Medical Policy
Positron Emission Tomography (PET) Oncology and Miscellaneous Applications

Policy Number: PG0450
Last Review: 07/01/2021

HMO & PPO
MARKETPLACE
MEDICARE – ELITE, MAP

GUIDELINES

- This policy does not certify benefits or authorization of benefits, which is designated by each individual policyholder terms, conditions, exclusions and limitations contract. It does not constitute a contract or guarantee regarding coverage or reimbursement/payment. Self-Insured group specific policy will supersede this general policy when group supplementary plan document or individual plan decision directs otherwise.
- Paramount applies coding edits to all medical claims through coding logic software to evaluate the accuracy and adherence to accepted national standards.
- This medical policy is solely for guiding medical necessity and explaining correct procedure reporting used to assist in making coverage decisions and administering benefits.

SCOPE

X Professional
X Facility - Prior Authorization is required for those procedures performed in an elective outpatient setting. A prior authorization is not required for the emergency department, facility observation setting or inpatient setting

DESCRIPTION

Positron emission tomography (PET) is a minimally invasive diagnostic imaging technology that can reveal both metabolic and anatomical information in various tissue sites. The metabolic information is what distinguishes it from other imaging modalities such as magnetic resonance imaging (MRI) and computed tomography (CT) that provide primarily anatomic information. PET scans can distinguish benign from malignant masses in certain circumstances and improve the accuracy of staging by detecting additional disease not detected by other imaging modalities. PET scans evaluate metabolism in normal tissues as well as in diseased tissues in conditions such as cancer, ischemic heart disease, and some neurologic disorders. PET scans measure concentrations of radioactive chemicals that are partially metabolized in the body region of interest. PET scans are based on the use of positron emitting radionuclide tracers coupled to organic molecules, such as glucose, ammonia, or water. The rate of the metabolism provides biochemical information related to the metabolism of the tissue being studied. The clinical value of PET scans is related both to the ability to image the relative metabolic activity of target tissues and the resolution associated with PET scanners. Dedicated PET scanners consist of multiple detectors arranged in a full or partial ring around the patient, permitting the simultaneous detection of the high-energy paired photons that are emitted at 180 degrees from one another.

Combined positron emission tomography (PET) computed tomography (CT) systems merge PET and CT imaging technology into one system. The combined PET/CT scans provide images that pinpoint the anatomic location of abnormal metabolic activity within the body. The combined scans have been shown to provide diagnoses that are more accurate than the two scans performed separately.

Varieties of tracers, intravenously injected or inhaled, are used for PET scanning, including oxygen-15, nitrogen-13, carbon-11, rubidium-82 and fluorine-18. The radiotracer most commonly used in oncology imaging has been fluorine-18 coupled with fluorodeoxyglucose (FDG (22[F18] fluoro-2-deoxy-D-glucose)) which has a metabolism related to glucose metabolism. FDG is an injected radionuclide (or radiopharmaceutical) that emits sub-atomic particles, known as positrons, as it decays. FDG uses a positron camera (tomograph) to measure the decay of

FDG. The rate of FDG decay provides biochemical information on glucose metabolism in the tissue being studied. As malignancies can cause abnormalities of metabolism and flood flow, FDG PET evaluation may indicate the probable presence or absence of a malignancy based upon observed differences in biologic activity compared to adjacent tissues. FDG has been considered potentially useful in cancer imaging, since tumor cells show increased metabolism of glucose.

Another radioactive tracer substance (radiopharmaceutical) example is F-18 sodium (NA) fluoride (F). NaF-18 PET has been recognized as an excellent technique for imaging areas of altered osteogenic activity in bone. The clinical value of detecting and assessing the initial extent of metastatic cancer in bone is attested by a number of professional guidelines for oncology. Imaging to detect bone metastases is also recommended when a patient, following completion of initial treatment, is symptomatic with bone pain suspicious for metastases from a known primary tumor.

POLICY

Paramount Commercial Insurance Plans and Medicare Advantage Plans
Effective: 12/1/2020

- **PET Scans for Oncology and Miscellaneous Applications - Procedure codes: 78608, 78609, 78811, 78812, 78813, 78814, 78815, 78816, G0235, G0252 Require Prior Authorization, both professional and facility.**

Effective 08/01/2021, an additional option for outpatient imaging prior authorization requests from Paramount participating in-plan providers; Paramount is recognizing the Protecting Access to Medicare Act (PAMA) scores greater than or equal to a score of 8, for administrative approvals across all product lines. The request form can be located at:
https://www.paramounthealthcare.com/assets/documents/provider/Fax-Request-Form-imaging.pdf

Prior Authorization is required for those procedures performed in an elective outpatient setting. A prior authorization is not required for the emergency department, facility observation setting or inpatient setting.

COVERAGE CRITERIA

PET-CT Fusion: The fusion of PET and CT imaging into a single system (PET/CT fusion) is considered medically necessary for any oncologic and miscellaneous indication where PET scanning is considered medically necessary. The use of the term PET/CT within this policy applies to both positron emission tomography (PET) scans and PET/Computed Tomography (CT) scans, i.e., PET scans with or without PET/CT fusion. The ultimate determination regarding which specific scan, PET or PET/CT, will be determined by the physician related to the members circumstances, symptoms presented and according to the therapeutic goals.

PET/CT is NOT covered as a screening test. It is the assumption that the results of the PET/CT scan will influence treatment decisions.

The radiopharmaceutical diagnostic imaging agents covered for PET/CT oncological and miscellaneous imaging extends only to FDA-approved labeled indications for uses of PET Tracers.

PET/CT for Oncologic Applications

General Criteria

One PET/CT study is covered for members who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the member's treating physician determines that the PET/CT study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

- To determine whether or not the member is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or

- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

Three PET scans are covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy. Coverage of more than three PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy shall be determined by Paramount Medical Director Review.

Diagnosis:
Diagnosis refers to use of PET, PET/CT imaging as part of the testing used in establishing whether or not an individual has cancer. A PET/CT may be indicated when the conventional imaging (CT, MRI or bone scan) reveals findings that are inconclusive or negative, with continued suspicion of recurrence. The PET/CT results may assist in avoiding an invasive diagnostic procedure, or the PET/CT results may assist in determining the optimal anatomic location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET/CT scanning. A baseline PET/CT scan is appropriate for patients who have solid tumors that are biopsy proven or strongly suspected bases on other diagnostic testing and when clinical management would differ depending on the stage of the cancer identified. PET/CT scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET/CT in the diagnosis of lymphoma, esophageal carcinoma, colorectal cancers, and melanoma is rarely considered medically necessary. PET/CT may be considered prior to biopsy in order to determine a more favorable site for biopsy when a prior biopsy was nondiagnostic or a relatively inaccessible site is contemplated which would require invasive surgical intervention for biopsy attempt.

Staging:
Staging refers to use of PET, PET/CT imaging to determine the stage (extent) of the cancer at the time of diagnosis, before any treatment is given. PET/CT is considered medically necessary in situations in which clinical management of the member would differ depending on the stage of the cancer identified and either:
- Imaging requested after biopsy confirmation and prior to starting specific treatment: or
- The stage of the cancer remains in doubt after completion of a standard diagnostic work-up, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); or
- The use of PET/CT would potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.

Restaging:
Restaging refers to PET, PET/CT imaging following treatment. PET/CT is considered medically necessary for restaging after completion of treatment for:
- The purpose of detecting residual disease, for detecting suspected recurrence in persons with signs or symptoms of recurrence, or
- To determine the extent of recurrence.
- Use of PET/CT is also considered medically necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.

PET/CT for post-treatment surveillance is considered experimental and investigational, where surveillance is defined as:
- Use of PET/CT beyond the completion of treatment, or
- In the absence of signs or symptoms of cancer recurrence or progression, or
- For the purpose of detecting:
    - Recurrence, or
    - Progression, or
    - Predicting outcome.

Monitoring:
PET/CT for monitoring tumor response refers to the assessment of early treatment response (i.e. during active treatment cycle for cancer, prior to completion of the treatment cycle, to determine whether the treatment being given should be maintained or changed).

Surveillance:
After the completion of treatment, PET/CT scanning in the absence of signs or symptoms of cancer recurrence or progression, to detect recurrence or progression, is considered surveillance

Paramount utilizes InterQual® Coverage Criteria Reviews/Determinations. InterQual® imaging criteria is derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and includes input from independent panels of clinical experts. To generate the most appropriate recommendations, InterQual® conducts a comprehensive literature review of the clinical evidence. Sources searched include PubMed, agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence is assessed for consistency, directness, precision, and effect size and publication bias.

Paramount considers PET/CT medically necessary for the following oncologic indications, not all-inclusive, when the general and disease-specific criteria for diagnosis, staging, restaging and monitoring are met, and the PET/CT scan is necessary to guide management:

- Acute myeloid leukemia
- Ampullary cancer
- Anal cancer
- Appendiceal cancer
- Brain tumors
- Breast cancer
- Cervical cancer
- Chordoma
- Colorectal cancer
- Esophageal cancer
- Ewing sarcoma and osteosarcoma
- Fallopian tube cancer
- Gastric cancer
- Gastrointestinal stromal tumors
- Head and neck cancers (excluding cancers of the central nervous system)
- Hodgkin lymphoma
- Melanoma
- Merkel cell carcinoma
- Mesothelioma
- Multiple myeloma and plasmacytomas
- Neuroendocrine tumors
- Non-Hodgkin's lymphoma
- Non-small cell lung carcinoma
- Occult primary cancers
- Ovarian cancer

- Pancreatic cancer
- Paraneoplastic syndrome
- Penile cancer
- Primary peritoneal cancer
- Small cell lung carcinoma
- Small bowel adenocarcinoma
- Soft tissue sarcoma
- Solitary pulmonary nodules
- Testicular cancer
- Thymic malignancies
- Thyroid cancer
- Vaginal cancer.

Medicare Advantage Plans

The chart below summarizes CMS PET/CT coverage for oncologic conditions:

FDG-PET for Cancers Tumor Type	Initial Treatment Strategy Diagnosis & Staging	Subsequent Treatment Strategy Restaging & Monitoring
Colorectal	Cover	Cover
Esophagus	Cover	Cover
Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	Non-cover*	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

***Cervix:**

- Non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy.
- All other indications for initial anti-tumor treatment strategy for cervical cancer are covered.
- Cover PET/CT imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging.

***Breast:**

- Non-covered for initial diagnosis and/or staging of axillary lymph nodes.
- All other indications for initial anti-tumor treatment strategy for breast cancer are covered.
- Cover PET/CT imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.

***Melanoma**:

- Non-covered for initial staging of regional lymph nodes.
  - Prior to surgical lymph node sampling
- All other indications for initial anti-tumor treatment strategy for melanoma are covered.
  - Metastatic disease or suspicious lesions seen on CT and/or bone scan.
  - After completion of surgical lymph node sampling in place of CT scans.

***Prostate:**

- Non-covered for initial anti-tumor treatment strategy in members who have adenocarcinoma of the prostate.
- Covered for suspected prostate cancer recurrence.

The only radiopharmaceutical diagnostic imaging agents covered by Paramount for the Elite/Paramount Medicare Plan product line, following CMS coverage, for PET cancer imaging are 2-[f-18] Fluoro-D-Glucose (FDG) and NaF-18 9sodium fluoride-18). All other PET radiopharmaceutical diagnostic imaging agents are non-covered for this indication.

PET/CT for Miscellaneous (Non-cardiac, Non-oncologic) Applications
PET (FDG) for Dementia and Neurodegenerative Diseases
Paramount will follow the CMS Medicare Criteria for PET/CT coverage r/t Alzheimer's disease:
National Coverage Determination (NCD) for PET/CT for Dementia and Neurodegenerative Diseases (CAG-00088N); (220.6.13) Implemented 10/30/09
"Medicare covers PET/CT scans for both the differential diagnosis of frontal-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Center for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of PET/CT in the diagnosis or treatment of dementing neurodegenerative diseases".

Nationally Covered Indications**:**

- PET/CT Requirements for Coverage in the Differential Diagnosis of AD and FTD:
  - A recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.
  - The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline.
  - Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD.
  - The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT)
  - The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
  - The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through PET/CT is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment.
  - The PET/CT scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia
  - A brain single photon emission computed tomography (SPECT) or PET/CT scan has not been obtained

for the same indication.
    - The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or PET/CT scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, a PET/CT scan may be covered after one year has passed from the time the first SPECT or PET/CT scan was performed.
- The referring and billing provider(s) have documented the appropriate evaluation
    - Date of onset of symptoms;
    - Diagnosis of clinical syndrome (normal aging; mild cognitive impairment or MCI; mild, moderate or severe dementia);
    - Mini mental status exam (MMSE) or similar test score;
    - Presumptive cause (possible, probable, uncertain AD);
    - Any neuropsychological testing performed;
    - Results of any structural imaging (MRI or CT) performed;
    - Relevant laboratory tests (B12, thyroid hormone); and,
    - Number and name of prescribed medications.

