting recurrence or progression, or for predicting outcome in the absence of signs or symptoms of cancer beyond the completion of treatment.

II. Comments

A PET/CT test has two components: a PET scan and a CT, which are done together to provide functional information about metabolic activity. The radiation exposure from CT has a very wide range depending on the type of test, the area of the body scanned and the purpose of the test.

The effective dose from a PET is modest and depends on the activity of the tracer injected. Most commonly, PET utilizes Fluorodeoxyglucose f-18 fdg (¹⁸F-FDG) as a radiotracer, the short half-life (110 min) of which reduces radiation exposure compared with other commonly used radionuclides such as ^{99m}Technetium (6 hours) and ²⁰¹Thallium (72 hours). The radiation exposure from ¹⁸F results in internal exposure to the patient and low-level external exposure to other people in their vicinity.

Radiation effects are known to be cumulative in nature when repeat radiological procedures are performed. Therefore, it is important that the provider is aware of all previous diagnostic imaging.

PET imaging is sometimes performed using non FDG radiotracers.

BENEFIT CONSIDERATIONS

- 1. Prior authorization **is required** for PET scans in the outpatient setting. Please see the prior authorization list for product specific prior authorization requirements.
- 2. Prior authorization is **NOT required** for PET scans in the inpatient hospital setting.
- 3. Coverage may vary according to the terms of the member's plan document.
- 4. Request for additional scans for the same indication for the sole purpose of changing providers is not medically necessary.
- 5. Radiotracers used in any of the diagnostic or therapeutic interventions listed in the policy must be FDA approved or conditionally approved for the intended use.
- 6. Positron emission tomography (PET) scan with or without computed tomography (CT) *is investigative and therefore, not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to:
 - a. Screening of asymptomatic patients, with or without risk factors for a specific condition or disease.
 - b. Routine surveillance imaging following completion of therapy unless otherwise notice in the Medical Necessity Criteria section.
 - c. Neurologic applications in disorders such as:

- 1) Congenital and Developmental Conditions
 - Attention-deficit hyperactivity disorder (ADHD),
 - Autism spectrum disorders
 - Developmental delay (Pediatric only)
 - Congenital anomalies (Chiari malformation, craniosynostosis, macrocephaly, microcephaly, ataxia-telangiectasia, fragile X syndrome, and congenital anomalies of the posterior fossa)
 - Schizophrenia
 - Sickle cell disease (Pediatric only)
- 2) Infectious Conditions (other than the indications listed in the Medical Necessity Criteria section),
- 3) Inflammatory Conditions such multiple sclerosis (MS) and other white matter diseases
- 4) Neurodegenerative Conditions for initial evaluation in disorders associated with impaired movement (Adult only) to exclude an underlying structural lesion, such as:
 - Hemifacial spasm
 - Huntington's disease
 - Multiple system atrophy
 - · Parkinson's disease with atypical features
 - Progressive supranuclear palsy
 - Secondary dystonia
 - Other focal or lateralizing movement disorder, such as hemiballismus, athetosis, or chorea
- 5) Head Trauma
- 6) Tumor or Neoplasm
 - Acoustic neuroma
 - Meningioma
 - Pituitary adenoma
- 7) Miscellaneous Conditions, such as:
 - Bell's palsy (peripheral facial nerve palsy)
 - Cerebrovascular disorders (e.g., stroke, transient ischemic attack (TIA), hematoma or hemorrhage – intracranial or extracranial)
 - Horner's syndrome
 - Hydrocephalus/ventricular assessment
 - Neurocutaneous disorders, includes neurofibromatosis, Sturge-Weber syndrome, tuberous sclerosis, and von Hippel-Lindau disease
 - Spontaneous intracranial hypotension (SIH)
 - Trigeminal neuralgia and persistent idiopathic facial pain (Adult only)
- 8) Perioperative/Periprocedural Imaging
 - Lumbar puncture risk assessment
 - Ataxia
 - Dizziness or vertigo
 - Headache
 - Hearing loss
 - Mental status change and encephalopathy
 - Papilledema
 - Syncope
 - Tinnitus
 - Visual disturbance
- d. Neurologic assessment of patients with substance abuse.
- e. Assessment of all other diseases or conditions not listed in the Medical Necessity Criteria section.
- 7. If the Medical Necessity Criteria and Benefit Considerations are met, Medica will authorize benefits within the limits in the member's plan document.
- 8. If it appears that the Medical Necessity Criteria and Benefit Considerations are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are reminded of the appeals process in their Medica Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

Advanced imaging using FDG-PET/CT is considered medically necessary for the diagnosis, diagnostic workup, surveillance, and/or management of the following medical conditions:

NOTE: Routine surveillance imaging following completion of therapy is not considered medically necessary unless notice otherwise (Please see Benefit Considerations section).