- PET/CT Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of PET/CT in the Diagnosis and Treatment of Neurodegenerative Dementing Diseases
    - A PET/CT scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the PET/CT scan.
    - The clinical trial must compare patients who do and do not receive a PET/CT scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:
        - Written protocol on file;
        - Institutional Review Board review and approval;
        - Scientific review and approval by two or more qualified individuals who are not part of the research team;
        - Certification that investigators have not been disqualified.

PET (FDG) for Infection and Inflammation

National Coverage Determination (NCD) for PET/CT for Infection and Inflammation (220.6.16) Implementation Date 7/28/08

CMS is continuing its national non-coverage of PET/CT for the requested indications. Based upon our review, CMS has determined that the evidence is inadequate to conclude that PET/CT for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that PET/CT for ~~chronic osteomyelitis~~, infection of hip arthroplasty, and fever of unknown origin is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act.

Effective January 1, 2021, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for FDG PET for Inflammation and Infection. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act.

Effective 01/01/2022:

Positron emission tomography (PET) using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG) may be considered established/covered for the diagnosis of chronic osteomyelitis. The purpose of FDG-PET in patients with chronic osteomyelitis is to confirm a diagnosis or to inform the decision on selecting treatment regimens. Diagnosing osteomyelitis is challenging and FDG-PET may provide additional information along the diagnostic pathway.

Currently, bone biopsy is considered the reference standard, and radiographs are often used as screening tests prior to bone biopsy. When radiographs are inconclusive, other imaging techniques have been used, such as MRI and CT. While MRI has been shown to have a high sensitivity in diagnosing osteomyelitis, FDG-PET has also been shown to have high sensitivity and can be used when MRI is inconclusive or not possible (e.g., patients with metal hardware).

PET beta amyloid imaging

Effective October 13, 2023, The Centers for Medicare & Medicaid Services (CMS) is removing the national coverage determination (NCD) at § 220.6.20*, ending coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act (the Act).

While methods other than PET amyloid-beta (Aβ) for identifying pathologic brain amyloid exist (cerebral spinal fluid [CSF] analysis, which requires a lumbar puncture), or may be emerging (simple blood tests), currently PET Aβ is the most used method for selecting patients for any investigational AD therapeutic trial. With the recent development of treatments directed against amyloid such as lecanemab, PET Aβ scans could not only help select patients suitable for treatment, but also demonstrate treatment response (sufficient brain amyloid beta clearance) thus potentially altering the course of treatment including when to taper, stop or restart the drug.

Medicare has expanded its coverage policy for PET brain scans. The Centers for Medicare & Medicaid Services (CMS) has decided to remove the national coverage determination (NCD) that limits patients' ability to qualify for new drugs, giving people with Alzheimer's disease symptoms a better path to treating the condition. Broader access to amyloid PET scans will enable earlier and more accurate diagnosis, and better care management. This policy will no longer limit amyloid PET scans, thus allowing patients a better chance of being prescribed a drug like Eisai's Leqembi, which clears beta amyloid proteins from the brain to slow the advances of Alzheimer's. Providers will screen patients to ensure they have plaques in the brain that would necessitate receiving a drug like Leqembi. Physicians can then screen patients again to see how effectively the drug is working.

Diagnosing Alzheimer's

Diagnosing Alzheimer's is complex. With no single test currently available, diagnosis is based on an individual's history, physical examination, and cognitive testing. PET scans can detect Alzheimer's disease before it shows up on other imaging tests. An amyloid-PET scan measures the build-up of abnormal amyloid protein in the brain, one of the key hallmarks of Alzheimer's disease. Amyloid PET imaging represents a potential major advance in the assessment of those with cognitive impairment. The scan visualizes plaques present in the brain, which are prime suspects in damaging and killing nerve cells in Alzheimer's. Before amyloid PET, these plaques could only be detected by examining the brain at autopsy. Additionally, tracking changes in a person's level of beta amyloid throughout the course of treatment may allow a pause in treatment, as the amyloid beta levels decrease.

Amyloid PET imaging enables clinicians to distinguish Alzheimer's disease from other causes of dementia or memory loss and help ensure appropriate medical care and treatment. The new CMS policy to pay for amyloid PET scans beyond clinical trials also removes the current limitation of one scan per lifetime.

*[CMS 220.6.20 *The Centers for Medicare & Medicaid Services (CMS) has determined that the evidence is insufficient to conclude that the use of positron emission tomography (PET) beta amyloid (also referred to as amyloid-beta (Aß)) imaging is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for Medicare beneficiaries with dementia or neurodegenerative disease, and thus PET Aß imaging is not covered under §1862(a)(1)(A) of the Social Security Act ("the Act").*]

The utility of PET/CT scanning for the diagnosis, staging and restaging, and surveillance of malignancies varies by type of cancer. Positron emission tomography (PET) imaging with or without combined positron emission tomography/computed tomography (PET/CT) with an FDA approved radiopharmaceutical and radiotracer meets the definition of medical necessity for the following indications.

All disease-specific criteria must meet the general medical necessity criteria for oncologic indications, as documented above.

Acute Myeloid Leukemia
Paramount considers PET/CT scan for acute myeloid leukemia (AML) medically necessary if extramedullary disease is suspected. Extramedullary presentation, including central nervous system (CNS) disease, is uncommon in patients with AML. However, if extramurally disease is suspected, a PET/CT is recommended.

PET/CT scanning is considered investigational for all other indications of acute myeloid leukemia

Ampulla Cancer
PET/CT scans are considered medically necessary for the following indications:
- Staging and restaging of cancer of ampulla where conventional imaging is equivocal or where it appears that disease is localized and potentially curative resection is being considered.

PET/CT scanning is considered investigational for all other indications of ampulla cancer.

Anal Cancer
PET/CT scans are considered medically necessary for the diagnosis of anal canal carcinomas when medical necessity criteria for oncologic indications are met. Anal carcinoma PET/CT may be considered in the workup and treatment planning for anal cancer; however, PET/CT scan does not replace a diagnostic CT.

If the PET/CT is available at the time of simulation, this may be helpful to define local and regional target structures. PET/CT scanning has been reported to be useful in the evaluation of pelvic nodes, even in patients with anal canal cancer.

Bladder Cancer
PET/CT scans are considered medically necessary in the staging or restaging of muscle-invasive bladder cancer when CT or MRI are not indicated or remained inconclusive on distant metastasis.

PET/CT scanning is considered investigational for all other indications in bladder cancer, including, but not limited to the following:
- PET/CT imaging is considered experimental or investigational for bladder tumors which have not invaded the muscle (stage < cT2).

Bone Cancer (Sarcoma) Ewing Sarcoma, Chordoma and Osteosarcoma
PET/CT scans are considered medically necessary for the following indications:
- Diagnosis
- Staging
- Restaging
- Prior to resection of an apparently solitary metastasis
- For grading unresectable lesions when the grade of the histopathological specimen is in doubt. It is eligible for both initial and subsequent anti-tumor treatment strategy
- When predictive information (e.g., tumor recurrence, response to chemotherapy) is needed to determine clinical management

PET/CT scanning is considered investigational for all other indications in Bone Cancer (Sarcoma) Ewing Sarcoma,

Chordoma and Osteosarcoma, including, but not limited to the following:

- PET/CT imaging is considered experimental or investigational for staging of chondrosarcoma, bone sarcoma. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes.

Brain Cancer

PET/CT scans are considered medically necessary for the following indications:

- Diagnosis and staging, where lesions metastatic from the brain are identified but no primary is found
- Restaging, to distinguish recurrent tumor from radiation necrosis

Imaging modalities available and used in neuro-oncology is primarily focused on making treatment decisions. The most common use of MR spectroscopy, MR perfusion, and PET/CT scanning is to differentiate radiation necrosis from active tumor, as this might obviate the need for surgery or the discontinuation of an effective therapy. Additionally the PET/CT may indicate a tumor grade or provide the optimal area for biopsy

PET/CT scanning is considered investigational for all other indications in brain cancer.

Breast Cancer

PET/CT scans are considered medically necessary for the following indications:

- Staging
- Restaging
- Initial staging of patients with stage III or higher when conventional imaging is equivocal
- Monitoring tumor response to treatment for persons with locally advanced and metastatic breast cancer when a change in therapy is contemplated
- Restaging of patients with known metastases
- Restaging of known bone metastasis to evaluate response to treatment
- Evaluating suspected locoregional or distant recurrence or metastasis (new palpable lesions in axilla or adjacent area, rising tumor markers, changes in other imaging that are equivocal, suspicious or inconclusive).

PET/CT is considered experimental and investigational in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on mammography
- Initial diagnosis of breast cancer
- Staging of axillary lymph nodes
- Predicting pathologic response to neoadjuvant therapy for locally advanced disease
- The use of PET/CT is generally discouraged for evaluating metastatic disease except in situations where the results of other imaging studies are equivocal.
- The use of PET/CT is not indicated in the staging of clinical stage I-II breast cancer due to the low probability of patients having detectable metastatic disease and the high rate of false-positive scans.

Cervical Cancer

PET/CT scans are considered medically necessary for the following indications:

- Diagnostic workup of cervical cancer, for detection of pre-treatment metastases (staging) in women who are newly diagnosed with cervical cancer and have negative conventional imaging (CT or MRI)
- Restaging of cervical cancer
- Suspected recurrence and chronic lymphocytic leukemia
- For cervical cancer Stage II-IV, whole body PET/CT is preferred over chest, abdominal, or pelvic CT to evaluate for metastatic disease
- PET/CT may be considered for Stage IB2 cervical cancer to exclude extrapelvic disease before deciding on a treatment plan.

- PET/CT imaging 2 to 3 months after chemoradiation treatment for Stage III-IVA cervical cancer is useful for predicting treatment failure and thus allowing therapeutic modifications with potential outcome improvement.

PET/CT scanning is considered investigational for all other indications in cervical cancer.

Chronic Lymphocytic Leukemia (CLL)
PET/CT imaging for chronic lymphocytic leukemia (CLL) meets the definition of medical necessity as the initial study with biopsy proven cancer or for detecting suspected cancer based on diagnostic testing (e.g., bone marrow aspiration, biopsy, CBC).

- PET/CT scan is warranted to direct nodal biopsy, if histologic transformation is suspected.
- PET/CT for avid lymphomas is warranted in determining the extent of the disease.

Colorectal Cancer and Small Bowel Adenocarcinoma
PET/CT scans are considered medically necessary for the following indications:

- Diagnosis – Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of colorectal cancer is rarely considered medically necessary.
- Staging - determining the presence of hepatic/extra-hepatic metastases in the primary staging of colorectal carcinoma, prior to selecting the treatment regimen
- Restaging - evaluating recurrent colorectal cancer or small bowel adenocarcinoma where the patient presents with clinical signs or symptoms of recurrence
- PET/CT may be considered a first-lone imaging study in the work-up of suspected, recurrent rectal cancer when carcinoembryonic antigen levels are elevated.
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when CT scan is negative.

PET/CT is appropriate for colon cancer when baseline-imaging studies indicate Stage IV metastatic disease that is potentially curable and three is a need to further assess for metastatic disease. PET/CT is most useful in evaluating patients with colon cancer and hepatic metastases being considered for resection, and may aid in determining if surgical exploration is necessary. Surgery, radiation therapy, and chemotherapy are treatment options for colon cancer. PET/CT can differentiate recurrent or residual tumor from postoperative or therapy changes.

PET/CT imaging is considered investigational for all other indications in colorectal cancer and small bowel adenocarcinoma, including, but not limited to the following:

- Assessment of the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer.
- Radiotherapy treatment planning.

Endometrial Cancer
PET/CT imaging for endometrial cancer meets the definition of medical necessity for the following indications:

- Staging of endometrial cancer
- Detection of lymph node metastases
- Assessment of endometrial cancer recurrence

PET/CT is considered appropriate to determine treatment when endometrial cancer is suspected to be metastatic, based on the results of a chest, abdomen or pelvic CT.

PET/CT scanning is considered investigational for all other indications in endometrial cancer.

Esophageal Cancer
PET/CT is considered medically necessary for the following indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore,

PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging of esophageal cancer/determining response to preoperative induction therapy

PET/CT scanning is considered investigational for all other indications in esophageal cancer, including,
- Detection of primary esophageal cancer but not limited to the following:

Gastric Cancer
PET/CT is considered medically necessary for the indications:
- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging of gastric cancer.
- Evaluation for recurrent gastric cancer after surgical resection, when other imaging modalities are inconclusive.

PET/CT scanning is considered investigational for all other indications in gastric cancer.

Gastrointestinal Stromal Tumors (GIST)
PET/CT is considered medically necessary for the indications:
- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging
- Evaluation in the response to tyrosine kinase inhibitor treatment in patients with gastrointestinal stromal tumors meets the definition medical necessity.

PET/CT scanning is considered investigational for all other indications in GIST.

Head and Neck Cancers
PET/CT scans are considered medically necessary for the indications:
- Diagnosis
- Staging
- Restaging of residual or recurrent disease during follow up
- Evaluation of the response to treatment

The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Persons with head and neck cancers may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Persons with cancer of the head and neck are left with two (2) options, either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET/CT scanning attempts to reveal the site of primary tumor to prevent adverse effects of random biopsies or unneeded radiation.