I. Brain Indications for PET Scan – Must meet one or more of the following

- A. Neurocognitive disorders (Adult only) Includes mild cognitive impairment, dementia, and variants (e.g., vascular, Alzheimer's disease, frontotemporal degeneration spectrum, diffuse Lewy body). PET imaging is considered medically necessary to direct management in **one or more of the following** scenarios:
 - FDG-PET/CT brain (diagnosis) One-time evaluation to differentiate between frontotemporal dementia and Alzheimer's disease when substantial diagnostic uncertainty remains after **all of the following**:
 - a. Neuropsychological testing
 - b. Evaluation by a physician experienced in neurodegenerative disease
 - c. Structural imaging (CT or MRI).
 - 2. Amyloid PET Imaging (diagnosis/management)
 - a. When performed under Coverage with Evidence Development (CED) in Medicare beneficiaries.
- B. Seizure disorder and epilepsy PET brain imaging is medically necessary in epilepsy refractory to optimal medical management in surgical candidates when done to identify a focus of seizure activity in **one or more of the following** scenarios:
 - 1. ADULT must meet **one or more** of the following:
 - a. PET-Diagnosis: Initial evaluation of a new or changing pattern of seizures, to rule out a structural brain lesion as a cause of seizure
 - b. PET-Management: Patients without a confident diagnosis of idiopathic generalized epilepsy in **one or more** of the following scenarios:
 - 1) Evaluation of seizures increasing in frequency or severity despite optimal medical management
 - 2) Prior to discontinuation of anticonvulsant therapy in patients who have not been previously imaged
 - 3) Epilepsy refractory to optimal medical management in surgical candidates.
 - 2. PEDIATRIC Must meet one or more of the following:
 - a. Neonatal/infantile seizure (age 2 years or younger) when **one or more of the following** is present:
 - 1) Initial evaluation of seizure not associated with fever
 - 2) Periodic follow up at 6-month intervals up to 30 months, if initial imaging study is nondiagnostic.
 - b. Childhood/adolescent seizure (over age 2) for diagnosis and management when **one or more of the following** is present:
 - 1) Focal neurologic findings at the time of the seizure
 - 2) Persistent neurologic deficit in the postictal period
 - 3) Idiopathic generalized epilepsy with atypical clinical course
 - 4) Partial seizures
 - 5) Electroencephalogram (EEG) findings inconsistent with idiopathic epilepsy or nondiagnostic EEG
 - 6) Management of patients without an established diagnosis of idiopathic generalized epilepsy in **one or more of the following** scenarios:
 - i. Evaluation of seizures increasing in frequency or severity despite optimal medical management
 - ii. Prior to discontinuation of anticonvulsant therapy in patients who have not been previously imaged
 - iii. Epilepsy refractory to optimal medical management in surgical candidates.
 - c. Complex febrile seizure (age 6 months to 5 years) when **one or more of the following** is present:
 1) More than one seizure during a febrile period

2) Seizure lasting longer than 15 minutes.

Note: Imaging is not generally indicated for simple febrile seizures.

- II. CHEST (Tumor or Neoplasm) Must meet one or more of the following:
 - A. Pulmonary nodule or mass PET scan imaging (FDG-PET, FDG-PET/CT) is considered medically necessary when **all of the following** criteria are met:
 - 1. Nodule is well-demarcated, solid, or part solid, and lacks a *benign calcification pattern.
 - 2. Size is greater than 8 mm in greatest diameter.

Notes:

- *Benign calcification patterns include granulomas and popcorn calcifications, for which routine follow up is not medically necessary.
- Follow up of calcified nodules other than those with benign calcification patterns* is at the discretion of the ordering provider.
- For solid nodules: see Appendix Table 3; for subsolid nodules: see Appendix Table 2. High-risk patients should usually proceed directly to FDG-PET/CT or biopsy.
- B. Thoracic Lymphadenopathy (defined as at least one lymph node greater than 1 cm in short axis diameter) FDG-PET/CT imaging is medically necessary for diagnosis, management, or surveillance in patients with multiple abnormal (by size or feature) lymph nodes when CT is insufficient to determine the optimal node to biopsy. **One or more of the following** scenarios must be met:
 - 1. Palpable thoracic or supraclavicular lymph nodes, when not amenable to percutaneous biopsy
 - 2. Mediastinal or hilar lymph nodes when **one or more of the following** is present:
 - a. Suspected by non-advanced imaging (i.e., chest radiography)
 - b. Single follow up at least 3 months after discovery of nodes with a short axis diameter greater than 1.4 cm without suspicious features
 - c. Associated clinical or lab findings suggestive of malignancy, especially lymphoma or testicular carcinoma
 - d. Lymphadenopathy with suspicious features, such as one or more of the following:
 - 1) Necrosis
 - 2) Loss of fatty hilar morphology
 - 3) Heterogenous or hypervascular enhancement
 - 4) Irregular borders
 - 5) Interval enlargement
 - 6) Multiple enlarged nodes on the same side of the mediastinum (ipsilateral/unilateral)

Note: See Oncologic Imaging section for patients with documented malignancy.

III. Extremities – All of the following must be met:

A. Osteomyelitis or Septic Arthritis - FDG-PET imaging for diagnosis and management of osteomyelitis or septic arthritis is considered medically necessary when radiograph, ultrasound, and/or arthrocentesis is nondiagnostic or not sufficient to guide treatment.

IV. Heart – One or more of the following must be met:

Note: Commonly Used Radiopharmaceuticals: Ammonia (13NH3), Rubidium Chloride (82 RbCl), 2-(18F) FLURO-2DEOXY-D-GLUCOSE (FDG).

- A. PET perfusion imaging is appropriate as the initial noninvasive stress imaging test when **one or more of the following** applies:
 - 1. Suspected CAD in symptomatic patients who have not had evaluation for CAD within the preceding 60 days. **One or more of the following**:
 - a. Chest pain with or without other symptoms of myocardial ischemia, with pretest probability of CAD > 15% (see Appendix, Table 1)
 - b. Patients without chest pain whose predominant symptom is dyspnea, with pretest probability of CAD > 15% (see Appendix, Table 1)
 - c. Patients with any cardiac symptom who have diseases/conditions with which CAD commonly coexists, such as **one or more of the following**:

- 1) Abdominal aortic aneurysm
- 2) Established and symptomatic peripheral vascular disease
- 3) Prior history of stroke, transient ischemic attack (TIA), carotid endarterectomy (CEA), or highgrade carotid stenosis (> 70%)
- 4) Chronic kidney disease
- 2. Established flow-limiting CAD in asymptomatic patients, one or more of the following:
 - Patients whose symptoms persist despite maximal anti-ischemic medical therapy or has contraindication thereto.
 Note: Patients with established CAD and typical angina pectoris despite maximal anti-ischemic therapy may be better served with invasive coronary angiography
 - b. To establish myocardial viability in patients who are candidates for revascularization and have left ventricular systolic dysfunction (LV ejection fraction < 55%)
- 3. Established flow-limiting CAD in patients who have new or worsening symptoms, **one or more of the following:**
 - Patients whose symptoms persist despite maximal anti-ischemic medical therapy or contraindication thereto.
 Note: Patients with established CAD and typical angina pectoris despite maximal anti-ischemic therapy may be better served with invasive coronary angiography
 - b. To establish myocardial viability in patients who are candidates for revascularization and have left ventricular systolic dysfunction (LV ejection fraction < 55%)
- 4. Established or suspected CAD, one or more of the following:
 - a. Patients who have undergone cardiac transplantation, one or more of the following:
 - 1) With new or worsening cardiac symptoms
 - 2) With new or worsening physical examination abnormalities
 - 3) Clinically stable patients who have not had evaluation for CAD in the preceding year.
 - b. Patients (symptomatic or asymptomatic) with **one or more of the following** new onset arrhythmias who have not had evaluation for CAD since the arrhythmia was recognized.
 - 1) Sustained (lasting more than 30 seconds) or nonsustained (more than 3 beats but terminating within 30 seconds) ventricular tachycardia
 - 2) Atrial fibrillation or flutter and high or intermediate risk of CAD (using ASCVD Pooled Cohort Equations)
 - 3) Atrial fibrillation or flutter and established CAD
 - Frequent premature ventricular contractions (PVC) defined as more than 30 PVCs per hour on ambulatory EKG (Holter) monitoring.
 Note: Perfusion PET is not clinically indicated for evaluation of infrequent premature atrial or
 - ventricular depolarizations
 Patients (symptomatic or asymptomatic) with new onset CHF or recently recognized LV systolic dysfunction who have not had evaluation for CAD since the onset of LV dysfunction/CHF must meet all of the following:
 - 1) For patients in this category with established CAD, or those with suspected CAD whose CAD risk (using ASCVD Pooled Cohort Equations) is high, coronary angiography may be more appropriate than noninvasive evaluation.
 - d. Abnormal resting EKG must meet one or more of the following:
 - 1) Patients with **one or more of the following** newly recognized and not previously evaluated resting EKG changes
 - I. Left bundle branch block
 - II. ST depression \geq 1 mm
 - III. Left ventricular hypertrophy with repolarization abnormality.
 - Patients who would otherwise undergo exercise EKG testing (without imaging) but have one or more of the following resting EKG findings that would render the interpretation of an exercise EKG test difficult or impossible:
 - I. Left bundle branch block
 - II. Ventricular paced rhythm

- III. Left ventricular hypertrophy with repolarization abnormality
- IV. Digoxin effect
- V. ST depression \geq 1 mm on a recent EKG (within the past 30 days)
- VI. Pre-excitation syndromes (e.g., Wolff-Parkinson-White syndrome).
- e. Patients with abnormal exercise treadmill test (performed without imaging) who have not undergone evaluation for CAD since the treadmill test. Abnormal findings on an exercise treadmill test include **one or more of the following**:
 - 1) Chest pain,
 - 2) ST segment change,
 - 3) Abnormal blood pressure response, or
 - 4) Complex ventricular arrhythmias.
- f. Patients who have undergone recent (within the past 60 days) stress testing with the following adjunctive imaging (SE, MPI, stress MRI) must meet **one of the following:**
 - 1) When the stress imaging test is technically suboptimal, technically limited, inconclusive, indeterminate, or equivocal, such that myocardial ischemia cannot be adequately excluded
 - 2) When the stress imaging test is abnormal and **ALL** of the following apply:
 - I. The stress test demonstrates moderate or severe ischemia
 - II. CCTA is requested to exclude left main CAD
 - III. In the absence of left main CAD guideline-directed medical therapy (GDMT) will be instituted
 - IV. Invasive coronary angiography will be reserved for persistent symptoms on GDMT

Note:

- A stress imaging test is deemed to be abnormal when there are abnormalities on the imaging portion of the test. Electrocardiographic abnormalities without imaging evidence of ischemia do not render a stress imaging test abnormal.
- Perfusion PET is not appropriate for patients who have had a recent normal or abnormal stress imaging test
- g. Preoperative cardiac evaluation of patients undergoing non-emergency non-cardiac surgery (includes surveillance for CAD in patients awaiting solid organ transplant) must meet **all of the following:**

Note: It is assumed that those who require emergency surgery will undergo inpatient preoperative evaluation.

- Prior to considering elective surgery, patients with active cardiac conditions such as unstable coronary syndromes (unstable angina), decompensated heart failure (NYHA class IV, worsening or new onset heart failure), significant arrhythmias (third degree AV block Mobitz II AV block, uncontrolled supraventricular arrhythmia, symptomatic ventricular arrhythmias, ventricular tachycardia), symptomatic bradycardia or severe stenotic valvular lesions should be evaluated and managed per ACC/AHA guidelines. That evaluation may include Perfusion
 - PET. Must meet one or more of the following:
 - I. Intermediate-risk surgery
 - II. Patients awaiting solid organ transplant (asymptomatic who have not undergone evaluation for CAD within the preceding one (1) year, or with symptoms consistent with myocardial ischemia).
- 5. Miscellaneous indications for PET perfusion imaging, one or more of the following:
 - a. Inability to perform exercise EKG test.
 - Patients who would otherwise undergo exercise EKG testing (without imaging) but are unable (for reasons other than obesity) to perform exercise to a degree that would yield a diagnostic test. This provision includes patients with musculoskeletal, neurological, or pulmonary limitation.
 - b. Established Kawasaki disease with coronary artery involvement. must meet **one or more of the following:**
 - 1) Evaluation every 2 years for confirmed small to medium-sized coronary artery aneurysm
 - 2) Annual evaluation for confirmed large (giant) coronary artery aneurysm, multiple or complex aneurysms, or coronary artery obstruction confirmed by angiography