PET/CT is considered for Stage II-IV head and neck cancer, including cancer of the oral cavity, oropharynx, hypopharynx, nasopharynx, larynx, and sinus tumors.

CT or MRI is preferred as the first imaging modality in evaluating new symptoms in patients with known head or neck cancer. PET/CT is performed in addition to CT or MRI because head or neck cancer is highly likely to metastasize and PET/CT provides better imaging of nodal disease and contralateral involvement than either CT or

MRI alone. CT or MRI of head and neck may show local recurrence but a PET/CT is appropriate for treatment planning.

PET/CT scanning is considered investigational for all other indications in head and neck cancer.

Hodgkin Lymphoma
PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Restaging after initial treatment is completed during follow-up over the first two years.

PET/CT scanning is considered investigational for all other indications in lymphoma.

Non-Hodgkin's Lymphoma (including post-transplant lymphoproliferative disorder and Castleman's disease)
PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging

PET/CT scanning is considered investigational for all other indications in lymphoma.

Lung Cancer: Non-Small Lung and Small Cell Lung
PET/CT is considered medically necessary for the indications:

- Non-Small Cell Lung Cancer
    - Diagnosis when strong clinical/radiographic suspicion
    - Staging of non-small cell lung cancer, following biopsy confirmation
    - Restaging technique in those with known non-small cell lung cancer
- Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between benign and malignant disease when prior CT scan and chest x-ray are inconclusive or discordant
    - Nodule is well-demarcated, solid or part solid, and lacks a benign calcification pattern; AND
    - Size is greater than 8 mm but less than 3 cm in greatest diameter; AND
    - Nodule is surrounded by aerated lung parenchyma; AND
    - There is no associated adenopathy, atelectasis or pleural effusion
- To determine resectability for presumed solitary metastatic lesion from lung cancer
- Staging small cell lung cancer if limited stage is suspected based on imaging (e.g., MRI, CT)
- Restaging and monitoring lung cancer (small cell) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities

When neoadjuvant induct therapy is planned for Stage II non-small cell lung cancer, interim PET/CT is appropriate to exclude disease progression; identification of treatment resistant disease is used to individualize treatment approach.

PET/CT has proven reliable in the detection of solitary pulmonary nodules larger than 8 mm and provides metabolic information that is helpful in characterizing these large nodules. Malignant cells rapidly accumulate radiotracer because of their increased metabolism.

PET/CT imaging is considered experimental or investigational for all other indications in non-small cell lung cancer, including, but not limited to the following:

- Staging of small-cell lung cancer if extensive stage is established and in all other aspects of managing small

cell lung cancer. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes.

Melanoma
PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- For assessing extranodal spread of malignant melanoma at initial staging or restaging during follow-up treatment for advanced disease (stage III or IV)

PET/CT is considered experimental and investigational for all other indications including, but not limited to the following:

- Managing stage 0, I, or II melanoma and use in evaluating regional nodes in persons with melanoma.
- To detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

Merkel Cell Carcinoma
PET/CT scans are considered medically necessary for the indications:

- The staging of Merkel cell carcinoma, related to:
  - The possibility of a skin metastasis from a non-cutaneous carcinoma (e.g., small cell carcinoma of the lung), especially in cases where CK20 is negative,
  - Regional and distant metastases, and
  - The extent of lymph node and/or visceral organ involvement.

PET/CT may be useful to identify and quantify regional and distant metastases. Imaging may also be useful to evaluate for the possibility of a skin metastasis from a noncutaneous primary neuroendocrine carcinoma (e.g., small cell lung cancer), especially in cases where CK20 is negative.

PET/CT scanning is considered investigational for all other indications in merkel cell carcinoma.

Mesothelioma: Malignant Pleural Mesothelioma
PET/CT scans are considered medically necessary for staging and restaging of malignant pleural mesothelioma when the general medical necessity criteria for oncologic indications are met. PET/CT scans may be useful in the pre-treatment evaluation of mesothelioma, prior to pleurodesis. PET/CT scans are mainly used to assess for metastatic disease.

Multiple Myeloma and Plasmacytomas
PET/CT scans are considered medically necessary for the indications:

- Evaluating suspected plasmacytomas (staging) in persons with multiple myeloma
- Re-staging of persons with solitary plasmacytomas, if the skeletal survey is negative

PET/CT scanning is considered investigational for all other indications in multiple myeloma, including, but not limited to the following:

- Staging of multiple myeloma

Neuroendocrine Tumors
PET/CT scans are considered medically necessary for the indications:

- Diagnosis, staging and re-staging of persons with pheochromocytoma/paragangliomas and other neuroendocrine tumors.
- PET imaging with gallium 68 meets the definition of medical necessity for staging neuroendocrine tumors

(e.g., carcinoid, pheochromocytoma) either during initial staging or for restaging at follow-up.
- PET/CT imaging meets the definition of medical necessity for restaging and monitoring of neuroendocrine cancer (e.g., carcinoid, pheochromocytoma) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging with other radiotracers is considered experimental or investigational in all aspects of managing neuroendocrine tumors, including, but not limited to the following:
- Evaluation of neuroendocrine tumors

Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer
PET/CT scans are considered medically necessary for the indications:
- Restaging (detecting signs and/or symptoms of recurrence) of previously treated women with a rising CA-125 level who have negative or equivocal conventional imaging (CT or MRI).

PET/CT scans are considered experimental and investigational for all other indications in these cancers, including, but not limited to the following:
- Diagnosis, staging, and monitoring of ovarian cancer, fallopian tube cancer and primary peritoneal cancer

Pancreatic Tumors
PET/CT scans are considered medically necessary for the indications:
- Diagnosis and staging of pancreatic tumors where imaging tests (CT or MRI) and biopsy are equivocal.
- Restaging and monitoring of pancreatic cancer only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging is considered experimental or investigational as a technique for evaluation of other aspects of pancreatic cancer. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes

Paraneoplastic Syndromes
PET/CT scans are considered medically necessary for the indications:
- Diagnosis and staging of persons suspected of having a paraneoplastic syndrome.

Penile Cancer
PET/CT scans are considered medically necessary for the indications:
- The evaluation of persons with penile cancer who have positive lymph nodes (PLNs) and an abnormal CT or MRI.

PET/CT scanning is considered investigational for all other indications in penile cancer, including, but not limited to the following:
- Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis

Prostate Cancer
The main treatment options for prostate cancer are radical prostatectomy, radiation therapy, androgen deprivation therapy, and active surveillance. Changes in PSA levels following any type of therapy can be an indication of recurrent or metastatic cancer. Following prostate treatment, the PSA level should drop. Imaging evaluation is appropriate if recurrence is suspected based on persistent elevation or increasing PSA levels. An increasing or persistent PSA level is indicative of residual, recurrent, or relapsing disease and PET/CT is a useful first-line imaging study.
PET/CT imaging of the prostate meets the definition of medical necessity for the following applications:
- PET/CT imaging with 11C-choline or with fluciclovine F18 (Axumin) meets the definition of medical necessity for evaluating suspected or biochemically recurrent prostate cancer after primary treatment to detect small volume disease in soft tissue, or
- PET/CT imaging meets the definition of medical necessity for evaluation of suspected recurrence when the PSA level is elevated or increasing, and

- PET/CT imaging for restaging and monitoring of prostate cancer meets the definition of medical necessity only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging with gallium 68 is considered experiment or investigational in prostate cancer.

PET/CT imaging for all other indications in known or suspected prostate cancer is considered experimental or investigational, including, but not limited to the following:

- Diagnosis and management of known or suspected prostate cancer

Renal Cell Cancer

PET/CT scans are considered medically necessary for the indications:

- Staging of renal cell cancer, or
- Restaging of known bone metastases to evaluate response to therapy.

Note: PET/CT alone is not a tool that is standardly used to diagnose kidney cancer or follow for evidence of relapse after nephrectomy.

PET/CT imaging is considered investigational for all indication of managing renal cancer.

Soft Tissue Sarcoma

PET/CT scans are rarely medically necessary for soft tissue sarcomas.
PET/CT scans are considered medically necessary for the indications:

- Staging prior to resection of an apparently solitary metastasis, or
- Grading unresectable lesions when the grade of the histopathological specimen is in doubt.

PET/CT scans are considered experimental and investigational for all other management of soft tissue sarcomas, including, but not limited to the following:

- Restaging of soft tissue sarcomas
- Distinguishing between low grade and high grades of soft tissue sarcoma
- Distinguishing between benign lesions and malignant soft tissue sarcoma
- Detecting locoreginal recurrence
- Detecting distant metastasis
- In the staging of chondrosarcoma
- In the staging of Ewing sarcoma

Biopsy is the gold standard for the initial staging of sarcoma but PET-CT is an important follow-up study to determine if metastatic disease, most commonly involving the lung and bone, is present, as this will influence treatment decisions.

Testicular Cancer

PET/CT scans are considered medically necessary for the indications:

- Restaging (detecting recurrence) of testicular cancer, when the following criteria as met:
  - Completed primary chemotherapy at least 6 weeks previously; and
  - Have a residual mass; and
  - Have normal or persistently elevated serum markers (e.g., alpha fetoprotein or serum Chorionic gonadotropin); and
  - Standard imaging such as CT is inconclusive

PET/CT is not indicated for the initial treatment planning related to testicular cancer, it is appropriate after primary chemotherapy for Stage II-III testicular cancer when residual mass greater than 3cm is identified by contrast-enhanced CT performed at least 6 weeks post-chemotherapy and serum tumor markers are within normal limits.

After completing treatment of testicular cancer, when serum tumor markers are elevated and contrast-enhanced CT is nondiagnostic for recurrence, PET/CT is appropriate to identify areas of active disease.

Except as noted above for seminoma, PET/CT imaging is considered experimental or investigational in evaluation of testicular cancer, including but not limited to the following:

- Initial staging, staging of asymptomatic males with normal tumor marker
- Monitoring of testicular cancer in response to chemotherapy (except for seminoma)
- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer
- Surveillance of symptomatic patients with no clinical, laboratory, or radiological evidence of recurrence

NCCN Clinical Practice Guidelines in Oncology, Testicular Cancer, and PET scanning does not contribute and routine use in not recommended for nonseminoma patients. They do state a PET to assess whether there is residual viable tumor is recommended for patients with residual tumor 3 cm or greater and normal markers.

Thymomas and Thymic Malignancies

PET/CT scans are considered medically necessary for the indications:

- Diagnosis
- Staging – after induction of chemotherapy to determine is resection is feasible.

PET/CT may be useful for determining whether extrathoracic metastases is present.

PET/CT screening is considered investigational for all other indications in thymic cancer.

Thyroid Cancer

PETCT scans are considered medically necessary for the indications:

- Staging of thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation
  - Restage when stimulated serum thyroglobulin > 5 ng/ml or high anti- thyroglobulin antibody (anti-Tg Ab) >1 year after treatment; AND Current stimulated whole body I-131/ I-123 scan is negative.
  - Medullary thyroid cancer when calcitonin levels ≥ 150 pg/mL post primary treatment.
  - Anaplastic: Initial and restaging after prior inconclusive/ insufficient CT/MRI.
- Evaluation of suspected recurrence when standard imaging, such as CT scan, is inconclusive.

PET/CT scanning may be considered medically necessary for Follicular or Papillary thyroid cancer when thyroglobulin levels are elevated (greater than 10ng/ml) and standard imaging is inconclusive.

PET/CT is considered not medically necessary for determining which members with metastatic thyroid cancer are at highest risk for death.

PET/CT scans are considered experimental and investigational for other thyroid cancer indications, including, but not limited to the following, but not limited to the following:

- Evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations
- Use for the initial staging of post-surgical thyroid cancer of cell types that concentrate I-131 poorly
- Use of PET/CT for re-staging of previously treated thyroid cancer of medullary cell origin in persons with an elevated serum calcitonin and negative standard imaging tests.

Unknown Primary

PETCT scans are considered medically necessary when all of the following indications are met:

- In patients with a single site of disease outside the cervical lymph nodes; and
- Patient is considering local or regional treatment for a single site of metastatic disease; and
- After a negative workup for an occult primary tumor; and
- PET/CT scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET/CT scanning is considered experimental/investigational for other indications in patients with an unknown primary, including, but not limited to the following:

- As part of the initial workup of an unknown primary; or
- As part of the workup of patients with multiple sites of disease

PET/CT is considered medically necessary for staging in carcinomas of unknown primary site in tumors of indeterminate histology where the primary site cannot be identified by endoscopy or other imaging studies (CT, MRI) and where loco-regional therapy for a single site of disease is being considered.
PET/CR scans are considered experimental and investigational for diagnosis or re-staging of carcinomas of unknown primary.

Uterine Sarcoma
PET/CT scans are considered medically necessary for the indications:

- Staging of uterine sarcoma
- Restaging for presurgical decision making of persons with uterine sarcoma in persons with known or suspected extrauterine disease

PET/CT scanning is considered investigational for all other indications in uterine sarcoma.

Vaginal Cancer
PET/CT scans are considered medically necessary for the diagnostic workup of vaginal cancer for evaluating the primary vaginal tumor and abnormal lymph nodes. PET/CT scans are considered medically necessary for evaluating tumor recurrence.

PET/CT scans are considered experimental and investigational for staging and restaging and for surveillance.

Vulvar Cancer
PET/CT scans are considered medically necessary for the indications:

- The diagnostic workup of vulvar cancer for evaluating regional lymph node metastases in some patients, and
- Hematogenous spread in rare patients with distant dissemination at the time of diagnosis.

PET/CT scans are considered experimental and investigational for staging and restaging of vulvar cancer.

Other Oncology
A subsequent PET/CT study may be considered medically necessary for tumor types other than those listed above when the patient's treating physician determines that the PET/CT study is needed to determine if there is a need to develop a treatment plan for subsequent anti-tumor treatment.
It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation. For example, the documentation should indication whether the prospective PET scan will lead to:

- A change in patient management to more appropriate palliative care; or
- A change in patient management to more appropriate curative care; or
- Improved quality of life; or
- Improved survival.

Experimental and Investigational Oncological Indications, unless indicated differently above:
Paramount considers PET/CT scans experimental and investigational for the evaluation of adrenal carcinoma, chondrosarcoma, clear cell carcinoma of the uterus, desmoid tumors/fibromatosis, extra-gonadal seminoma including mediastinal seminoma, follow-up of amyloidosis in bone marrow transplant recipients, gallbladder cancer,

gestational trophoblastic neoplasia, giant cell tumor of the bone, hemangioendothelioma, hepatic sarcoma, hepatobiliary cancer, hepatocellular carcinoma, hypercalcemia of malignancy, kidney cancer, leukemia (other than AML), lymphangiomatosis, malignant degeneration of neurofibromas, neuroblastoma, neurofibromatosis, Paget's disease (including extra-mammary Paget's disease), peri-ampullary cancer, pilar tumor, pituitary adenoma, placental cancer, plasmacytoid dendritic cell neoplasm, pleomorphic adenoma, prostate cancer, schwannoma, serous papillary endometrial carcinoma, skin cancer, spindle cell sarcoma, staging of biopsy-proven solitary fibrous tumor of pleura, ureteral cancer, uterine papillary mesothelioma, Wilms tumor, or for other oncologic indications (e.g., treatment planning for atypical teratoid/rhabdoid tumor) not listed as medically necessary in this policy because of insufficient evidence of effectiveness. Paramount considers PET-probe guided surgical resection experimental and investigational for recurrent ovarian cancer and other indications because its effectiveness has not been established.

PET/CT Imaging is NOT indicated for, not all-inclusive:

- Infection, inflammation, trauma, post-operative healing, granulomatous disease, rheumatological conditions
- Concomitantly with separate diagnostic CT studies
- Distant or diffuse metastatic disease
- Metastatic disease in the central nervous system (CNS)
- Lesions less than 8 mm in size
- Follow up after localized therapy (i.e. radiofrequency ablation, embolization, stereotactic radiation, etc.)
- Rare malignancies, due to lack of available evidence regarding the diagnostic accuracy of PET/CT in rare cancers
- Surveillance
    - Serial monitoring of FDG avidity until resolution.
    - PET/CT avidity in a residual mass at the end of planned therapy is not an indication for PET/CT imaging during surveillance.
    - Residual mass that has not changed in size since the last conventional imaging does not justify PET/CT imaging
- There is insufficient evidence to conclude that PET/CT for chronic osteomyelitis, infection of hip arthroplasty and fever of unknown origin are reasonable and necessary
- Once PET/CT has been documented to be negative for a given patient’s cancer or all PET/CT-avid disease has been surgically resected, PET/CT should not be used for continued disease monitoring or surveillance

PET/CT for Miscellaneous (Non-cardiac, Non-oncologic) Applications
Epilepsy
PET/CT scans are considered medically necessary for the indications:

- The assessment of selected patients with epileptic seizures who are candidates for surgery

In patients with epileptic seizures, appropriate candidates are patients with complex partial seizures who have failed to respond to medical therapy and have been advised to have a resection of a suspected epileptogenic focus located in a region of the brain accessible to surgery. Further, for the purposes of this review, conventional noninvasive techniques for seizure localization must have been tried with results suggesting a seizure focus but not sufficiently conclusive to permit surgery. The purpose of the PET/CT examination should be to avoid subjecting the patient to extended preoperative electroencephalographic recording with implanted electrodes or to help localize and minimize the number of sites for implanted electrodes to reduce the morbidity of that procedure.
PET/CT scanning is considered investigational for all other indications in epileptic seizures.
Chronic Osteomyelitis
PET/CT scans are considered medically necessary for the indications:

- The diagnosis of chronic osteomyelitis

The purpose of PET/CT in patients with chronic osteomyelitis is to confirm a diagnosis or to inform the decision on selecting treatment regimens.
PET/CT scanning is considered investigational for all other indications in osteomyelitis, including, but not limited to the following:

- Previously documented osteomyelitis with suspected recurrence

- Symptoms of osteomyelitis for more than 6 weeks (including diabetic foot ulcers)

Pulmonary Langerhans Cell Histiocytosis
PET/CT scans are considered medically necessary for the indications:
- Initial staging with biopsy confirmed pulmonary Langerhans Cell histiocytosis

PET/CT scanning is considered experimental/investigational for other indications in patients with pulmonary Langerhans Cell Histiocytosis, including, but not limited to the following:
- Restaging
- Surveillance
- Monitoring

Biopsy of pulmonary lesions is the standard approach to diagnosis, and PET/PET-CT is not commonly performed in patients with PLCH because 1) it is not definitive in diagnosing or excluding PLCH; 2) older lesions may not have uptake of the radioisotope; 3) other inflammatory and malignant diseases may demonstrate uptake of 2-3 FDG; 4) patients with predominantly cystic disease often show no uptake of 2-3 FDG; and 5) patients with small isolated florid granulomas may not demonstrate radioisotope uptake due to small size. The major value of PET/CT following histologic diagnosis of PLCH is for possible demonstration of activity in other organs, which may be helpful in management of the patient's disease.

PET beta amyloid imaging - **Paramount will follow CMS PET beta amyloid imaging coverage for the Paramount Commercial Insurance Plans**.
Effective October 13, 2023, The Centers for Medicare & Medicaid Services (CMS) is removing the national coverage determination (NCD) at § 220.6.20*, ending coverage with evidence development (CED) for positron emission tomography (PET) beta amyloid imaging and permitting Medicare coverage determinations for PET beta amyloid imaging to be made by the Medicare Administrative Contractors (MACs) under § 1862(a)(1)(A) of the Social Security Act (the Act).

While methods other than PET amyloid-beta (Aβ) for identifying pathologic brain amyloid exist (cerebral spinal fluid [CSF] analysis, which requires a lumbar puncture), or may be emerging (simple blood tests), currently PET Aβ is the most used method for selecting patients for any investigational AD therapeutic trial. With the recent development of treatments directed against amyloid such as lecanemab, PET Aβ scans could not only help select patients suitable for treatment, but also demonstrate treatment response (sufficient brain amyloid beta clearance) thus potentially altering the course of treatment including when to taper, stop or restart the drug.

Medicare has expanded its coverage policy for PET brain scans. The Centers for Medicare & Medicaid Services (CMS) has decided to remove the national coverage determination (NCD) that limits patients' ability to qualify for new drugs, giving people with Alzheimer's disease symptoms a better path to treating the condition. Broader access to amyloid PET scans will enable earlier and more accurate diagnosis, and better care management. This policy will no longer limit amyloid PET scans, thus allowing patients a better chance of being prescribed a drug like Eisai's Leqembi, which clears beta amyloid proteins from the brain to slow the advances of Alzheimer's. Providers will screen patients to ensure they have plaques in the brain that would necessitate receiving a drug like Leqembi. Physicians can then screen patients again to see how effectively the drug is working.

Diagnosing Alzheimer's
Diagnosing Alzheimer's is complex. With no single test currently available, diagnosis is based on an individual's history, physical examination, and cognitive testing. PET scans can detect Alzheimer's disease before it shows up on other imaging tests. An amyloid-PET scan measures the build-up of abnormal amyloid protein in the brain, one of the key hallmarks of Alzheimer's disease. Amyloid PET imaging represents a potential major advance in the assessment of those with cognitive impairment. The scan visualizes plaques present in the brain, which are prime suspects in damaging and killing nerve cells in Alzheimer's. Before amyloid PET, these plaques could only be detected by examining the brain at autopsy. Additionally, tracking changes in a person's level of beta amyloid throughout the course of treatment may allow a pause in treatment, as the amyloid beta levels decrease.

Amyloid PET imaging enables clinicians to distinguish Alzheimer's disease from other causes of dementia or memory loss and help ensure appropriate medical care and treatment. The new CMS policy to pay for amyloid PET scans beyond clinical trials also removes the current limitation of one scan per lifetime.

The PET/CT for all other miscellaneous indications is investigational, including, but not limited to:

- CNS diseases
    - Autoimmune disorders with CNS manifestations, including:
        - Behet's syndrome
        - lupus erythematosus
    - Cerebrovascular diseases, including:
        - arterial occlusive disease (arteriosclerosis, atherosclerosis)
        - carotid artery disease
        - cerebral aneurysm
        - cerebrovascular malformations (AVM and Moya disease)
        - hemorrhage
        - infarct
        - ischemia
    - Degenerative motor neuron diseases, including:
        - amyotrophic lateral sclerosis
        - Friedreich's ataxia
        - olivopontocerebellar atrophy
        - Parkinson's disease
        - progressive supranuclear palsy
        - Shy-Drager syndrome
        - spinocerebellar degeneration
        - Steele-Richardson-Olszewski disease
        - Tourette's syndrome
    - Dementias, including:
        - ~~Alzheimer's disease~~ – see coverage statement above
        - multi-infarct dementia
        - Pick's disease
        - frontotemporal
        - dementia with Lewy-Bodies
        - presenile dementia
    - Demyelinating diseases, such as multiple sclerosis
    - Developmental, congenital, or inherited disorders, including:
        - adrenoleukodystrophy
        - Down's syndrome
        - Huntingtons chorea
        - kinky-hair disease (Menkesâ syndrome)
        - Sturge-Weber syndrome (encephalofacial angiomatosis) and the phakomatoses
    - Miscellaneous
        - chronic fatigue syndrome
        - sick building syndrome
        - post-traumatic stress disorder
    - Nutritional or metabolic diseases and disorders, including:
        - acanthocytosis
        - hepatic encephalopathy
        - hepatolenticular degeneration
        - metachromatic leukodystrophy
        - mitochondrial disease
        - subacute necrotizing encephalomyelopathy
    - Psychiatric diseases and disorders, including:

        - affective disorders
        - depression
        - obsessive-compulsive disorder
        - psychomotor disorders
        - schizophrenia
    - Pyogenic infections, including:
        - aspergillosis
        - encephalitis
    - Substance abuse, including the CNS effects of alcohol, cocaine, and heroin
    - Trauma, including brain injury and carbon monoxide poisoning
    - Viral infections, including:
        - acquired immune deficiency syndrome (AIDS)
        - AIDS dementia complex
        - Creutzfeldt-Jakob syndrome
        - progressive multifocal leukoencephalopathy
        - progressive rubella encephalopathy
        - subacute sclerosing panencephalitis
    - Mycobacterium infection
    - Migraine
    - Anorexia nervosa
    - Assessment of cerebral blood flow in newborns
    - Vegetative versus "locked-in" state

- Pulmonary diseases
    - Adult respiratory distress syndrome
    - Diffuse panbronchiolitis
    - Emphysema
    - Obstructive lung disease
    - Pneumonia

- Musculoskeletal diseases
    - Spondylodiscitis
    - Joint replacement follow-up

- Other
    - Infection and inflammation related indications, including, but not limited to:
        - suspected infection of hip prosthesis
        - Fever of unknown origin in patients with a febrile illness of > 3 weeks' duration, a temperature of > 38.3 degrees Centigrade on at least two occasions, and uncertain diagnosis after a thorough history, physical examination, and one week of proper investigation.
        - Evaluation of metastatic infection and of high-risk patients with bacteremia
        - Primary evaluation of vasculitides (e.g., giant cell arteritis)
        - Evaluation of potentially infected liver and kidney cysts in polycystic disease
        - AIDS-associated opportunistic infections, associated tumors, and Castleman disease
        - Endocarditis
    - Giant cell arteritis
    - Vasculitis
    - Vascular prosthetic graft infection
    - Inflammatory bowel disease
    - Sarcoidosis
    - Inflammation of unknown origin

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid Appropriate Use Criteria Program: The Protecting Access to Medicare Act (PAMA) of 2014, Section 218(b), established a new program to increase the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries. Examples of such advanced imaging services include:

- computed tomography (CT)
- positron emission tomography (PET)
- nuclear medicine, and
- magnetic resonance imaging (MRI)

PAMA scores are validation of medical necessity to reduce unnecessary costs, poor patient experience, and operational inefficiency is a top priority for hospital leaders. Appropriate use criteria (AUC) programs exist to help ensure that appropriate medical procedures, where the anticipated health benefits exceed potential health risks to the patient, are performed.