- c. Prior to initiation of Interleukin-2, when a decision has been made to treat the patient with Interleukin-2.
- B. Indication for PET Perfusion performed in conjunction with Metabolic PET
 - Cardiac sarcoidosis
 Note: PET perfusion imaging is considered medically necessary in the evaluation of patients with
 suspected or established cardiac sarcoidosis when performed in conjunction with metabolic PET
 imaging.
- C. Indications for Metabolic PET Imaging must meet all of the following:
 - 1. Evaluation of myocardial viability

Metabolic PET imaging is considered medically necessary for evaluation of myocardial viability when **all of the following** criteria are met:

- a. Patient has established CAD
- b. Left ventricular systolic dysfunction
- c. Viability status is not defined by other testing
- d. Revascularization is being considered
- 2. Cardiac sarcoidosis Metabolic PET imaging (with or without perfusion imaging) is considered medically necessary.
- V. Oncologic Imaging (Cancer screening, not otherwise specified) must meet one or more of the following:
 - A. Anal Cancer must meet one of the following::
 - 1. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or is nondiagnostic for metastatic disease.
 - 2. Management FDG-PET/CT is considered medically necessary for one or more of the following:
 - a. Radiation planning for definitive treatment only
 - b. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.

Note: PET/CT does not replace a diagnostic CT scan.

- B. Bladder/Urothelial Cancers: Muscle Invasive- must meet one of the following:
 - 1. Diagnostic FDG-PET/CT workup is indicated in one or more of the following:
 - a. Evaluation of stage II or stage III bladder cancer prior to definitive treatment when standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - b. When bone metastasis is suspected based on signs and symptoms and standard imaging cannot be performed or is nondiagnostic.
 - 2. Management FDG-PET/CT (e.g., chemotherapy monitoring) is indicated when standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.

Note: PET is not indicated for surveillance or for bladder tumors which have not invaded the muscle (stage < cT2).

- C. Brain and Spinal Cord Malignancy must meet one of the following:
 - 1. FDG-PET/CT brain is indicated in the management for differentiation of posttreatment scarring from residual or recurrent disease or radiation necrosis from active tumor
 - 2. FDG-PET/CT whole body diagnostic workup is indicated for evaluation of possible systemic disease in proven CNS lymphoma.

Note: PET is not indicated for surveillance or Brain and Spinal Cord Malignancy.

- D. Breast Cancer must meet one of the following:
 - 1. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following**:
 - a. Locally advanced disease (stage IIIA-IIIC) has been established and standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - b. Clinical suspicion for metastatic disease when standard imaging cannot be performed or is non diagnostic for metastatic disease.
 - 2. Management FDG-PET/CT is considered medically necessary for one or more of the following:

- a. Radiation planning for treatment of locoregional recurrence
- b. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
- c. Evaluation of elevated LFTs or rising tumor markers when standard imaging has not clearly identified a site of recurrence or progression
- d. Restaging/treatment response when bone is the only site of measurable disease in the chest, abdomen, and pelvis.

Note:

- Routine surveillance imaging following completion of therapy is not considered medically necessary.
- 18F-fluoroestradiol (18F-FES) PET/CT is not indicated in breast cancer.
- E. Cancers of Unknown Primary / Cancers Not Otherwise Specified **One of the following** must be met:
 - 1. Diagnostic FDG-PET/CT workup or FDG-PET/CT management may be utilized for cancers not addressed elsewhere in this guideline, including cancers of unknown primary
 - a. Indicated when standard imaging cannot be performed or is nondiagnostic in determining the extent of disease.
- F. Cervical Cancer must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated for patients with a definitive diagnosis of stage IB1 or higher as an alternative to CT chest, abdomen, and pelvis
 - 2. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - a. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
 - b. Following radiation or chemoradiation when performed at least 12 weeks following completion of therapy
 - c. Signs or symptoms concerning for recurrent or metastatic disease.
- G. Colorectal Cancer must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated when standard imaging (CT Chest, Abdomen and Pelvis) cannot be performed or is non-diagnostic for surgically curable metastatic disease
 - 2. FDG-PET/CT management Indicated in one or more of the following scenarios:
 - a. CT is equivocal for metastatic disease and lesion(s) is/are greater than 1 cm in diameter
 - b. CT demonstrates recurrence that is potentially curable with surgery
 - c. CT does not demonstrate a focus of recurrence, but carcinoembryonic antigen (CEA) level is rising
 - d. Signs or symptoms are suggestive of recurrence and CT is contraindicated.
- H. Esophageal and Gastroesophageal Junction Cancers must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or does not demonstrate distant (M1) metastatic disease
 - 2. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - a. Radiation planning for preoperative or definitive treatment only
 - b. Single assessment of response to chemoradiation (as definitive treatment or prior to surgery) when performed at least 5 weeks after completion of therapy
 - c. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- I. Gastric Cancer must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated for tumors initially stage IB or higher when standard imaging cannot be performed or does not demonstrate distant (M1) metastatic disease, and the patient is a candidate for curative surgery.
 - 2. Management FDG-PET/CT is indicated in one or more of the following scenarios:
 - a. Radiation planning for preoperative or definitive treatment only
 - b. To determine resectability of residual disease following completion of primary (neoadjuvant) treatment, when follow-up evaluation with standard modalities does not demonstrate metastatic disease
 - c. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.