Effective 08/01/2021, an additional option for outpatient imaging prior authorization requests from Paramount participating in-plan providers; Paramount is recognizing the Protecting Access to Medicare Act (PAMA) scores greater than or equal to a score of 8, for administrative approvals across all product lines. The request form can be located at: https://www.paramounthealthcare.com/assets/documents/provider/Fax-Request-Form-imaging.pdf

CODING/BILLING INFORMATION

The inclusion or exclusion of a code in this section does not necessarily indicate coverage. Codes referenced in this clinical policy are for informational purposes only.

Codes that are covered may have selection criteria that must be met.

Payment for supplies may be included in payment for other services rendered.

CPT CODES	
78608	Brain imaging, positron emission tomography (PET); metabolic evaluation
78609	Brain imaging, positron emission tomography (PET); perfusion evaluation
78811	Positron emission tomography (PET) imaging; limited area (e.g., chest, head/neck)
78812	Positron emission tomography (PET) imaging; skull base to mid-thigh
78813	Positron emission tomography (PET) imaging; whole body
78814	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; limited area (e.g., chest, head/neck)
78815	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; skull base to mid-thigh
78816	Positron emission tomography (PET) with concurrently acquired computed tomography (CT) for attenuation correction and anatomical localization imaging; whole body
G0219	PET imaging whole body; melanoma for non-covered indications
G0235	PET imaging, any site, not otherwise specified
G0252	PET imaging, full and partial-ring PET scanners only, for initial diagnosis of breast cancer and/ or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes)

REVISION HISTORY EXPLANATION

ORIGINAL DATE: 11/28/2018

Date	Explanation & Changes
11/28/2018	• PET scans for oncology applications do not require prior authorization
10/01/2020	• Medical Policy updated to reflect the most up-to-date coverage criteria • PET/CT scans for Oncology and Miscellaneous Applications require a Prior Authorization effective 12/1/2020
10/28/2020	• Updated: clarified prior authorization requirement, prior authorization required for both professional and facility • Prior Authorization is required for those procedures performed in an elective outpatient

	setting • A prior authorization is not required for the emergency department, facility observation setting or inpatient setting
12/09/2020	• Medical policy placed on the new Paramount Medical Policy Format
07/12/2021	• As a secondary option for prior authorization requests, Paramount is including PAMA scores, greater than or equal to a score of 8, to submit a High Dollar Imaging requests for administrative approvals across all product lines
03/06/2023	• Medical Policy updated to reflect Medicaid coverage to Anthem as of 02/01/2023
10/24/2023	• Updated the medical policy to reflect the CMS coverage update for Alzheimer's Disease testing, for ALL product lines: Medicare Advantage Plans and Paramount Commercial Insurance Plans

Paramount reserves the right to review and revise our policies periodically when necessary. When there is an update, we will publish the most current policy to https://www.paramounthealthcare.com/services/providers/medical-policies/ .

REFERENCES/RESOURCES

Centers for Medicare and Medicaid Services, CMS Manual System and other CMS publications and services

Centers for Medicare and Medicaid Services. Beta Amyloid Positron Emission Tomography in Dementia and Neurodegenerative Disease. CAG-00431N. Decision Memo. https://www.cms.gov/medicare-coverage-database/view/ncacal-tracking-sheet.aspx?ncaid=265& Last updated September 27, 2013. Accessed January 25, 2022.

American Medical Association, *Current Procedural Terminology (CPT®)* and associated publications and services

Centers for Medicare and Medicaid Services, Healthcare Common Procedure Coding System, HCPCS Release and Code Sets

Hayes, Inc.

Industry Standard Review

National Comprehensive Cancer Network (NCCN)

InterQual

POLICY

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid Effective: 12/1/2020

PET Scans for Oncology and Miscellaneous Applications - Procedure codes: 78608, 78609, 78811, 78812, 78813, 78814, 78815, 78816, G0235, G0252 Require Prior Authorization, both professional and facility.

Effective 08/01/2021, an additional option for outpatient imaging prior authorization requests from Paramount participating in-plan providers; Paramount is recognizing the Protecting Access to Medicare

Act (PAMA) scores greater than or equal to a score of 8, for administrative approvals across all product lines. The request form can be located at:
https://www.paramounthealthcare.com/assets/documents/provider/Fax-Request-Form-imaging.pdf

Prior Authorization is required for those procedures performed in an elective outpatient setting. A prior authorization is not required for the emergency department, facility observation setting or inpatient setting.

COVERAGE CRITERIA
PET-CT Fusion: The fusion of PET and CT imaging into a single system (PET/CT fusion) is considered medically necessary for any oncologic and miscellaneous indication where PET scanning is considered medically necessary. The use of the term PET/CT within this policy applies to both positron emission tomography (PET) scans and PET/Computed Tomography (CT) scans, i.e., PET scans with or without PET/CT fusion. The ultimate determination regarding which specific scan, PET or PET/CT, will be determined by the physician related to the members circumstances, symptoms presented and according to the therapeutic goals.

PET/CT is NOT covered as a screening test. It is the assumption that the results of the PET/CT scan will influence treatment decisions.

The radiopharmaceutical diagnostic imaging agents covered for PET/CT oncological and miscellaneous imaging extends only to FDA-approved labeled indications for uses of PET Tracers.

PET/CT for Oncologic Applications
General Criteria
One PET/CT study is covered for members who have cancers that are biopsy proven or strongly suspected based on other diagnostic testing when the member's treating physician determines that the PET/CT study is needed to determine the location and/or extent of the tumor for the following therapeutic purposes related to the initial anti-tumor treatment strategy:

- To determine whether or not the member is an appropriate candidate for an invasive diagnostic or therapeutic procedure; or
- To determine the optimal anatomic location for an invasive procedure; or
- To determine the anatomic extent of tumor when the recommended anti-tumor treatment reasonably depends on the extent of the tumor.

Three PET scans are covered when used to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy. Coverage of more than three PET scans to guide subsequent management of anti-tumor treatment strategy after completion of initial anti-tumor therapy shall be determined by Paramount Medical Director Review.

Diagnosis:
Diagnosis refers to use of PET, PET/CT imaging as part of the testing used in establishing whether or not an individual has cancer. A PET/CT may be indicated when the conventional imaging (CT, MRI or bone scan) reveals findings that are inconclusive or negative, with continued suspicion of recurrence. The PET/CT results may assist in avoiding an invasive diagnostic procedure, or the PET/CT results may assist in determining the optimal anatomic location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET/CT scanning. A baseline PET/CT scan is appropriate for patients who have solid tumors that are biopsy proven or strongly suspected bases on other diagnostic testing and when clinical management would differ depending on the stage of the cancer identified. PET/CT scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET/CT in the diagnosis of lymphoma, esophageal carcinoma, colorectal cancers, and melanoma is rarely considered medically necessary. PET/CT may be considered prior to biopsy in order to determine a more favorable site for biopsy when a prior biopsy was nondiagnostic or a relatively inaccessible site is contemplated which would require invasive surgical

intervention for biopsy attempt.

Staging:
Staging refers to use of PET, PET/CT imaging to determine the stage (extent) of the cancer at the time of diagnosis, before any treatment is given. PET/CT is considered medically necessary in situations in which clinical management of the member would differ depending on the stage of the cancer identified and either:

- Imaging requested after biopsy confirmation and prior to starting specific treatment: or
- The stage of the cancer remains in doubt after completion of a standard diagnostic work-up, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound); or
- The use of PET/CT would potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.

Restaging:
Restaging refers to PET, PET/CT imaging following treatment. PET/CT is considered medically necessary for restaging after completion of treatment for:

- The purpose of detecting residual disease, for detecting suspected recurrence in persons with signs or symptoms of recurrence, or
- To determine the extent of recurrence.
- Use of PET/CT is also considered medically necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the member.

PET/CT for post-treatment surveillance is considered experimental and investigational, where surveillance is defined as:

- Use of PET/CT beyond the completion of treatment, or
- In the absence of signs or symptoms of cancer recurrence or progression, or
- For the purpose of detecting:
    - Recurrence, or
    - Progression, or
    - Predicting outcome.

Monitoring:
PET/CT for monitoring tumor response refers to the assessment of early treatment response (i.e. during active treatment cycle for cancer, prior to completion of the treatment cycle, to determine whether the treatment being given should be maintained or changed).

Surveillance:
After the completion of treatment, PET/CT scanning in the absence of signs or symptoms of cancer recurrence or progression, to detect recurrence or progression, is considered surveillance

Paramount utilizes InterQual® Coverage Criteria Reviews/Determinations. InterQual® imaging criteria is derived from the systematic, continuous review and critical appraisal of the most current evidence-based literature and includes input from independent panels of clinical experts. To generate the most appropriate recommendations, InterQual® conducts a comprehensive literature review of the clinical evidence. Sources searched include PubMed, agency for Healthcare Research and Quality (AHRQ) Comparative Effectiveness Reviews, the Cochrane Library, Choosing Wisely, Centers for Medicare & Medicaid Services (CMS) National Coverage Determinations, and the National Institute of Health and Care Excellence (NICE). Other medical literature databases, medical content providers, data sources, regulatory body websites, and specialty society resources may also have been used. Relevant studies were assessed for risk of bias following principles described in the Cochrane Handbook. The resulting evidence is assessed for consistency, directness, precision, and effect size and publication bias.

Paramount considers PET/CT medically necessary for the following oncologic indications, not all-inclusive, when the general and disease-specific criteria for diagnosis, staging, restaging and monitoring are met, and the PET/CT scan is necessary to guide management:

- Acute myeloid leukemia
- Ampullary cancer
- Anal cancer
- Appendiceal cancer
- Brain tumors
- Breast cancer
- Cervical cancer
- Chordoma
- Colorectal cancer
- Esophageal cancer
- Ewing sarcoma and osteosarcoma
- Fallopian tube cancer
- Gastric cancer
- Gastrointestinal stromal tumors
- Head and neck cancers (excluding cancers of the central nervous system)
- Hodgkin lymphoma
- Melanoma
- Merkel cell carcinoma
- Mesothelioma
- Multiple myeloma and plasmacytomas
- Neuroendocrine tumors
- Non-Hodgkin's lymphoma
- Non-small cell lung carcinoma
- Occult primary cancers
- Ovarian cancer
- Pancreatic cancer
- Paraneoplastic syndrome
- Penile cancer
- Primary peritoneal cancer
- Small cell lung carcinoma
- Small bowel adenocarcinoma
- Soft tissue sarcoma
- Solitary pulmonary nodules
- Testicular cancer
- Thymic malignancies
- Thyroid cancer
- Vaginal cancer.

Medicare Advantage Plans
The chart below summarizes CMS PET/CT coverage for oncologic conditions:

FDG-PET for Cancers Tumor Type	Initial Treatment Strategy Diagnosis & Staging	Subsequent Treatment Strategy Restaging & Monitoring
Colorectal	Cover	Cover
Esophagus	Cover	Cover

Head and Neck (not thyroid, CNS)	Cover	Cover
Lymphoma	Cover	Cover
Non-small cell lung	Cover	Cover
Ovary	Cover	Cover
Brain	Cover	Cover
Cervix	Cover with exceptions *	Cover
Small cell lung	Cover	Cover
Soft tissue sarcoma	Cover	Cover
Pancreas	Cover	Cover
Testes	Cover	Cover
Prostate	Non-cover*	Cover
Thyroid	Cover	Cover
Breast (male and female)	Cover with exceptions *	Cover
Melanoma	Cover with exceptions *	Cover
All other solid tumors	Cover	Cover
Myeloma	Cover	Cover
All other cancers not listed	Cover	Cover

***Cervix:**

- Non-covered for the initial diagnosis of cervical cancer related to initial anti-tumor treatment strategy.
- All other indications for initial anti-tumor treatment strategy for cervical cancer are covered.
- Cover PET/CT imaging for the detection of pre-treatment metastasis (i.e., staging) in newly diagnosed cervical cancers following conventional imaging.

***Breast:**

- Non-covered for initial diagnosis and/or staging of axillary lymph nodes.
- All other indications for initial anti-tumor treatment strategy for breast cancer are covered.
- Cover PET/CT imaging for the initial anti-tumor treatment strategy for male and female breast cancer only when used in staging distant metastasis.

***Melanoma**:

- Non-covered for initial staging of regional lymph nodes.
  - Prior to surgical lymph node sampling
- All other indications for initial anti-tumor treatment strategy for melanoma are covered.
  - Metastatic disease or suspicious lesions seen on CT and/or bone scan.
  - After completion of surgical lymph node sampling in place of CT scans.

***Prostate:**

- Non-covered for initial anti-tumor treatment strategy in members who have adenocarcinoma of the prostate.
- Covered for suspected prostate cancer recurrence.

The only radiopharmaceutical diagnostic imaging agents covered by Paramount for the Elite/Paramount Medicare Plan product line, following CMS coverage, for PET cancer imaging are 2-[f-18] Fluoro-D-Glucose (FDG) and NaF-18 9sodium fluoride-18). All other PET radiopharmaceutical diagnostic imaging agents are non-covered for this indication.

PET/CT for Miscellaneous (Non-cardiac, Non-oncologic) Applications

Paramount will follow the CMS Medicare Criteria for PET/CT coverage r/t Alzheimer's disease:
National Coverage Determination (NCD) for PET/CT for Dementia and Neurodegenerative Diseases (CAG-00088N); (220.6.13) Implemented 10/30/09

"Medicare covers PET/CT scans for both the differential diagnosis of frontal-temporal dementia (FTD) and Alzheimer's disease (AD) under specific requirements; OR, its use in a Center for Medicare & Medicaid Services (CMS)-approved practical clinical trial focused on the utility of PET/CT in the diagnosis or treatment of dementing neurodegenerative diseases".

Nationally Covered Indications:

- PET/CT Requirements for Coverage in the Differential Diagnosis of AD and FTD:
  - A recent diagnosis of dementia and documented cognitive decline of at least 6 months, who meet diagnostic criteria for both AD and FTD. These patients have been evaluated for specific alternate neurodegenerative diseases or other causative factors, but the cause of the clinical symptoms remains uncertain.
  - The patient's onset, clinical presentation, or course of cognitive impairment is such that FTD is suspected as an alternative neurodegenerative cause of the cognitive decline.
  - Specifically, symptoms such as social disinhibition, awkwardness, difficulties with language, or loss of executive function are more prominent early in the course of FTD than the memory loss typical of AD.
  - The patient has had a comprehensive clinical evaluation (as defined by the American Academy of Neurology (AAN)) encompassing a medical history from the patient and a well-acquainted informant (including assessment of activities of daily living), physical and mental status examination (including formal documentation of cognitive decline occurring over at least 6 months) aided by cognitive scales or neuropsychological testing, laboratory tests, and structural imaging such as magnetic resonance imaging (MRI) or computed tomography (CT)
  - The evaluation of the patient has been conducted by a physician experienced in the diagnosis and assessment of dementia;
  - The evaluation of the patient did not clearly determine a specific neurodegenerative disease or other cause for the clinical symptoms, and information available through PET/CT is reasonably expected to help clarify the diagnosis between FTD and AD and help guide future treatment.
  - The PET/CT scan is performed in a facility that has all the accreditation necessary to operate nuclear medicine equipment. The reading of the scan should be done by an expert in nuclear medicine, radiology, neurology, or psychiatry, with experience interpreting such scans in the presence of dementia
  - A brain single photon emission computed tomography (SPECT) or PET/CT scan has not been obtained for the same indication.
  - The indication can be considered to be different in patients who exhibit important changes in scope or severity of cognitive decline, and meet all other qualifying criteria listed above and below (including the judgment that the likely diagnosis remains uncertain). The results of a prior SPECT or PET/CT scan must have been inconclusive or, in the case of SPECT, difficult to interpret due to immature or inadequate technology. In these instances, a PET/CT scan may be covered after one year has passed from the time the first SPECT or PET/CT scan was performed.
- The referring and billing provider(s) have documented the appropriate evaluation
  - Date of onset of symptoms;
  - Diagnosis of clinical syndrome (normal aging; mild cognitive impairment or MCI; mild, moderate or severe dementia);
  - Mini mental status exam (MMSE) or similar test score;
  - Presumptive cause (possible, probable, uncertain AD);
  - Any neuropsychological testing performed;
  - Results of any structural imaging (MRI or CT) performed;
  - Relevant laboratory tests (B12, thyroid hormone); and,
  - Number and name of prescribed medications.

- PET/CT Requirements for Coverage in the Context of a CMS-approved Practical Clinical Trial Utilizing a Specific Protocol to Demonstrate the Utility of PET/CT in the Diagnosis and Treatment of Neurodegenerative Dementing Diseases

- A PET/CT scan is considered reasonable and necessary in patients with mild cognitive impairment or early dementia only in the context of an approved clinical trial that contains patient safeguards and protections to ensure proper administration, use and evaluation of the PET/CT scan.
- The clinical trial must compare patients who do and do not receive a PET/CT scan and have as its goal to monitor, evaluate, and improve clinical outcomes. In addition, it must meet the following basic criteria:
  - Written protocol on file;
  - Institutional Review Board review and approval;
  - Scientific review and approval by two or more qualified individuals who are not part of the research team;
  - Certification that investigators have not been disqualified.

National Coverage Determination (NCD) for PET/CT for Infection and Inflammation (220.6.16) Implementation Date 7/28/08
"The CMS is continuing its national non-coverage of PET/CT for the requested indications. Based upon our review, CMS has determined that the evidence is inadequate to conclude that PET/CT for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin improves health outcomes in the Medicare populations, and therefore has determined that PET/CT for chronic osteomyelitis, infection of hip arthroplasty, and fever of unknown origin is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act."(87)

Paramount Commercial Insurance Plans and Paramount Advantage Medicaid
Disease-Specific Criteria
The utility of PET/CT scanning for the diagnosis, staging and restaging, and surveillance of malignancies varies by type of cancer. Positron emission tomography (PET) imaging with or without combined positron emission tomography/computed tomography (PET/CT) with an FDA approved radiopharmaceutical and radiotracer meets the definition of medical necessity for the following indications.

All disease-specific criteria must meet the general medical necessity criteria for oncologic indications, as documented above.

Acute Myeloid Leukemia
Paramount considers PET/CT scan for acute myeloid leukemia (AML) medically necessary if extramedullary disease is suspected. Extramedullary presentation, including central nervous system (CNS) disease, is uncommon in patients with AML. However, if extramurally disease is suspected, a PET/CT is recommended.

PET/CT scanning is considered investigational for all other indications of acute myeloid leukemia

Ampulla Cancer
PET/CT scans are considered medically necessary for the following indications:
- Staging and restaging of cancer of ampulla where conventional imaging is equivocal or where it appears that disease is localized and potentially curative resection is being considered.

PET/CT scanning is considered investigational for all other indications of ampulla cancer.

Anal Cancer
PET/CT scans are considered medically necessary for the diagnosis of anal canal carcinomas when medical necessity criteria for oncologic indications are met. Anal carcinoma PET/CT may be considered in the workup and treatment planning for anal cancer; however, PET/CT scan does not replace a diagnostic CT.

If the PET/CT is available at the time of simulation, this may be helpful to define local and regional target structures. PET/CT scanning has been reported to be useful in the evaluation of pelvic nodes, even in patients with anal canal cancer.

Bladder Cancer

PET/CT scans are considered medically necessary in the staging or restaging of muscle-invasive bladder cancer when CT or MRI are not indicated or remained inconclusive on distant metastasis.

PET/CT scanning is considered investigational for all other indications in bladder cancer, including, but not limited to the following:

- PET/CT imaging is considered experimental or investigational for bladder tumors which have not invaded the muscle (stage < cT2).

Bone Cancer (Sarcoma) Ewing Sarcoma, Chordoma and Osteosarcoma

PET/CT scans are considered medically necessary for the following indications:

- Diagnosis
- Staging
- Restaging
- Prior to resection of an apparently solitary metastasis
- For grading unresectable lesions when the grade of the histopathological specimen is in doubt. It is eligible for both initial and subsequent anti-tumor treatment strategy
- When predictive information (e.g., tumor recurrence, response to chemotherapy) is needed to determine clinical management

PET/CT scanning is considered investigational for all other indications in Bone Cancer (Sarcoma) Ewing Sarcoma, Chordoma and Osteosarcoma, including, but not limited to the following:

- PET/CT imaging is considered experimental or investigational for staging of chondrosarcoma, bone sarcoma. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes.

Brain Cancer

PET/CT scans are considered medically necessary for the following indications:

- Diagnosis and staging, where lesions metastatic from the brain are identified but no primary is found
- Restaging, to distinguish recurrent tumor from radiation necrosis

Imaging modalities available and used in neuro-oncology is primarily focused on making treatment decisions. The most common use of MR spectroscopy, MR perfusion, and PET/CT scanning is to differentiate radiation necrosis from active tumor, as this might obviate the need for surgery or the discontinuation of an effective therapy. Additionally the PET/CT may indicate a tumor grade or provide the optimal area for biopsy

PET/CT scanning is considered investigational for all other indications in brain cancer.

Breast Cancer

PET/CT scans are considered medically necessary for the following indications:

- Staging
- Restaging
- Initial staging of patients with stage III or higher when conventional imaging is equivocal
- Monitoring tumor response to treatment for persons with locally advanced and metastatic breast cancer when a change in therapy is contemplated
- Restaging of patients with known metastases
- Restaging of known bone metastasis to evaluate response to treatment
- Evaluating suspected locoregional or distant recurrence or metastasis (new palpable lesions in axilla or adjacent area, rising tumor markers, changes in other imaging that are equivocal, suspicious or inconclusive).

PET/CT is considered experimental and investigational in the evaluation of breast cancer for all other applications, including but not limited to the following:

- Differential diagnosis in patients with suspicious breast lesions or an indeterminate/low suspicion finding on

mammography
- Initial diagnosis of breast cancer
- Staging of axillary lymph nodes
- Predicting pathologic response to neoadjuvant therapy for locally advanced disease
- The use of PET/CT is generally discouraged for evaluating metastatic disease except in situations where the results of other imaging studies are equivocal.
- The use of PET/CT is not indicated in the staging of clinical stage I-II breast cancer due to the low probability of patients having detectable metastatic disease and the high rate of false-positive scans.

Cervical Cancer
PET/CT scans are considered medically necessary for the following indications:
- Diagnostic workup of cervical cancer, for detection of pre-treatment metastases (staging) in women who are newly diagnosed with cervical cancer and have negative conventional imaging (CT or MRI)
- Restaging of cervical cancer
- Suspected recurrence and chronic lymphocytic leukemia
- For cervical cancer Stage II-IV, whole body PET/CT is preferred over chest, abdominal, or pelvic CT to evaluate for metastatic disease
- PET/CT may be considered for Stage IB2 cervical cancer to exclude extrapelvic disease before deciding on a treatment plan.
- PET/CT imaging 2 to 3 months after chemoradiation treatment for Stage III-IVA cervical cancer is useful for predicting treatment failure and thus allowing therapeutic modifications with potential outcome improvement.

PET/CT scanning is considered investigational for all other indications in cervical cancer.

Chronic Lymphocytic Leukemia (CLL)
PET/CT imaging for chronic lymphocytic leukemia (CLL) meets the definition of medical necessity as the initial study with biopsy proven cancer or for detecting suspected cancer based on diagnostic testing (e.g., bone marrow aspiration, biopsy, CBC).
- PET/CT scan is warranted to direct nodal biopsy, if histologic transformation is suspected.
- PET/CT for avid lymphomas is warranted in determining the extent of the disease.

Colorectal Cancer and Small Bowel Adenocarcinoma
PET/CT scans are considered medically necessary for the following indications:
- Diagnosis – Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of colorectal cancer is rarely considered medically necessary.
- Staging - determining the presence of hepatic/extra-hepatic metastases in the primary staging of colorectal carcinoma, prior to selecting the treatment regimen
- Restaging - evaluating recurrent colorectal cancer or small bowel adenocarcinoma where the patient presents with clinical signs or symptoms of recurrence
- PET/CT may be considered a first-lone imaging study in the work-up of suspected, recurrent rectal cancer when carcinoembryonic antigen levels are elevated.
- To evaluate a rising and persistently elevated carcinoembryonic antigen (CEA) level when CT scan is negative.

PET/CT is appropriate for colon cancer when baseline-imaging studies indicate Stage IV metastatic disease that is potentially curable and three is a need to further assess for metastatic disease. PET/CT is most useful in evaluating patients with colon cancer and hepatic metastases being considered for resection, and may aid in determining if surgical exploration is necessary. Surgery, radiation therapy, and chemotherapy are treatment options for colon cancer. PET/CT can differentiate recurrent or residual tumor from postoperative or therapy changes.

PET/CT imaging is considered investigational for all other indications in colorectal cancer and small bowel

adenocarcinoma, including, but not limited to the following:

- Assessment of the presence of scarring versus local bowel recurrence in patients with previously resected colorectal cancer.
- Radiotherapy treatment planning.

Endometrial Cancer

PET/CT imaging for endometrial cancer meets the definition of medical necessity for the following indications:

- Staging of endometrial cancer
- Detection of lymph node metastases
- Assessment of endometrial cancer recurrence

PET/CT is considered appropriate to determine treatment when endometrial cancer is suspected to be metastatic, based on the results of a chest, abdomen or pelvic CT.

PET/CT scanning is considered investigational for all other indications in endometrial cancer.

Esophageal Cancer

PET/CT is considered medically necessary for the following indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging of esophageal cancer/determining response to preoperative induction therapy

PET/CT scanning is considered investigational for all other indications in esophageal cancer, including,

- Detection of primary esophageal cancer but not limited to the following:

Gastric Cancer

PET/CT is considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging of gastric cancer.
- Evaluation for recurrent gastric cancer after surgical resection, when other imaging modalities are inconclusive.