- J. Head and Neck Cancer must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following** scenarios:
 - a. Evaluation of locoregionally advanced cancers (T3-T4 primary or ≥ N1 nodal staging) of the oral cavity, oropharynx, hypopharynx, nasopharynx, larynx, and sinus
 - b. Following biopsy suggestive of a head and neck primary tumor (squamous cell cancer, adenocarcinoma, or anaplastic undifferentiated epithelial tumor) when CT or MRI evaluation of the neck has not detected a primary site of tumor.
 - 2. Management FDG-PET/CT is indicated in one or more of the following scenarios:
 - a. Radiation planning for preoperative or definitive treatment only
 - b. Treatment response evaluation, no sooner than 12 weeks after completion of radiation therapy or concurrent chemoradiation therapy
 - c. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
 - d. Follow up of an equivocal post-treatment PET scan, no sooner than 4 weeks after the study, to determine need for further intervention such as neck dissection.

Note:

- PET is not generally indicated for initial evaluation of lip and salivary gland cancers, regardless of stage.
- PET imaging is not indicated for adjuvant radiation therapy planning when all known disease has been removed.
- K. Hepatocellular and Biliary Tract Cancers must meet **one of the following** criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or is nondiagnostic regarding the extent of disease.
 - 2. Management FDG-PET/CT is indicated when standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- L. Histiocytic Neoplasms must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated in **one of the following** scenarios:
 - a. Patients with LCH and high-risk bone lesions and/or suspected multisystem disease
 - b. Patients with ECD or RDD.
 - 2. Management FDG-PET/CT is indicated for one or more of the following scenarios:
 - a. Following radiation therapy
 - b. Treatment response after 2-3 cycles of systemic therapy and at completion
 - c. After completion of surgical curettage
 - d. Treatment response of ECD.
 - 3. Surveillance FDG-PET/CT is Indicated for **one or more of the following** scenarios:
 - a. LCH: every 3-6 months for first 2 years following treatment completion, then annually
 - b. ECD/RDD: every 3-6 months after starting therapy until stabilization of disease.
- M. Lung Cancer Non-Small Cell must meet **one of the following** criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated for evaluation of extent of disease following biopsy confirmation of non-small cell lung cancer, if not previously performed
 - 2. FDG-PET/CT management is indicated in **one or more of the following** scenarios:
 - a. Radiation planning for preoperative or definitive treatment
 - b. Evaluation following induction or neoadjuvant therapy, to determine eligibility for resection
 - c. Assessment of response to definitive chemoradiation when performed at least 12 weeks following therapy
 - d. Standard imaging cannot be performed, or is nondiagnostic for recurrent or progressive disease
 - e. Surveillance CT Chest demonstrates recurrence.
- N. Lung Cancer Small Cell must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup: Indicated prior to definitive therapy when standard imaging is nondiagnostic for extent of disease
 - 2. Management FDG-PET/CT: Indicated prior to initiation of radiation therapy.

- O. Lymphoma Hodgkin must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup: Indicated (note: especially useful as an adjunct to CT imaging)
 - 2. Management FDG-PET/CT: Indicated in one or more of the following scenarios:
 - a. Radiation planning for definitive or consolidative treatment
 - b. Interim restaging following 2-4 cycles of treatment
 - c. Baseline post-treatment evaluation at least 3 weeks following completion of all cycles of chemotherapy or 12 weeks following completion of radiation therapy
 - d. Single follow up when first post-treatment baseline PET showed Deauville 4 or 5 findings*
 - e. Clinical suspicion for recurrence or progression of disease based on standard imaging or objective signs/symptoms.
- P. Lymphoma Non-Hodgkin and Leukemia must meet one of the following criteria:
 - 1. Acute Leukemia must meet one of the following criteria:
 - a. Diagnostic FDG-PET/CT workup: Indicated in one or more of the following scenarios:
 - 1) Clinical suspicion for extramedullary disease or lymphadenopathy
 - 2) When standard imaging cannot be performed or is nondiagnostic
 - b. Management FDG-PET/CT: Indicated in one or more of the following scenarios:
 - 1) Relapsed or refractory extramedullary disease
 - 2) Treatment response of ALL with lymphomatous extramedullary disease
 - 3) When standard imaging cannot be performed or is nondiagnostic
 - 2. Chronic lymphocytic leukemia or small lymphocytic lymphoma must meet **one of the following** criteria:
 - a. Diagnostic FDG-PET/CT workup: Indicated for suspicion of Richter's transformation when PET is utilized to direct biopsy
 - b. Management FDG-PET/CT: Indicated for suspicion of Richter's transformation when PET is utilized to direct biopsy.
 - 3. Lymphoma Non-Hodgkin: Indolent non-Hodgkin lymphoma must meet **one of the following** criteria:
 - a. Diagnostic FDG-PET/CT workup is indicated in one or more of the following scenarios:
 - 1) Initial evaluation of suspected lymphoma when lymph nodes are not amenable to biopsy
 - 2) Evaluation of suspected transformation to a more aggressive lymphoma based on clinical signs or symptoms
 - 3) Prior to initiation of therapy
 - b. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - 1) Radiation planning prior to definitive or consolidative treatment
 - 2) Evaluation at completion of therapy, when initial PET scan demonstrated FDG uptake
 - 3) Evaluation of suspected recurrence or progression of disease based on standard imaging when there is an indication to resume systemic treatment
 - 4) Evaluation of suspected transformation to a more aggressive lymphoma based on clinical signs or symptoms.
 - 4. Lymphoma Non-Hodgkin: Intermediate and high-grade non-Hodgkin lymphoma must meet **one of the following** criteria:
 - a. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following** scenarios:
 - 1) Initial evaluation of suspected lymphoma when lymph nodes are not amenable to biopsy
 - 2) Initial staging (often used as an adjunct to CT chest/abdomen/pelvis)
 - b. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - 1) Radiation planning prior to definitive or consolidative treatment
 - 2) Interim restaging following 2-4 cycles of treatment
 - 3) Evaluation at completion of therapy
 - 4) Evaluation of suspected recurrence or progression of disease based on standard imaging or objective signs/symptoms.