PET/CT scanning is considered investigational for all other indications in gastric cancer.

Gastrointestinal Stromal Tumors (GIST)

PET/CT is considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Pre-surgical staging
- Evaluation in the response to tyrosine kinase inhibitor treatment in patients with gastrointestinal stromal tumors meets the definition medical necessity.

PET/CT scanning is considered investigational for all other indications in GIST.

Head and Neck Cancers
PET/CT scans are considered medically necessary for the indications:

- Diagnosis
- Staging
- Restaging of residual or recurrent disease during follow up
- Evaluation of the response to treatment

The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Persons with head and neck cancers may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Persons with cancer of the head and neck are left with two (2) options, either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET/CT scanning attempts to reveal the site of primary tumor to prevent adverse effects of random biopsies or unneeded radiation.

PET/CT is considered for Stage II-IV head and neck cancer, including cancer of the oral cavity, oropharynx, hypopharynx, nasopharynx, larynx, and sinus tumors.

CT or MRI is preferred as the first imaging modality in evaluating new symptoms in patients with known head or neck cancer. PET/CT is performed in addition to CT or MRI because head or neck cancer is highly likely to metastasize and PET/CT provides better imaging of nodal disease and contralateral involvement than either CT or MRI alone. CT or MRI of head and neck may show local recurrence but a PET/CT is appropriate for treatment planning.

PET/CT scanning is considered investigational for all other indications in head and neck cancer.

Hodgkin Lymphoma
PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- Restaging after initial treatment is completed during follow-up over the first two years.

PET/CT scanning is considered investigational for all other indications in lymphoma.

Non-Hodgkin's Lymphoma (including post-transplant lymphoproliferative disorder and Castleman's disease)
PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging

PET/CT scanning is considered investigational for all other indications in lymphoma.

Lung Cancer: Non-Small Lung and Small Cell Lung
PET/CT is considered medically necessary for the indications:

- Non-Small Cell Lung Cancer
    - Diagnosis when strong clinical/radiographic suspicion
    - Staging of non-small cell lung cancer, following biopsy confirmation
    - Restaging technique in those with known non-small cell lung cancer
- Patients with a solitary pulmonary nodule as a single scan technique (not dual-time) to distinguish between

benign and malignant disease when prior CT scan and chest x-ray are inconclusive or discordant
    - Nodule is well-demarcated, solid or part solid, and lacks a benign calcification pattern; AND
    - Size is greater than 8 mm but less than 3 cm in greatest diameter; AND
    - Nodule is surrounded by aerated lung parenchyma; AND
    - There is no associated adenopathy, atelectasis or pleural effusion
- To determine resectability for presumed solitary metastatic lesion from lung cancer
- Staging small cell lung cancer if limited stage is suspected based on imaging (e.g., MRI, CT)
- Restaging and monitoring lung cancer (small cell) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities

When neoadjuvant induct therapy is planned for Stage II non-small cell lung cancer, interim PET/CT is appropriate to exclude disease progression; identification of treatment resistant disease is used to individualize treatment approach.

PET/CT has proven reliable in the detection of solitary pulmonary nodules larger than 8 mm and provides metabolic information that is helpful in characterizing these large nodules. Malignant cells rapidly accumulate radiotracer because of their increased metabolism.

PET/CT imaging is considered experimental or investigational for all other indications in non-small cell lung cancer, including, but not limited to the following:

- Staging of small-cell lung cancer if extensive stage is established and in all other aspects of managing small cell lung cancer. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes.

Melanoma

PET/CT scans are considered medically necessary for the indications:

- Diagnosis - Note: A diagnostic tissue sample is usually obtainable without PET/CT localization. Therefore, PET/CT for diagnosis of esophageal cancer is rarely considered medically necessary.
- Staging
- Restaging
- For assessing extranodal spread of malignant melanoma at initial staging or restaging during follow-up treatment for advanced disease (stage III or IV)

PET/CT is considered experimental and investigational for all other indications including, but not limited to the following:

- Managing stage 0, I, or II melanoma and use in evaluating regional nodes in persons with melanoma.
- To detect regional lymph node metastases in patients with clinically localized melanoma who are candidates to undergo sentinel node biopsy.

Merkel Cell Carcinoma

PET/CT scans are considered medically necessary for the indications:

- The staging of Merkel cell carcinoma, related to:
    - The possibility of a skin metastasis from a non-cutaneous carcinoma (e.g., small cell carcinoma of the lung), especially in cases where CK20 is negative,
    - Regional and distant metastases, and
    - The extent of lymph node and/or visceral organ involvement.

PET/CT may be useful to identify and quantify regional and distant metastases. Imaging may also be useful to evaluate for the possibility of a skin metastasis from a noncutaneous primary neuroendocrine carcinoma (e.g., small cell lung cancer), especially in cases where CK20 is negative.

PET/CT scanning is considered investigational for all other indications in merkel cell carcinoma.

Mesothelioma: Malignant Pleural Mesothelioma
PET/CT scans are considered medically necessary for staging and restaging of malignant pleural mesothelioma when the general medical necessity criteria for oncologic indications are met. PET/CT scans may be useful in the pre-treatment evaluation of mesothelioma, prior to pleurodesis. PET/CT scans are mainly used to assess for metastatic disease.

Multiple Myeloma and Plasmacytomas
PET/CT scans are considered medically necessary for the indications:

- Evaluating suspected plasmacytomas (staging) in persons with multiple myeloma
- Re-staging of persons with solitary plasmacytomas, if the skeletal survey is negative

PET/CT scanning is considered investigational for all other indications in multiple myeloma, including, but not limited to the following:

- Staging of multiple myeloma

Neuroendocrine Tumors
PET/CT scans are considered medically necessary for the indications:

- Diagnosis, staging and re-staging of persons with pheochromocytoma/paragangliomas and other neuroendocrine tumors.
- PET imaging with gallium 68 meets the definition of medical necessity for staging neuroendocrine tumors (e.g., carcinoid, pheochromocytoma) either during initial staging or for restaging at follow-up.
- PET/CT imaging meets the definition of medical necessity for restaging and monitoring of neuroendocrine cancer (e.g., carcinoid, pheochromocytoma) if other imaging modalities (e.g., ultrasound, CT, MRI) are inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging with other radiotracers is considered experimental or investigational in all aspects of managing neuroendocrine tumors, including, but not limited to the following:

- Evaluation of neuroendocrine tumors

Ovarian Cancer, Fallopian Tube Cancer and Primary Peritoneal Cancer
PET/CT scans are considered medically necessary for the indications:

- Restaging (detecting signs and/or symptoms of recurrence) of previously treated women with a rising CA-125 level who have negative or equivocal conventional imaging (CT or MRI).

PET/CT scans are considered experimental and investigational for all other indications in these cancers, including, but not limited to the following:

- Diagnosis, staging, and monitoring of ovarian cancer, fallopian tube cancer and primary peritoneal cancer

Pancreatic Tumors
PET/CT scans are considered medically necessary for the indications:

- Diagnosis and staging of pancreatic tumors where imaging tests (CT or MRI) and biopsy are equivocal.
- Restaging and monitoring of pancreatic cancer only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging is considered experimental or investigational as a technique for evaluation of other aspects of pancreatic cancer. The evidence is insufficient to determine the effects of PET/CT imaging on health outcomes

Paraneoplastic Syndromes
PET/CT scans are considered medically necessary for the indications:

- Diagnosis and staging of persons suspected of having a paraneoplastic syndrome.

Penile Cancer

PET/CT scans are considered medically necessary for the indications:

- The evaluation of persons with penile cancer who have positive lymph nodes (PLNs) and an abnormal CT or MRI.

PET/CT scanning is considered investigational for all other indications in penile cancer, including, but not limited to the following:

- Staging inguinal lymph nodes in patients with squamous cell carcinoma of the penis

Prostate Cancer

The main treatment options for prostate cancer are radical prostatectomy, radiation therapy, androgen deprivation therapy, and active surveillance. Changes in PSA levels following any type of therapy can be an indication of recurrent or metastatic cancer. Following prostate treatment, the PSA level should drop. Imaging evaluation is appropriate if recurrence is suspected based on persistent elevation or increasing PSA levels. An increasing or persistent PSA level is indicative of residual, recurrent, or relapsing disease and PET/CT is a useful first-line imaging study.

PET/CT imaging of the prostate meets the definition of medical necessity for the following applications:

- PET/CT imaging with 11C-choline or with fluciclovine F18 (Axumin) meets the definition of medical necessity for evaluating suspected or biochemically recurrent prostate cancer after primary treatment to detect small volume disease in soft tissue, or
- PET/CT imaging meets the definition of medical necessity for evaluation of suspected recurrence when the PSA level is elevated or increasing, and
- PET/CT imaging for restaging and monitoring of prostate cancer meets the definition of medical necessity only if other imaging (e.g., ultrasound, CT, MRI) is inconclusive in determining a treatment plan or if unable to perform imaging modalities.

PET/CT imaging with gallium 68 is considered experiment or investigational in prostate cancer.

PET/CT imaging for all other indications in known or suspected prostate cancer is considered experimental or investigational, including, but not limited to the following:

- Diagnosis and management of known or suspected prostate cancer

Renal Cell Cancer

PET/CT scans are considered medically necessary for the indications:

- Staging of renal cell cancer, or
- Restaging of known bone metastases to evaluate response to therapy.

Note: PET/CT alone is not a tool that is standardly used to diagnose kidney cancer or follow for evidence of relapse after nephrectomy.

PET/CT imaging is considered investigational for all indication of managing renal cancer.

Soft Tissue Sarcoma

PET/CT scans are rarely medically necessary for soft tissue sarcomas.

PET/CT scans are considered medically necessary for the indications:

- Staging prior to resection of an apparently solitary metastasis, or
- Grading unresectable lesions when the grade of the histopathological specimen is in doubt.

PET/CT scans are considered experimental and investigational for all other management of soft tissue sarcomas, including, but not limited to the following:

- Restaging of soft tissue sarcomas
- Distinguishing between low grade and high grades of soft tissue sarcoma

- Distinguishing between benign lesions and malignant soft tissue sarcoma
- Detecting locoreginal recurrence
- Detecting distant metastasis
- In the staging of chondrosarcoma
- In the staging of Ewing sarcoma

Biopsy is the gold standard for the initial staging of sarcoma but PET-CT is an important follow-up study to determine if metastatic disease, most commonly involving the lung and bone, is present, as this will influence treatment decisions.

Testicular Cancer
PET/CT scans are considered medically necessary for the indications:
- Restaging (detecting recurrence) of testicular cancer, when the following criteria as met:
  - Completed primary chemotherapy at least 6 weeks previously; and
  - Have a residual mass; and
  - Have normal or persistently elevated serum markers (e.g., alpha fetoprotein or serum Chorionic gonadotropin); and
  - Standard imaging such as CT is inconclusive

PET/CT is not indicated for the initial treatment planning related to testicular cancer, it is appropriate after primary chemotherapy for Stage II-III testicular cancer when residual mass greater than 3cm is identified by contrast-enhanced CT performed at least 6 weeks post-chemotherapy and serum tumor markers are within normal limits.

After completing treatment of testicular cancer, when serum tumor markers are elevated and contrast-enhanced CT is nondiagnostic for recurrence, PET/CT is appropriate to identify areas of active disease.

Except as noted above for seminoma, PET/CT imaging is considered experimental or investigational in evaluation of testicular cancer, including but not limited to the following:
- Initial staging, staging of asymptomatic males with normal tumor marker
- Monitoring of testicular cancer in response to chemotherapy (except for seminoma)
- Distinguishing between viable tumor and necrosis/fibrosis after treatment of testicular cancer
- Surveillance of symptomatic patients with no clinical, laboratory, or radiological evidence of recurrence

NCCN Clinical Practice Guidelines in Oncology, Testicular Cancer, and PET scanning does not contribute and routine use in not recommended for nonseminoma patients. They do state a PET to assess whether there is residual viable tumor is recommended for patients with residual tumor 3 cm or greater and normal markers.

Thymomas and Thymic Malignancies
PET/CT scans are considered medically necessary for the indications:
- Diagnosis
- Staging – after induction of chemotherapy to determine is resection is feasible.

PET/CT may be useful for determining whether extrathoracic metastases is present.

PET/CT screening is considered investigational for all other indications in thymic cancer.

Thyroid Cancer
PETCT scans are considered medically necessary for the indications:
- Staging of thyroid cancer of follicular cell origin previously treated by thyroidectomy and radioiodine ablation
  - Restage when stimulated serum thyroglobulin > 5 ng/ml or high anti- thyroglobulin antibody (anti-Tg Ab) >1 year after treatment; AND Current stimulated whole body I-131/ I-123 scan is negative.

- Medullary thyroid cancer when calcitonin levels ≥ 150 pg/mL post primary treatment.
- Anaplastic: Initial and restaging after prior inconclusive/ insufficient CT/MRI.