- Q. Melanoma must meet **one of the following** criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following** scenarios:
 - a. To determine the extent of involvement in mucosal melanoma or stage III and IV cutaneous melanoma, when used in place of CT chest, abdomen, and pelvis
 - b. Standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - c. When the primary site is unknown and standard imaging is negative
 - 2. Management FDG-PET/CT is indicated in one or more of the following scenarios:
 - a. Radiation planning for definitive treatment
 - b. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
 - c. To assess treatment response in mucosal melanoma or unresectable stage III and IV cutaneous melanoma, when used in place of CT chest, abdomen, and pelvis.
- R. Merkel Cell Carcinoma must meet all of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup and management as clinically indicated (whole-body PET/CT or PET/MRI or chest/abdomen/pelvis CT) is considered medically necessary of documented Merkel cell carcinoma.
- S. Multiple Myeloma must meet all of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated for multiple myeloma, smoldering myeloma, or solitary plasmacytoma
 - 2. Management FDG-PET/CT is indicated for one or more of the following scenarios:
 - a. Multiple myeloma
 - b. Smoldering myeloma or solitary plasmacytoma: restaging/treatment response, or follow-up every 12 months
- T. Neuroendocrine Tumors One or more of the following must be met:
 - 1. Well-differentiated neuroendocrine tumor
 - a. Diagnostic FDG-PET/CT workup is indicated in one or more of the following scenarios:
 - 1) Biopsy-proven well-differentiated neuroendocrine tumor
 - 2) Suspected well-differentiated neuroendocrine tumor based on endoscopy, conventional imaging¹, or biochemical markers² not amenable to biopsy.
 - b. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - 1) Prior to planned peptide receptor radioligand therapy (PRRT) for well-differentiated neuroendocrine tumor
 - 2) When identification of more extensive disease will change management and **one or more of the following** criteria are met:
 - I. Equivocal findings of disease progression on conventional imaging
 - II. Clinical or biochemical progression with negative conventional imaging
 - III. When the original disease was only detectable by somatostatin receptor-based imaging.
 - 2. Poorly-differentiated neuroendocrine tumor must meet one or more of the following criteria:
 - a. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - b. Management FDG-PET/CT is indicated to assess treatment response when PET used for initial staging.
- U. Ovarian Cancer All Variants must meet one or more of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated to direct management of indeterminate lesions detected by other imaging modalities

- 2. Management FDG-PET/CT is indicated when standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- V. Pancreatic Cancer **One of the following** criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated when all of the following are true:
 - a. Dedicated, high-quality imaging of the pancreas has been performed
 - b. Extra-pancreatic disease has not been clearly identified
 - c. ANY of the following high-risk features are present:
 - d. Cancer antigen 19-9 level greater than 100 U/ml
 - e. Primary tumor greater than 2 cm in size
 - f. Enlarged regional nodes
 - g. Tumor is considered borderline resectable.
 - 2. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - a. Radiation planning for preoperative or definitive treatment in patients without distant metastasis
 - b. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- W. Paraneoplastic Syndrome must meet one of the following criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated for initial evaluation of individuals with paraneoplastic syndrome.
 - 2. Management FDG-PET/CT is indicated for further management based on primary cancer identified.
- X. Penile, Vaginal, and Vulvar Cancers must meet **one of the following** criteria:
 - 1. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following** scenarios:
 - a. Standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - b. Staging of penile cancer when pelvic lymph nodes are enlarged on CT or MRI and needle biopsy is not technically feasible.
 - 2. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - a. Radiation planning for preoperative or definitive treatment only
 - b. Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
 - c. Restaging of local recurrence when pelvic exenteration surgery is planned.
- Y. Prostate Cancer must meet one or more of the following criteria:
 - 1. 18F Fluciclovine PET/CT or 11C Choline PET/CT for prostate cancer management is indicated when **all of the following** criteria are met:
 - a. Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy, with biochemically recurrent/persistent disease
 - b. Negative or nondiagnostic imaging based on most recent PSA value (if applicable):
 - c. PSA ≤ 1 ng/ml and rising: Prostate/Pelvic MRI (within past 60 days)
 - d. PSA ≥ 10 ng/ml: Any conventional imaging (within past 60 days)
 - e. Patient is a candidate for curative intent salvage therapy³
 - f. PET/CT with 18F Fluciclovine or 11C Choline has not been performed within the past 3 months.
 - 2. PET/CT Diagnostic Workup using 68Ga- or 18F-labeled radiotracers targeting prostate-specific membrane antigen (PSMA) is indicated for unfavorable intermediate or high-risk disease with equivocal or nondiagnostic conventional imaging, when confirmation may inform decisions about prostatectomy and/or radiation therapy.
 - 3. PET/CT for management of prostate cancer using 68Ga- or 18F-labeled radiotracers targeting prostate-specific membrane antigen (PSMA is indicated in **one or more of the following** scenarios:
 - a. When **all of the following criteria** are met:
 - 1) Original clinical stage T1-T3 and NX or N0 treated with prostatectomy and/or radiation therapy, with biochemically recurrent/persistent disease

- 2) Negative or nondiagnostic conventional imaging² (within 60 days) if PSA ≥ 10 ng/ml
- 3) Patient is a candidate for curative intent salvage therapy
- 4) PET/CT has not been performed within the past 3 months.
- b. Evaluation of metastatic castrate-resistant disease for radioligand therapy when previously treated with taxane-based chemotherapy, AND **one or more of the following** androgen-receptor pathway inhibitors:
 - 1) Abiaterone
 - 2) Apalutamide
 - 3) Enzalutamide
 - 4) Darolutamide.

Note: FDG-PET/CT Diagnostic or Management workup is not indicated in prostate cancer.

- Z. Sarcomas of Bone/Soft Tissue One or more of the following criteria are met:
 - 1. Bone Sarcoma One of the following criteria are met:
 - a. Diagnostic FDG-PET/CT workup is indicated in one or more of the following scenarios:
 - 1) Initial work-up of Ewing sarcoma and osteosarcoma if curative treatment planned
 - 2) Standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - 3) Standard imaging suggests a resectable solitary metastasis
 - 4) Baseline study prior to neoadjuvant chemotherapy.
 - b. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - 1) Following completion of neoadjuvant chemotherapy
 - 2) Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
 - 2. Soft Tissue Sarcoma One or more of the following criteria are met:
 - a. Diagnostic FDG-PET/CT workup is indicated in **one or more of the following** scenarios (excluding desmoid tumors):
 - 1) Standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - 2) Standard imaging suggests a resectable solitary metastasis
 - 3) Baseline study prior to neoadjuvant chemotherapy
 - 4) Initial staging for rhabdomyosarcoma.
 - b. Management FDG-PET/CT is indicated in **one or more of the following** scenarios:
 - 1) Following completion of neoadjuvant chemotherapy
 - 2) Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
 - 4. Gastrointestinal stromal tumor (GIST) **One or more of the following** scenarios:
 - a. Diagnostic FDG-PET/CT workup is indicated in one or more of the following scenarios:
 - 1) Standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - 2) Standard imaging suggests a resectable solitary metastasis
 - 3) Baseline study prior to neoadjuvant chemotherapy.
 - b. Management FDG-PET/CT is indicated in one or more of the following scenarios:
 - 1) Assess treatment response following completion of neoadjuvant chemotherapy
 - 2) Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- AA. Testicular Cancer One of the following criteria are met:
 - 1. Seminoma One of the following criteria are met:
 - a. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or is nondiagnostic for metastatic disease
 - b. Management FDG-PET/CT is indicated in one or more of the following scenarios:

- 1) Standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease
- 2) Residual mass greater than 3 cm and normal tumor markers after completion of chemotherapy.

Note: Nonseminoma – Imaging study with FDG-PET/CT diagnostic workup or management **is not indicated** for nonseminoma cancer.

- BB. Cancers of the Pleura, Thymus, Heart, and Mediastinum One or more of the following criteria are met:
 1. Diagnostic FDG-PET/CT workup is indicated in one of the following scenarios:
 - a. When surgical resection is being considered and metastatic disease has not been detected by CT or MRI
 - b. For surgical evaluation of malignant pleural mesothelioma (clinical stage I-IIIA and epithelioid histology), after CT chest and abdomen.
 - 2. FDG-PET/CT management is indicated in **one of the following** scenarios:
 - a. Radiation planning for definitive treatment
 - b. Restaging after induction chemotherapy if patient is a surgical candidate.

CC. Thyroid Cancer – One or more of the following criteria are met:

- 1. Diagnostic FDG-PET/CT workup is indicated for one of the following subtypes:
 - a. Poorly differentiated papillary
 - b. Anaplastic
 - c. Oncocytic (Hürthle Cell) carcinoma.
- 2. FDG-PET/CT management is indicated in **one or more of the following** scenarios:
 - a. Follow up of poorly differentiated papillary or anaplastic carcinoma
 - Suspected recurrence of well-differentiated papillary, follicular, or oncocytic (Hürthle cell) cancer when I-131 scan is negative (or has been negative in the past) and stimulated thyroglobulin level is > 2 ng/dL
 - c. Suspected recurrent medullary carcinoma when detectable basal calcitonin or elevated CEA, and standard imaging is negative.
 - 1) Somatostatin receptor (SSR) PET/CT diagnostic is indicated for medullary carcinoma
 - Somatostatin receptor (SSR) PET/CT management is indicated for suspected recurrent medullary carcinoma when detectable basal calcitonin or elevated CEA, and standard imaging is negative.
- DD. Uterine Cancer- One or more of the following criteria are met:
 - 1. Diagnostic FDG-PET/CT workup is indicated when standard imaging cannot be performed or is nondiagnostic for extent of metastatic disease
 - 2. FDG-PET/CT management is indicated when standard imaging cannot be performed or is nondiagnostic for recurrent or progressive disease.
- EE. Suspected or Known Metastases when the following criteria are met:
 - 1. NaF PET/CT (diagnostic, management, or surveillance) is indicated when performed as part of coverage under evidence determination (CED) in Medicare beneficiaries.
- VI. Spine: When the following criteria are met:
 - A. Spinal infection: All of the following criteria are met:
 - FDG-PET/CT imaging of the spine is considered medically necessary for chronic vertebral osteomyelitis, or when MRI cannot be performed and CT is nondiagnostic, and one or more of the following scenarios:

- a. Diagnosis in patients with new or worsening spinal pain or neurological abnormalities, and **one or more of the following:**
 - 1) Documented fever
 - 2) Elevated ESR or CRP
 - 3) Known bloodstream infection
 - 4) Risk factors: **One or more of the following:**
 - I. Diabetes mellitus
 - II. Intravenous drug use
 - III. Malignancy
 - IV. HIV
 - V. Dialysis
 - VI. Recent spinal intervention (examples include: surgery with or without hardware placement, stimulator implantation, or pain injection)
 - VII. Decubitus ulcer or wound overlying the spine
 - b. Management in patients with a poor response to therapy based on clinical and laboratory (ESR or CRP) assessment.