- Evaluation of suspected recurrence when standard imaging, such as CT scan, is inconclusive.

PET/CT scanning may be considered medically necessary for Follicular or Papillary thyroid cancer when thyroglobulin levels are elevated (greater than 10ng/ml) and standard imaging is inconclusive.

PET/CT is considered not medically necessary for determining which members with metastatic thyroid cancer are at highest risk for death.

PET/CT scans are considered experimental and investigational for other thyroid cancer indications, including, but not limited to the following, but not limited to the following:

- Evaluation of known or suspected differentiated or poorly differentiated thyroid cancer in all other situations
- Use for the initial staging of post-surgical thyroid cancer of cell types that concentrate I-131 poorly
- Use of PET/CT for re-staging of previously treated thyroid cancer of medullary cell origin in persons with an elevated serum calcitonin and negative standard imaging tests.

Unknown Primary

PETCT scans are considered medically necessary when all of the following indications are met:

- In patients with a single site of disease outside the cervical lymph nodes; and
- Patient is considering local or regional treatment for a single site of metastatic disease; and
- After a negative workup for an occult primary tumor; and
- PET/CT scan will be used to rule out or detect additional sites of disease that would eliminate the rationale for local or regional treatment.

PET/CT scanning is considered experimental/investigational for other indications in patients with an unknown primary, including, but not limited to the following:

- As part of the initial workup of an unknown primary; or
- As part of the workup of patients with multiple sites of disease

PET/CT is considered medically necessary for staging in carcinomas of unknown primary site in tumors of indeterminate histology where the primary site cannot be identified by endoscopy or other imaging studies (CT, MRI) and where loco-regional therapy for a single site of disease is being considered.
PET/CR scans are considered experimental and investigational for diagnosis or re-staging of carcinomas of unknown primary.

Uterine Sarcoma

PET/CT scans are considered medically necessary for the indications:

- Staging of uterine sarcoma
- Restaging for presurgical decision making of persons with uterine sarcoma in persons with known or suspected extrauterine disease

PET/CT scanning is considered investigational for all other indications in uterine sarcoma.

Vaginal Cancer

PET/CT scans are considered medically necessary for the diagnostic workup of vaginal cancer for evaluating the primary vaginal tumor and abnormal lymph nodes. PET/CT scans are considered medically necessary for evaluating tumor recurrence.

PET/CT scans are considered experimental and investigational for staging and restaging and for surveillance.

Vulvar Cancer

PET/CT scans are considered medically necessary for the indications:

- The diagnostic workup of vulvar cancer for evaluating regional lymph node metastases in some patients, and
- Hematogenous spread in rare patients with distant dissemination at the time of diagnosis.

PET/CT scans are considered experimental and investigational for staging and restaging of vulvar cancer.

Other Oncology
A subsequent PET/CT study may be considered medically necessary for tumor types other than those listed above when the patient's treating physician determines that the PET/CT study is needed to determine if there is a need to develop a treatment plan for subsequent anti-tumor treatment.
It will be necessary for the provider to submit medical records and/or additional documentation to determine coverage in this situation. For example, the documentation should indication whether the prospective PET scan will lead to:

- A change in patient management to more appropriate palliative care; or
- A change in patient management to more appropriate curative care; or
- Improved quality of life; or
- Improved survival.

Experimental and Investigational Oncological Indications, unless indicated differently above:
Paramount considers PET/CT scans experimental and investigational for the evaluation of adrenal carcinoma, chondrosarcoma, clear cell carcinoma of the uterus, desmoid tumors/fibromatosis, extra-gonadal seminoma including mediastinal seminoma, follow-up of amyloidosis in bone marrow transplant recipients, gallbladder cancer, gestational trophoblastic neoplasia, giant cell tumor of the bone, hemangioendothelioma, hepatic sarcoma, hepatobiliary cancer, hepatocellular carcinoma, hypercalcemia of malignancy, kidney cancer, leukemia (other than AML), lymphangiomatosis, malignant degeneration of neurofibromas, neuroblastoma, neurofibromatosis, Paget's disease (including extra-mammary Paget's disease), peri-ampullary cancer, pilar tumor, pituitary adenoma, placental cancer, plasmacytoid dendritic cell neoplasm, pleomorphic adenoma, prostate cancer, schwannoma, serous papillary endometrial carcinoma, skin cancer, spindle cell sarcoma, staging of biopsy-proven solitary fibrous tumor of pleura, ureteral cancer, uterine papillary mesothelioma, Wilms tumor, or for other oncologic indications (e.g., treatment planning for atypical teratoid/rhabdoid tumor) not listed as medically necessary in this policy because of insufficient evidence of effectiveness. Paramount considers PET-probe guided surgical resection experimental and investigational for recurrent ovarian cancer and other indications because its effectiveness has not been established.

PET/CT Imaging is NOT indicated for, not all-inclusive:

- Infection, inflammation, trauma, post-operative healing, granulomatous disease, rheumatological conditions
- Concomitantly with separate diagnostic CT studies
- Distant or diffuse metastatic disease
- Metastatic disease in the central nervous system (CNS)
- Lesions less than 8 mm in size
- Follow up after localized therapy (i.e. radiofrequency ablation, embolization, stereotactic radiation, etc.)
- Rare malignancies, due to lack of available evidence regarding the diagnostic accuracy of PET/CT in rare cancers
- Surveillance
    - Serial monitoring of FDG avidity until resolution.
    - PET/CT avidity in a residual mass at the end of planned therapy is not an indication for PET/CT imaging during surveillance.
    - Residual mass that has not changed in size since the last conventional imaging does not justify PET/CT imaging
- There is insufficient evidence to conclude that PET/CT for chronic osteomyelitis, infection of hip arthroplasty

and fever of unknown origin are reasonable and necessary
- Once PET/CT has been documented to be negative for a given patient's cancer or all PET/CT-avid disease has been surgically resected, PET/CT should not be used for continued disease monitoring or surveillance

PET/CT for Miscellaneous (Non-cardiac, Non-oncologic) Applications

Epilepsy

PET/CT scans are considered medically necessary for the indications:
- The assessment of selected patients with epileptic seizures who are candidates for surgery

In patients with epileptic seizures, appropriate candidates are patients with complex partial seizures who have failed to respond to medical therapy and have been advised to have a resection of a suspected epileptogenic focus located in a region of the brain accessible to surgery. Further, for the purposes of this review, conventional noninvasive techniques for seizure localization must have been tried with results suggesting a seizure focus but not sufficiently conclusive to permit surgery. The purpose of the PET/CT examination should be to avoid subjecting the patient to extended preoperative electroencephalographic recording with implanted electrodes or to help localize and minimize the number of sites for implanted electrodes to reduce the morbidity of that procedure.

PET/CT scanning is considered investigational for all other indications in epileptic seizures.

Chronic Osteomyelitis

PET/CT scans are considered medically necessary for the indications:
- The diagnosis of chronic osteomyelitis

The purpose of PET/CT in patients with chronic osteomyelitis is to confirm a diagnosis or to inform the decision on selecting treatment regimens.

PET/CT scanning is considered investigational for all other indications in osteomyelitis, including, but not limited to the following:
- Previously documented osteomyelitis with suspected recurrence
- Symptoms of osteomyelitis for more than 6 weeks (including diabetic foot ulcers)

Pulmonary Langerhans Cell Histiocytosis

PET/CT scans are considered medically necessary for the indications:
- Initial staging with biopsy confirmed pulmonary Langerhans Cell histiocytosis

PET/CT scanning is considered experimental/investigational for other indications in patients with pulmonary Langerhans Cell Histiocytosis, including, but not limited to the following:
- Restaging
- Surveillance
- Monitoring

Biopsy of pulmonary lesions is the standard approach to diagnosis, and PET/PET-CT is not commonly performed in patients with PLCH because 1) it is not definitive in diagnosing or excluding PLCH; 2) older lesions may not have uptake of the radioisotope; 3) other inflammatory and malignant diseases may demonstrate uptake of 2-3 FDG; 4) patients with predominantly cystic disease often show no uptake of 2-3 FDG; and 5) patients with small isolated florid granulomas may not demonstrate radioisotope uptake due to small size. The major value of PET/CT following histologic diagnosis of PLCH is for possible demonstration of activity in other organs, which may be helpful in management of the patient's disease.

The PET/CT for all other miscellaneous indications is investigational, including, but not limited to:
- CNS diseases
    - Autoimmune disorders with CNS manifestations, including:
        - Behet's syndrome
        - lupus erythematosus
    - Cerebrovascular diseases, including:
        - arterial occlusive disease (arteriosclerosis, atherosclerosis)
        - carotid artery disease
        - cerebral aneurysm

        - cerebrovascular malformations (AVM and Moya disease)
        - hemorrhage
        - infarct
        - ischemia
    - Degenerative motor neuron diseases, including:
        - amyotrophic lateral sclerosis
        - Friedreich's ataxia
        - olivopontocerebellar atrophy
        - Parkinson's disease
        - progressive supranuclear palsy
        - Shy-Drager syndrome
        - spinocerebellar degeneration
        - Steele-Richardson-Olszewski disease
        - Tourette's syndrome
    - Dementias, including:
        - Alzheimer's disease
        - multi-infarct dementia
        - Pick's disease
        - frontotemporal
        - dementia with Lewy-Bodies
        - presenile dementia
    - Demyelinating diseases, such as multiple sclerosis
    - Developmental, congenital, or inherited disorders, including:
        - adrenoleukodystrophy
        - Down's syndrome
        - Huntingtons chorea
        - kinky-hair disease (Menkesâ syndrome)
        - Sturge-Weber syndrome (encephalofacial angiomatosis) and the phakomatoses
    - Miscellaneous
        - chronic fatigue syndrome
        - sick building syndrome
        - post-traumatic stress disorder
    - Nutritional or metabolic diseases and disorders, including:
        - acanthocytosis
        - hepatic encephalopathy
        - hepatolenticular degeneration
        - metachromatic leukodystrophy
        - mitochondrial disease
        - subacute necrotizing encephalomyelopathy
- Psychiatric diseases and disorders, including:
    - affective disorders
    - depression
    - obsessive-compulsive disorder
    - psychomotor disorders
    - schizophrenia
- Pyogenic infections, including:
    - aspergillosis
    - encephalitis
- Substance abuse, including the CNS effects of alcohol, cocaine, and heroin
- Trauma, including brain injury and carbon monoxide poisoning
- Viral infections, including:
    - acquired immune deficiency syndrome (AIDS)
    - AIDS dementia complex

        - Creutzfeldt-Jakob syndrome
        - progressive multifocal leukoencephalopathy
        - progressive rubella encephalopathy
        - subacute sclerosing panencephalitis
    - Mycobacterium infection
    - Migraine
    - Anorexia nervosa
    - Assessment of cerebral blood flow in newborns
    - Vegetative versus "locked-in" state

- Pulmonary diseases
    - Adult respiratory distress syndrome
    - Diffuse panbronchiolitis
    - Emphysema
    - Obstructive lung disease
    - Pneumonia

- Musculoskeletal diseases
    - Spondylodiscitis
    - Joint replacement follow-up

- Other
    - Infection and inflammation related indications, including, but not limited to:
        - suspected infection of hip prosthesis
        - Fever of unknown origin in patients with a febrile illness of > 3 weeks' duration, a temperature of > 38.3 degrees Centigrade on at least two occasions, and uncertain diagnosis after a thorough history, physical examination, and one week of proper investigation.
        - Evaluation of metastatic infection and of high-risk patients with bacteremia
        - Primary evaluation of vasculitides (e.g., giant cell arteritis)
        - Evaluation of potentially infected liver and kidney cysts in polycystic disease
        - AIDS-associated opportunistic infections, associated tumors, and Castleman disease
        - Endocarditis
    - Giant cell arteritis
    - Vasculitis
    - Vascular prosthetic graft infection
    - Inflammatory bowel disease
    - Sarcoidosis
    - Inflammation of unknown origin

Paramount Commercial Insurance Plans, Medicare Advantage Plans, and Paramount Advantage Medicaid Appropriate Use Criteria Program: The Protecting Access to Medicare Act (PAMA) of 2014, Section 218(b), established a new program to increase the rate of appropriate advanced diagnostic imaging services provided to Medicare beneficiaries. Examples of such advanced imaging services include:

- computed tomography (CT)
- positron emission tomography (PET)
- nuclear medicine, and
- magnetic resonance imaging (MRI)

PAMA scores are validation of medical necessity to reduce unnecessary costs, poor patient experience, and operational inefficiency is a top priority for hospital leaders. Appropriate use criteria (AUC) programs exist to help ensure that appropriate medical procedures, where the anticipated health benefits exceed potential health risks to the patient, are performed.

Effective 08/01/2021, an additional option for outpatient imaging prior authorization requests from Paramount participating in-plan providers; Paramount is recognizing the Protecting Access to Medicare Act (PAMA) scores greater than or equal to a score of 8, for administrative approvals across all product lines. The request form can be located at: https://www.paramounthealthcare.com/assets/documents/provider/Fax-Request-Form-imaging.pdf