VII. Repeat FDG-PET/CT - One or more of the following criteria are met:

A. Repeat diagnostic FDG-PET/CT 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 **one or more of the following** scenarios:

- 1. Repeated diagnostic testing at the same facility due to technical issues
- 2. Repeated diagnostic testing requested at a different facility due to provider preference or quality concerns
- 3. Repeated diagnostic testing of the same anatomic area based on persistent symptoms with no clinical change, treatment, or intervention since the previous study
- 4. Repeated diagnostic testing of the same anatomic area by different providers for the same member over a short period of time.
- B. Repeat FDG-PET/CT Therapeutic Intervention **ALL of the following** criteria are met:
 - 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. Requests for on-going services may depend on completion of previously authorized services in situations where a patient's response to authorized services is relevant to a determination of clinical appropriateness.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

• For Medicare members, refer to the following, as applicable at: <u>https://www.cms.gov/medicare-coverage-database/new-search/search.aspx</u>

MINNESOTA HEALTH CARE PROGRAMS (MHCP)

 For MHCP members, refer to Lab/Pathology, Radiology & Diagnostic Services Manual Section– Radiology/Diagnostic Services at: <u>https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelection</u> <u>Method=LatestReleased&dDocName=dhs16_144355</u> DOCUMENT HISTORY

| Original Effective Date | <u>May 01, 2024</u> |
|-------------------------|---------------------|
| Administrative Updates | |

Appendix

Pretest Probability and CAD Risk Assessment

Reliability of noninvasive testing in accurately diagnosing or excluding CAD is dependent upon the likelihood of disease, which takes into account both **pretest probability** and **atherosclerotic disease risk.**

In those with low likelihood of disease, there is an unacceptably high rate of false-positive results, thus rendering these tests unreliable and potentially harmful.

Pretest probability may be estimated based on the quality of symptoms, age, and gender.

- Cardiac chest pain is centrally located, provoked by stress (exercise or emotional), and relieved by rest
- Possible cardiac chest pain has two of the three characteristics associated with cardiac chest pain
- Non-cardiac chest pain has one (or none) of the three characteristics associated with cardiac chest pain

The table below shows the pretest probability of obstructive CAD for patients presenting with chest pain and dyspnea stratified by age, gender, and the nature of the symptoms.

| | Cardiac | Cardiac | Possible cardiac | Possible cardiac | Noncardiac | Noncardiac | Dyspnea [#] | Dyspnea [#] |
|-------------|---------|---------|------------------|------------------|------------|------------|----------------------|----------------------|
| Age (years) | Male | Female | Male | Female | Male | Female | Male | Female |
| 30-39 | 3 | 5 | 4 | 3 | 1 | 1 | 0 | 3 |
| 40-49 | 22 | 10 | 10 | 6 | 3 | 2 | 12 | 3 |
| 50-59 | 32 | 13 | 17 | 6 | 11 | 3 | 20 | 9 |
| 60-69 | 44 | 16 | 26 | 11 | 22 | 6 | 27 | 14 |
| 70+ | 52 | 27 | 34 | 19 | 24 | 10 | 32 | 12 |

Table 1. Pretest Probability (%) of CAD by Age, Gender, and Symptoms

#Applies to patients who have dyspnea without chest pain

Adapted from Knuuti J, Wijns W, Saraste A, et al. 2019 ESC guidelines for the diagnosis and management of chronic coronary syndromes. Eur Heart J. 2020;41: 407–477.

| Table 2. Follow-u | p recommendations for | or subsolid | noncalcified | pulmonary | y nodules |
|-------------------|-----------------------|-------------|--------------|-----------|-----------|
| | | | | | |

| Subsolid nodule size | Solitary ground glass | Solitary part solid | Multiple subsolid | |
|----------------------------------|---|---|---|--|
| Less than 6 mm | No routine follow up | No routine follow up | 3 to 6 months 24 months 48 months | |
| Greater than or equal to 6 mm | 6 to 12 months Every 2 years thereafter for a total of 5 years | 3 to 6 months Every year for 5 years | 3 to 6 months Follow up based on most suspicious nodule (part solid or ground glass) | |

Abbreviation: Lung-RADS[™], American College of Radiology Lung CT Screening Reporting and Data System. Adapted from MacMahon H, Naidich DP, Goo JM, et al. *Radiology*. 2017; 284(1):228-243.¹²

| Solid nodule size | Risk | Solitary | Multiple | |
|---|-------|--|--|--|
| Less than 6 mm | Low | No follow up | No follow up | |
| Less than 6 mm | High* | Optional follow-up exam at 12 months | Optional follow-up exam at 12 months | |
| 6 mm to 8 mm | N/A | 6 to 12 months 18 to 24 months | 3 to 6 months 18 to 24 months | |
| More than 8 mm | N/A | 3 months 6 months 18 to 24 months unless FDG-PET/CT or tissue sampling performed and provided a definitive diagnosis | 3 to 6 months 18 to 24 months | |
| Any size when prior imaging has documented 24 months of stability | N/A | No follow up | No follow up | |

Table 3. Follow-up recommendations for solid noncalcified pulmonary nodules

*High risk includes the following:

- Smoking history (any)
- First-degree relative with lung cancer
- Significant exposure to asbestos, uranium and/or radon, typically through high-risk profession

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Oncology – PET Imaging

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